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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 third 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 and second revision of the Guidelines which form the basis for this revision. In particular, the Authority is thankful to all staff who participated in incorporating new ideas in this edition making it more useful to applicants of food registration. All the other staff, the TFDA management and TFDA stakeholders who in one way or another contributed to development of this useful document are very much acknowledged. I thank them all.

R. N. Wigenge
DIRECTOR FOR FOOD SAFETY

FOREWORD

TFDA is responsible for, among other things, protecting the 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 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 Act.

Experience gained in the three more years of implementing the first revision, necessitated revision of the guidelines to develop the second revision in 2009. The aim being to address the challenges with a view to making the food registration process more practical.

Due to changes made in the TFDA Client Service Charter, Food Registration Regulations and review of the provision relating to Fees and Charges Regulations, 2011, necessitated the development of the third revision.

It is our hope that applicants will find the document easier to follow and be encouraged to apply for registration of the products they deal in as part of their contribution to safeguard consumers' health.

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

INTRODUCTION

Section 28 of the Tanzania Food, Drugs and Cosmetics Act, 2003 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 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 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, conditions for sale of prepackaged food containing food additives and request to add or change a food additive in the list of permissible food additives have been annexed to these guidelines

CHAPTER I
DEFINITIONS

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

1. Act

Means the Tanzania Food, Drugs and Cosmetics Act, 2003

2. Applicant

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

3. Authority

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

4. Brand name

Means a trade name for the food

5. Codex

Means the Codex Alimentarius Commission responsible for execution of the joint FAO or WHO food standards programme;

6. Competent Authority

Means institution responsible for food safety control recognized by the government of the country of origin.

7. Common name

Means any name by which a food is commonly known (name established in a standard recognised by the Authority).

8. Country of origin

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

9. 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 receptacle;

10. Director General

Means the Chief Executive of The Tanzania Food and Drugs Authority appointed under section 8 (1) of the Act.

11. 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;

12. 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;

13. Food product registration

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

14. Food registration certificate

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

15. “Food supplement”, “nutritional supplement”, “dietary supplement”

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, essential 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, softgel, gelcap, granules or liquid.
- c. Is not represented for use as a convectional food or as a sole item of a meal or the diet.
- d. Is labelled as food supplement.

16. Food 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.

17. 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.

18. 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.

19. 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

20. High risk food

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 chemical toxins

21. 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

22. Ingredient

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

23. 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;

24. 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

25. 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;

26. Manufacturer

Means a person or company that is engaged in the manufacture of food

27. Minister

Means the Minister for the time being responsible for Health

28. National standard

Means a Standard *gazetted* under the Tanzania Standards Act, 1975

29. “Perishable Food”

Means Pre-packaged or non pre-packaged food in which the shelf life does not exceed thirty days.

30. 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.

31. Qualified Person

Means a person who is a holder of at least diploma in food science and technology 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

32. 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.

CHAPTER II

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- pre packaged foods, food dealers must ascertain that the foods they wish to sale in Tanzania have been registered with TFDA. Non pre packaged foods are foods that are not pre packed including 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.

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.

Manufacture of genetically modified food or foods derived thereof, must take into account the national legislation on environmental assessment.

1. Applicants and responsible persons

(a) Applicant

An application for registration of food products can be made by owner of the product who may be:

- (i) A person (an individual, body corporate, partnerships registered business] responsible for the manufacture or the person to whose order the product is manufactured (i.e. principal) or
- (ii) Any person (an individual, body corporate, partnerships, registered business) who intends to sell a food product in Tanzania.

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.

(b) Resident responsible person

Applicant who is not a resident of Tanzania shall nominate a person who resides in Tanzania to be a responsible person. Every nominee shall submit to the Authority a power of attorney as evidence of his/her nomination.

The 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.
- (iii) Handle product recalls whenever necessary.

2. Application documents

- a) A complete application file shall be required for each food product or food product variant. Different packaging units (net contents) of the same food are not considered as variants.
- b) The following documents shall be required to make a complete application file
 - i. Duly filled in application in the forms annexed to these Guidelines as Annexed II for High Risk Food for Special Nutritional Purpose or Annex III for High Risk Food for General Purpose or Annex IV for Low Risk Foods.
 - ii. Any other requirements prescribed for each category of food in Chapter III of the guidelines

3. 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.

