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THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR

MINISTRY OF HEALTH

ZANZIBAR FOOD AND DRUGS BOARD

GUIDELINES FOR APPLICATION OF REGISTRATION OF PRE-PACKAGE FOOD

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ABBREVIATIONS

1.	FAO	-	Food and Agriculture Organisation
2.	GMP	-	Good Manufacturing Practices
3.	HACCP	-	Hazard Analysis Critical Control Points
4.	ISO	-	International Standards Organisation
5.	TBS	-	Tanzania Bureau of Standards
6.	ZFDB	-	Zanzibar Food and Drugs Board
7.	ZFDCA	-	Zanzibar Food, Drugs and Cosmetics Act
8.	WHO	-	World Health Organization

FOREWORD

The Zanzibar Food and Drugs Board (ZFDB) is responsible for among other things, protecting consumers against health hazards associated with food. As one of the means for achieving this goal all pre-packaged food have been undergoing pre-market evaluation to ascertain their compliance with set standards of quality and safety prior to their registration.

Advancements in science and technology have resulted in the preparation of complex food products which require extensive and systematic documentation to be able to assess their quality and safety hence necessitating development of these guidelines. It is my hope that this guide will go a long way to assist food registration applicants to prepare the required documentation in a systemic manner. This will speed up the evaluation process and make it more transparent because the criteria of acceptance or rejection are now more clear. In this way the efficiency and effectiveness of ZFDB in protecting the public against health hazards associated with food will be enhanced.

Preparations of these guidelines would not have been possible without the contribution of various stakeholders who worked tirelessly in drafting, reviewing and refining them at one stage or another. On behalf of the ZFDB I would like to thank them all. I am particularly indebted to the management of ZFDB for guiding and participating actively in the whole process of development of these guidelines.

DR. BURHANI OTHMAN SIMAI
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INTRODUCTION

Section 36 of the Zanzibar Food, Drugs and Cosmetics Act, 2006 prohibits the manufacture, sell, distribution, importation, or exposure for sale of any pre-packaged food unless it has been registered by the Zanzibar Food and Drugs Board.

The objective of food registration is to safeguard public health by ensuring that all foods meet national standards before being allowed to circulate in the Zanzibar market. These guidelines for registration have been developed to guide those who may wish to engage in importation or manufacture of pre packaged food for sale in Zanzibar.

Though every attempt has been made to make it as comprehensive as possible applicants are at liberty to include any additional information which may improve the presentation and assist the evaluation of the product. The requirements in the guidelines have been divided into 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, notification of alterations, and application for renewal of registration. Chapter three contains product specific requirements for registration of food. The product specific requirements are meant to guide applicants on food quality control data required for adequate evaluation of quality and safety of pre-packaged food. Chapter four prescribes information to be declared on pre-packaged food label and how the information should be presented. This is meant to ensure harmonized labeling of pre-packaged food to be sold in the country.

In order to ensure safe use of food additives in Zanzibar, 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. For every food product to be marketed in Zanzibar an application in the form prescribed in Annex II of these guidelines has to be made to the Board. A dully filled in application form must be accompanied with product information, supporting documents, and samples as prescribed under chapter three.

Registration of food products shall only be made upon compliance with these guidelines and suitability of the premises used in their manufacture. However, high risk foods will only be registered if HACCP system has been applied in their manufacture.

CHAPTER I

DEFINITIONS

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

Board
Means the Zanzibar Food and Drugs Board, or its acronym "ZFDB" established under section 4 of the Zanzibar Food, Drugs and Cosmetics Act, 2006.

Codex
Means the Codex Alimentarius Commission responsible for execution of the joint FAO/WHO food standards programme for the purpose of protecting the health of food consumers and ensuring fair practices in the international food trade.

Common name
Means any name in Kiswahili or English by which any food is generally known.

Composition of food
Means the ingredients including additives of which it consists, proportions, quality and purity in which those ingredients are contained.

Container
Means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptacle.

Contaminants
Means any substance not intentionally added to food which is present in such food as a result of production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination).

Registrar
Means the Registrar of the Zanzibar Food and Drug Board appointed under section 6(1) of the ZFDCA, 2006.

Drained Weight
Means the net weight of a food product after draining the liquid medium in which it is packed.

Finished product
Means a product that has undergone all stages of production, including packaging in its final container and labeling

Food
Means any article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in manufacture or treatment of food.

Food Additive
Means any substance not normally consumed as food by itself and not normally used as a typical ingredient of the food, 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 food. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.

Hazard Analysis Critical Control Points (HACCP)
Means a system which identifies, evaluates and controls hazards which are significant for food safety along the food chain.

HACCP plan
Means a document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Certification of GMP, HACCP or ISO Compliance
Means a certificate or warranty accompanying an application for registration of food to be imported into Zanzibar issued by competent authority acceptable by ZFDB certifying that the manufacturing practices comply with GMP or HACCP or any applicable ISO standards.