4. Compilation of application documents

- a) The registration file shall be compiled in a well-presented and orderly manner with pages sequentially numbered.
- b) Drawings, tables, diagrams, graphs etc. where required, shall be well-annotated, numbered and appropriate references or cross-references clearly indicated.

5. Paper size and quality of text

- a) Application form papers shall be of A4 type.
- b) Quality of paper used should be such that it allows firm binding and long time storage. All copies must be legible
- c) Support documents shall as far as possible be of the same size
- d) Font of text on paper or CD-Rom where appropriate shall be at least 11 size of Bookman Old Style.

6. Reference to official standards and/or technical regulations

- a) All food intended to be registered in Tanzania shall comply with the National Standard of the respective food and where national standard does not exist, Codex standards or any other standard recognized by TFDA.
- b) On application, applicants are required to cite the standard to which the food for which registration is being sought conforms.

7. Submission of application

a) Application file

One hard copy of an application file and a CD-ROM if any, the sample and label shall be submitted to: *The Director General, Tanzania Food and Drugs Authority, EPI Mabibo External, P. O. Box 77150, Dar es Salaam, Tanzania.*

b) Sample

- i. Every application file shall be accompanied by a sample or in case food in different packaging sizes, samples of the food.
- ii. Size of a sample must be enough to enable evaluation and analysis of the products as per tests prescribed in the National Standard or in case there is no National Standard, Codex Standard.
- iii. For products in packaging units of not more than 5kg or liters, five units of sample shall accompany the respective application.
- iv. In case of products marketed in packaging unit exceeding 5kg or litres, five units each of at least ½kg or litres shall be drawn and submitted to TFDA.

c) Label

The application file and sample shall be accompanied with an empty well labeled container or label artwork of the way the product will be marketed.

d) 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. Applicant who, for any reason, might require the Authority to fast track, his application, shall effect payment in amount twice as much as the amount he would have effected in accordance with guideline d (I) of this guideline
- iii. Payment of fees may be made by bank transfer to: Tanzania Food and Drugs Authority account number 2041100069 (NMB Kariakoo branch) and account number 01J1021399100 (CRDB Holland House branch) for local currency. For foreign currency in USD, payments may be made to Tanzania Food and Drugs Authority *Account No. 02J1021399100* (CRDB Holland House branch) and *Account No. 100380013* (Citibank, Tanzania Ltd. Dar es Salaam, Head office Peugeot House 36 Upanga Road, Dar es Salaam. Swift Code: CITITZTZ) or by bank draft in favour of Tanzania Food and Drugs Authority.
- iv. All bank charges shall be borne by the applicant.

8. Acknowledgement of application

- a) Acknowledgement letter bearing a reference number for the application shall be issued for every product.
- b) Reference number issued in respect of a product must be stated in all correspondences with the Authority in connection with the product.

9. 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 in the Guidelines.
- b) Applicant who may wish to make changes or submit additional information to his or her application, is allowed to do so within 14 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 units of sample or information as the case may be.
- d) Processing of the application for which additional sample or information 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.
- e) In the event applicant does not submit, or cause to be submitted without reasonable cause to the Authority, a complete application as prescribed in these guidelines or/and additional requirements as prescribed in guideline 9(d) by the end of four months from the date when the matter was communicated to the applicant, the application shall be invalid.

- f) 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.
- g) 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.

10. Product registration approval

In a period, not shorter than 45 days but not exceeding 60 days from the date the application was received at TFDA, applicants will be informed whether their application was successful or not and if successful applicants will be issued with a certificate of registration in the form shown in Annex V to these Guidelines

11. Refusal of registration of the product

The Authority may refuse, suspend, revoke registration of any food or amend conditions subject to which the food was registered whenever it is deemed that by doing so is for the safety and interest of the consumer

12. 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, unless suspended or revoked by TFDA or terminated by the registration holder:

13. Termination of Product Registration

Unless otherwise renewed by the holder; of food registration certificate, registration will be terminated if:

- a) Application for renewal of the registration is not submitted to the Authority according to these guidelines.
- b) Payment of the annual retention fee per product for the remaining four years for each product and registration certificate is not made to the Authority as prescribed under the Fees and Charges Regulation made under the Act.
- c) The Authority receives a notice in writing issued by the registrant to informing it of his intention to withdraw from dealing with the food;
- d) Registrant is issued with any lawful order including but not limited to revocation, suspension or cancellation of registration certificate

14. Notification of change/Alteration

- a) If for any reason a registrant wishes to changes any matter related to a registered food (eg change of composition, packaging, labeling etc) shall before marketing the changed product, notify the alteration and obtain approval from the Authority.