High risk food products
Means food products, which by their nature are prone to support growth of microorganisms or other toxic conditions or food products intended for vulnerable population such as infants, pregnant women and the elderly.

Ingredient
Means any substance, including a food additive, used in the manufacture or preparation of food and present in the finished product although possibly in a modified form.

Irradiated food
Means food, which has been treated with ionizing radiation with the objective of extending its shelf life.

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 prepackaged food.

Large scale manufacturing facility
Means a food manufacturing facility with annual turnover of not less than one hundred million shillings.

Lot/Batch
Means a definitive quantity of commodity produced essentially under the same conditions.

Manufacture
Means and includes all operations involved in the production preparation, processing, filling, transforming, packaging and repackaging and labeling.

Manufacturer
Means a person or firm that is engaged in the manufacture of food under the categories of large scale or medium scale

Medium scale manufacturing facility Means a food manufacturing facility with a capital investment of not less than two hundred million shillings but not exceeding eight hundred million shillings

Micro scale facility
Means a food manufacturing facility with a capital investment not exceeding five million shillings

National Standard
Means a Tanzania Standard prescribed by the Tanzania Bureau of Standards (TBS).

Pre-packaged food
Means a food that is packaged or made up in advance in a container, ready for offer to the consumer or for catering purposes. The term does not include single ingredient food which have not undergone considerable treatments such as for the control of health hazards associated with such foods, for the purpose of consistently, improving safety and quality.

Processing Aid
Means a substance or material, not including apparatus or utensils and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the finished product.

Product variants
Means products manufactured by same manufacturer in same premises using same typical food ingredients at same levels but differing in food additives or type of packaging material used to achieve a technological purposes.

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.

Sale
Means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or

possess for purposes of sale, and barter or exchange supply or dispose of to any person whether for a consideration or otherwise;

Small scale manufacturing facility
Means a food manufacturing facility with a capital investment exceeding five million shillings but less than two hundred million shillings.

Transgenic food product
Means a food product derived from genetic engineering or a food product containing an ingredient, which has been derived from genetic engineering.

CHAPTER II

GENERAL REQUIREMENTS

Every person who intends to market any prepackaged food in Zanzibar must apply to ZFDB for registration of the product. When applying to ZFDB for registration, the applicant is obliged to follow strictly the instructions prescribed in this guide.

Since evaluation and processing of an application takes about 60 days applicants will be informed of the fate of their application immediately after completion of the evaluation process. In order to avoid unnecessary delays, applicants are strongly urged to read the whole of this guide carefully as it will enable them prepare and submit acceptable applications. Submission of an application contrary to the requirements prescribed in this guide may result in delays, queries or its rejection.

1 Application formalities

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 Zanzibar.

The applicant shall be responsible for the product and all information supplied in support of his application for registration of the product, and alterations thereof.

b) Resident responsible person

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

The responsible person shall:

i) Monitor the product in the market (both in Zanzibar and wherever the product is sold) and inform the Board immediately after the detection of any problem relating to the registered product such as serious manufacturing defects which may endanger public health.
ii) Facilitate communication between the applicant and the Board on matters relating to the product.
iii) Handle product recalls whenever necessary.

2 Documentation

The following documents shall be required to make a complete application:

i) Dully filled in application form
ii) Registration file consisting of information as prescribed in these guidelines

iii) For products to be imported, certification of GMP, HACCP or ISO compliance issued by competent authorities from the country of origin of the product as prescribed in these guidelines. A separate application is required for each product, i.e. products containing different ingredients or manufactured by different manufacturers shall require separate applications.

However, product variants or products manufactured by same manufacturer in same premises using same ingredients in same levels, but differing only in pack size require one application.

a) Language

All the prescribed information shall be submitted in English or Kiswahili and all communications regarding the application shall be made in any of these two languages.

b) Compilation

The registration file shall be compiled in a well-presented and orderly manner. Pages of the file shall be sequentially numbered. Drawings, tables, diagrams, graphs etc. should also be well-annotated and numbered and appropriate references or cross-references clearly indicated.

c) Paper size and quality

Data should be presented on A4 paper and font size should be at least 11 of Bookman Old Style for documents prepared by applicant. Supporting documents, etc. should as far as possible be of the same size. Quality of paper used should be such that it allows firm binding and long time storage. All copies must be legible.

d) Reference to official standards

All food intended to be registered in Tanzania and Zanzibar shall comply with the National Standard of the respective food and where it does not exist, Codex standards or any other standard recognized by ZFDB. The standard used must be cited.

3 Sample size

Sample size of samples to be submitted together with an application for registration of food 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.