- b) 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 samples of the registered and changed product
- c) 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
- d) In case of change of manufacturing site or processing technology, the application shall, in addition to alteration fee, be accompanied with GMP inspection fees as prescribed under the Fees and Charges Regulations made under the Act.
- e) In case of 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, the application shall, in addition to alteration fee, be accompanied with laboratory analysis fee necessary for verification of the changes and as prescribed under the Fees and Changes Regulations made under the Act.
- f) However, 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.

15. Renewal of registration

All applications for renewal of registration shall be made as prescribed under guideline 2 through 7 of these guidelines and shall reach the Authority at least 60 days before expiry of the existing registration

16. 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.
- b) However if after reconsideration of the application, the Authority still rejects the application, the applicant shall appeal to the Minister for Health.

CHAPTER III

FOOD CATEGORY SPECIFIC APPLICATION REQUIREMENTS

Food categories

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

Category one: High risk foods for special nutritional purposes

- 1) Food products under this category shall include food for special nutritional purpose such as food supplement or infant formulae whose intrinsic properties have the potential of being contaminated with pathogens and or chemical toxins causing high health risks in vulnerable groups who due to their physiological conditions are targets for these products. The foods are but not limited to those listed below:
 - a) Infant formulae and
 - b) Follow-up formulae
 - c) Complementary foods for infants and young children
 - d) Dietetic foods intended for special medical purposes including dietetic formulae for slimming purposes and weight control/reduction/management
 - e) Food supplements

- 2) Applicant who intends to apply for registration of any food product falling under this category shall in addition to fulfilling the requirements in guidelines 2 through 7 of these Guidelines, effect payment as prescribed under the Fees and Charges regulations made under the Act to facilitate performance of GMP inspection by TFDA in the site used to manufacture the product

Category two: High risk foods for general purpose

- 1) High risk foods 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, excluding those high risk foods for Special Nutritional Purposes and including:-
 - a) Dairy products and analogues
 - i. Milk and dairy-based drinks
 - ii. Fermented and renneted milk products (plain)
 - iii. Condensed milk and analogues (plain)

- iv. Cream (plain) and the like
- v. Milk powder and cream powder and powder analogues (plain)
- vi. Cheese and analogues
- vii. Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt, ice cream)
- viii. Whey and whey products
- 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
 - 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
 - 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
 - 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
 - viii. Other protein products
- f) Processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
- g) Ready-to-eat savories
 - i. Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)
 - ii. Snacks - fish based
- h) Composite foods - foods that could not be categorized in other groups
- i) Potable Water (including drinking water)

- 2) Applicant who intends to apply for registration of any food product falling under this category shall in addition to fulfilling the requirements in guidelines 2 through 7 of these Guidelines, submit to TFDA Health certificate issued by competent food regulatory Authority in the country of origin of the food showing that the food is fit for human consumption and that it meets the standards prescribed by the food regulatory Authority of the country of origin, stating such standards

Category three: Low risk foods

- 1) This category shall include pre-packaged foods, the risk of which is relatively lower than is for food products grouped in category one and two. These foods include:-
- a) Fats and oils, and fat emulsions
 - i. Fats and oils essentially free from water
 - ii. Fat emulsions mainly of type water-in-oil
 - iii. Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions
 - iv. Fat-based desserts
 - b) Edible ices, including sherbet and sorbet
 - c) Processed Fruits
 - i. Dried fruit
 - ii. Fruit in vinegar, oil, or brine
 - iii. Canned or bottled (pasteurized) fruit
 - iv. Jams, jellies, marmalades
 - v. Fruit-based spreads
 - vi. Candied fruit
 - vii. Fruit preparations, including pulp, purees, fruit toppings and coconut milk
 - viii. Fruit-based desserts, incl. fruit-flavoured water-based desserts
 - ix. Fermented fruit products
 - x. Fruit fillings for pastries
 - xi. Cooked fruit
 - d) Confectionery
 - i. Cocoa products and chocolate products including imitations and chocolate substitutes
 - ii. Confectionery including hard and soft candy, nougats, etc
 - iii. Chewing gum
 - iv. Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces
 - e) Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares
 - i. Whole, broken, or flaked grain, including rice