For products in packaging unit of not more than 5kg or liters, five units of sample shall accompany the respective application. In case of products marketed in packaging unit exceeding 5kg or liters, five units each of at least ½kg or liters shall be drawn and submitted to ZFDB together with the respective application. The application file and samples shall be accompanied with an empty but well labeled container in the way the product is marketed.

4 Submission

a) Submission of application

One hard copy of an application file and a CD-ROM if any, should be submitted to: *The Registrar, Zanzibar Food and Drugs Board, P. O. Box 236, Zanzibar.*

b) Payment of Fees

All applications shall be accompanied by relevant non refundable fees as prescribed in the Fees and Charges Regulations, 2007 made under the Zanzibar Food, Drugs and Cosmetics Act, 2006.

Payment of fees may be made by bank transfer to: *Zanzibar Food and Drugs Board, Account No. 021103000241, THE PEOPLE'S BANK OF ZANZIBAR LIMITED. ZANZIBAR.*

Note: All bank charges shall be borne by the applicant.

5 Processing of application

a) An application shall only be accepted and processed if all the following conditions are complied with:

i) Submission of a dully filled in application form.
ii) Submission of a application file with complete product information as prescribed in these guidelines.
iii) Payment of relevant fees.
iv) Submission of sufficient samples as prescribed in these guidelines.

b) When an application for registration is accepted, an acknowledgement receipt will be issued together with a reference number for each product. This reference number must be stated in all correspondence with the Board in connection with the product.

c) The Board may during the assessment of the product require the applicant to submit additional information, give explanations, or provide clarification. The processing of the application shall be kept on hold until such information is provided.

d) Applicants will be informed after the processing of their application has been completed, and if the application is successful applicants will be issued with a certificate of registration, together with conditions of registration (if any).

6 Validity of registration

Subject to payment of annual retention fees, the registration of a product shall be valid for five years unless sooner suspended, cancelled or revoked by the Board.

7 Notification of change/Alteration

a) If for any reason the registration holder changes any matter related to a registered food (example, change of composition, packaging, labeling etc) shall before marketing the changed product, notify the alteration and obtain an approval from the Board.

b) Reasons, data supporting documentation and samples of the changed product shall accompany such a notification.

c) In case of change of manufacturing site the notification shall be accompanied with GMP inspection fees.

8 Renewal of registration

a) All applications for renewal of registration shall be made on an application for renewal form at least 60 days before expiry of the existing registration.
b) All alterations made prior to expiry of the existing registration shall be compiled and submitted to the Board.
c) All applications for renewal of registration shall be accompanied with application for renewal fee, GMP inspection fee and samples as prescribed in these guidelines.

9 Refusal or revocation of registration

The Board may by giving reasons refuse, suspend, cancel, revoke or amend registration of any product.

10 Appeals

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

11 Termination of product Registration by Holder of Registration Certificate

Whenever a product registration holder wishes to terminate the registration before the end of its validity he shall notify the Board in writing at least sixty days prior to the date of termination, giving reasons thereof.

CHAPTER III

PRODUCT SPECIFIC REQUIREMENTS

1 Brief description of the product

Describe briefly the physical characteristics of the product.

2 Intended use of the product

Describe briefly the use of the product (as raw material or for direct consumption) and the target end user, e.g. infants, children, adults, elderly, diabetics and HIV/AIDS patients.

3 Ingredients used

Give names of all ingredients and quantities per unit measure (proportion) and their corresponding uses in that product. Food additives shall be used in accordance with the National Standard or regulations of permissible and their levels of use.

4 Manufacturing process

Give a well-annotated flow diagram of the manufacturing process.

5 Quality and safety control data

i) Give a complete account of the quality and safety tests, which are routinely carried out on each batch of the product and its ingredients.

ii) List in process quality control tests and checks performed, the stages at which tests are done, the frequency of sampling and number of samples taken each time a test is done.

iii) For each test state the limit or criteria of acceptance or rejection.

6 Packaging Materials

Give a brief description of the type and properties of packaging material and the seal and its liner if any and provide justification for the suitability of the packaging material and the seal and its liner used.

7 Shelf life and storage conditions

Give a brief description of the method used for the determination of shelf life. State the recommended storage conditions and shelf life of the product including any relevant information after the product is opened for use or reconstituted.

8 Food Labeling:

All food products shall be labeled in the manner prescribed in these guidelines except to the extent otherwise expressly provided in an individual National Standard or where there is no such a National Standard, an individual Codex standard.

9 Additional requirements for high risk food

High risk food products shall be manufactured in accordance with HACCP system of food safety control. In case one is applying for registration of any of the hereunder listed high risk products submit a HACCP plan and certification of your compliance with the plan.

a. Poultry products
b. Meat and meat products
c. Eggs and egg products
d. Sea foods, fish and fish products
e. Dairy products such as milk, cream, cheese, yogurt, deserts and ice cream
f. Irradiated food products
g. Dressings and spreads
h. Food for infants and under fives
i. Food for the elderly, pregnant women and lactating mothers
j. Vegetable products
k. Any of the low acid foods

10 Foods suspected to be contaminated with radioactive material

Countries with history of radioactive products should not be allowed to enter Zanzibar market, despite of certificates. This is due to our lack of equipments and expertise to verify that certificate.

CHAPTER IV

REQUIREMENTS FOR LABELLING OF PREPACKAGED FOODS

1 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 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 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.

2.1.6 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 'Starch' chemically modified starches

All species of fish where 'Fish' the fish Constitutes an ingredient of another Food and provided presentation of such food does not refer to a specific species of fish.

All types of poultry meat where 'Poultry meat' 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.

All types of cheese where the 'Cheese'. cheese or mixture of cheese constitutes an ingredient of another food and provided such food does not refer to a specific type of cheese.

All spices and spice extracts 'Spice', 'spices', or not exceeding 2% by weight 'mixed spices', as appropriate either singly or in combination in the food.

All herbs or parts of herbs 'Herbs' or 'mixed herbs' not exceeding 2% by weight as appropriate. either singly or in combination in the food.

All types of gum preparations 'Gum base' used in the manufacture of gum base of chewing gum.

All types of sugar 'Sugar' Anhydrous dextrose and 'Dextrose' or 'Glucose' monohydrate

All types of caseinates 'Caseinates'. Press, expeller or refined "Cocoa butter'. cocoa butter.

All crystallized fruit not 'Crystallized fruit'. exceeding 10% of the weight of the food.

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.

Acids
Anticaking Agent
Antioxidant
Food Color
Emulsifier
Emulsifying Salt
Flavor Enhancer
Preservative
Stabilizer
Sweetener
Thickeners/gelling agents
Antioxidant synergists
Carrier solvents
Enzymes
Flavors
Buffering agents

2.2.2.4 The expression "flavors" 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 ("System 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 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.

2.4 **Name and Address**

Name and address 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 Zanzibar 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 "dates of manufacture and 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.

2.7.2 In addition to the dates of manufacture and 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 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 a raw materials, which has been irradiated, the label of the product shall contain a statement indicating the treatment.

4 Exemptions from mandatory labeling requirements

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

5 Presentation of labeling information

5.1 **General**

5.1.1 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 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.

2 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 Board 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 Approval to change or addition in the list

The Board 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.

ANNEX II

ZFDB /FSQD/AFM/012….

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH
ZANZIBAR FOOD AND DRUGS BOARD

APPLICATION FORM FOR REGISTRATION OF PREPACKAGED FOOD

Date: …… Application Number (for official use only)……

1. **Particulars of product:**
   - 1.1 Brand Name:.…
   - 1.2 Common Name: ……..
   - 1.3 Product form (Solid, Liquid, etc.,) ……
   - 1.4 Intended use: ……
     ……
   - 1.5 Type of packaging material and seals: ..……
     ……..
   - 1.6 Packaging unit: …….
   - 1.7 Shelf life: …….
   - 1.8 Shelf life (after first opening of container) ……
   - 1.9 Shelf life (after reconstitution, where applicable) ……
   - 1.10 Recommended storage conditions: ……
     ……..

2. **Particulars of Applicant**
   Name: ……..
   Physical Address: ……..
   Postal Address: ……..
   Telephone:……...Fax:……..
   Email:……

3. **Particulars of a resident responsible person (for foods to be imported only)**
   Name: ……..
   Physical Address: ……..
   Postal address …….
   Phone: …… Fax: ……
   Email: …….. ……

4. **Manufacturer and qualified person for manufacture of the product**
   a. **Manufacturer**
   Name: ……
   Physical Address: ……
   Postal Address: ……
   Phone: …… Fax: …… .

Email: …….. ……..……

b. **Qualified person:**
Name: ……
Qualification: ……
……..……
Address: ……..……
Phone: …… Fax: ……..
Email: …….. ……..……

5. **Status of registration of the product in the country of origin, authorization/registration number and date (where applicable and for foods to be imported only).**
……..
……..

6. **Nutritional information of the product.**
……. …….
……..……..

7. **Ingredients used**

A. Typical food ingredients

SN	Name	Proportion (% or Ratio)	Purpose

B. Food Additives

SN	Chemical/scientific name	level	Purpose

8. Declarations by an applicant

I, the undersigned do hereby certify that all the information in this form and all the accompanying documentations is correct. I further confirm that the information referred to in my application file is available for verification.

I also agreed that I am obliged to comply with Zanzibar Food, Drugs and Cosmetics Act No. 2, 2006 requirements related to pre-packaged food.

Name:……
Position in the Company:……..

Signature and official stamp:…….....

Date:……