- ii. Flours and starches
 - iii. Breakfast cereals, including rolled oats
 - iv. Pastas and noodles and like products (e.g. rice paper, rice vermicelli, soybean pastas and noodles)
 - v. Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)
 - vi. Batters (e.g., for breading or batters for fish or poultry)
 - vii. Pre-cooked or processed rice products
- f) Bakery wares
 - i. Bread and ordinary bakery wares and mixes
 - ii. Fine bakery wares (sweet, salty, savoury) and mixes
 - g) Sweeteners, including honey
 - i. Refined and raw sugars
 - ii. Brown sugar
 - iii. Sugar solutions and syrups,
 - iv. Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)
 - v. Honey
 - vi. Table-top sweeteners, including those containing high-intensity sweeteners
 - h) Beverages, excluding dairy products
 - i. Non-alcoholic ("soft") beverages
 - ii. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts
 - i) Salt and salt substitutes
 - j) Vinegars
- 2) Applicant who intends to apply for registration of any food product falling under this category shall, in addition to fulfilling the requirements in guidelines 2 through 7 of these Guidelines, submit to TFDA evidence that the supplier of the food is a registered company.

CHAPTER IV

REQUIREMENTS FOR LABELLING OF PREPACKAGED FOODS

1.0 General Requirements

- 1.1 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.
- 1.2 Prepackage food 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.

2.0 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.

2.1 Name of the food

- 2.1.1 The common name shall indicate the true nature of the food and normally be specific and not generic.
- 2.1.2 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.
- 2.1.3 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.
- 2.1.4 "Brand" name or "trade mark" shall be used to accompany the common name. A fanciful brand name is not acceptable.
- 2.1.5 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packing medium, style, and the condition or type of treatment it has undergone; for example: dried, concentrated, reconstituted, smoked.

- 2.1.5.1 Label for food containing more than 6% transgenic ingredient(s) shall bear the statement “produced from genetically modified (name of organism).”

2.2 List of ingredients

- 2.2.1 Except for single ingredient foods, a list of ingredients shall be declared on the label.
- 2.2.1.1 The list of ingredients shall be headed or preceded by an appropriate title, which consists of or includes the term ‘ingredient’.
- 2.2.1.2 All ingredients shall be listed in descending order of ingoing weight (m/m) at time of manufacture of the food.
- 2.2.1.3 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.
- 2.2.1.4 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.
- 2.2.1.5 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.
- 2.2.2 A specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in requirement 2.2.1 of these requirements except that:-
- 2.2.2.1 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 combination in the food.	'Herbs' or 'mixed herbs' as appropriate.

	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'.
2.2.2.2	Notwithstanding the provision set out in requirement 2.2.2.1 of these requirements pork fat, lard and beef fat shall always be declared by their specific names.	
2.2.2.3	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.	
	<ul style="list-style-type: none"> 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 	
2.2.2.4	The expression "flavours" shall be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate.	

2.2.3 Processing Aids and Carry-Over of Food Additives.

2.2.3.1 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.

2.2.3.2 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.

2.2.4 Transgenic food ingredient

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

2.3 Net Contents and Drained Weight

2.3.1 The net contents shall be declared in the metric system (“Système International” units).

2.3.2 The net contents shall be declared in the following manner:

- (i) for liquid foods, by volume;
- (ii) for solid foods, by weight;
- (iii) for semi-solid or viscous foods, either by weight or volume.

2.3.3 In addition 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.

2.4 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.

2.5 Country of Origin

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

2.5.2 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.

2.6 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.

2.7 Date Marking and Storage Instructions

2.7.1 If not otherwise determined in an individual National or Codex standard, the following date marking shall apply:

- (i) The “date of expiry” shall be declared.
- (ii) This shall consist at least of
 - the day and the month for products with a minimum durability of not more than three months
 - the month and the year for products with a minimum durability of more than three months.
- (iii) The words referred to in paragraph (iii) shall be accompanied by:
 - either the date itself; or
 - a reference to where the date is given
- (iv) The day, month and year shall be declared in uncoded numerical sequence except that the month may be indicated by letters.
- (v) Notwithstanding requirement 2.7.1 (ii) of these requirements an indication of the date of expiry shall not be required for:
 - (a) wines, liqueur wines, sparkling wines, aromatized wines, fruit wines and sparkling fruit wines;
 - (b) beverages containing 10% or more by volume of alcohol;
 - (c) vinegar
 - (d) solid sugars
 - (e) confectionery products consisting of flavoured and/or coloured sugars.
 - (f) Chewing gum.

2.7.2 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.

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

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

2.8 **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.

3.0 **Requirements for irradiated food**

3.1 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.



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

3.3 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.

4.0 **Exemptions from mandatory labeling requirements**

With the exception of spice and herbs, small units, where the largest surface area is less than 10 cm², shall be exempted from the requirements 2.2 and 2.6 to 2.8 of these guidelines.

5.0 Presentation of labelling information

5.1 General

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

5.1.2 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.

5.1.3 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.

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

5.2 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

PERMISSIBLE FOOD ADDITIVES AND THEIR LEVEL OF USE

1.0. Condition for sale of prepackaged foods containing food additives

No person shall sell food containing food additive unless that food additive is listed as permissible food additive in the National Standard of permissible food additives and their levels of use and/or in any other standard recognized by the Authority.

2.0 Condition for request to add or change food additive

A request that a food additive be added to or a change made in the list of permissible food additives shall be accompanied by a submission to the Authority and shall include:

- (i) A description of the food additive including its chemical name and the name under which it is proposed to be sold, method of its manufacture, chemical and physical properties, composition and specification;
- (ii) A suggestion of the amount of the food additive proposed for use, and the purpose for which it is proposed, together with all directions, recommendations and suggestions for use;
- (iii) Data establishing that the food additive shall have the intended physical or other technological effect;
- (iv) Detailed reports of tests made to establish the safety of the food additive under the recommended conditions of use;
- (v) Data to indicate the residues that may remain in or upon the finished food when the food additive is used in accordance with good manufacturing practice;
- (vi) A proposed maximum limit for residues of the food additive in or upon the finished food;
- (vii) Specimens of the labeling proposed for the food additive; and
- (viii) A sample of the food additive in the form in which it is proposed to be used in foods, a sample of the active ingredient and, on request, a sample of food containing the food additive.

3.0 Approval to change or addition in the list

The Authority shall inform in writing the person filing the submission of its decision to approve or disapprove the request for the addition or change in the list of permissible food additives.



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, 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/seal and liner if any
.....
.....

1.8 Retail packaging unit 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
.....
- 1.13 Recommended storage conditions after opening
.....
- 1.14 Standard used in the manufacture of the product.....

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.....
- 2.5 Fax.....
- 2.6 E-Mail.....
- 2.7 Name of the would be importer (in case of food for importation)
.....

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 Fax

3.6 E-Mail.....

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 unit/mass or volume)	%, or lt, or	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.....

.....

For official use only

Name of receiving officer.....

Date:.....

ANNEX III



**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, colour etc).....
.....

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

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

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

1.8 Retail packaging unit 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
.....

1.13 Recommended storage conditions after opening
.....

1.14 Standard used in the manufacture of the product.....

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.....

2.5 Fax.....

2.6 E-Mail.....

2.7 Name of the importer (in case importer is not the applicant)
.....

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 Fax

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)

5.2 Food additives

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

.....

For official use only

Name of receiving officer.....

Date:.....

ANNEX IV



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, 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/seal and liner if any
.....
.....

- 1.8 Retail packaging unit 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
.....
- 1.13 Recommended storage conditions after opening
.....
- 1.14 Standard used in the manufacture of the product.....

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.....
- 2.5 Fax.....
- 2.6 E-Mail.....
- 2.7 Name of the would be importer (in case the importer is not the applicant)
.....

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 Fax
- 3.6 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.....

.....

For official use only

Name of receiving officer.....

Date:.....

ANNEX V



CERTIFICATE OF PREPACKAGED FOOD REGISTRATION

*(Made under Regulation 10 of the Tanzania Food, Drugs and Cosmetics
(Registration of Foods) Regulations, 2011*

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

Brand name.....
Common 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 food 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.

Revision History

In order to guide applicants on how to prepare and submit to TFDA applications for registration of food, in 2004, TFDA formulated the guidelines to applicants which have been implemented and reviewed with time according to changing needs and challenges.

In 2011, the Minister for Health and Social Welfare approved regulations for food registration which prescribe new requirements. He also approved changes to the Fees and Charges Regulations affecting fees and charges for registration food. As another recent development TFDA reduced the waiting time for an applicant to wait for feedback. These new developments necessitated the review of the Food Registration Guidelines.