GUIDELINES FOR REGISTRATION AND PERMIT OF FOOD PREMISES

November, 2018

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ABBREVIATIONS

1. ZFDA
   - Zanzibar Food, Drugs and Cosmetics Agency

2. ZFDCA
   - Zanzibar Food, Drugs and Cosmetics Act 2/2006 and Amendment Act 3/2017
ACKNOWLEDGEMENT

The guidelines have been prepared by team members basing on their experience and knowledge on premises registration and licensing.

I would like to express my sincere gratitude to all those who contributed to the drafting and writing of these guidelines. Thanks to the Members of the drafting team; Dr. Burhani Othman Simai, Dr. Khami Ali Omar, Ms. Khadija Ali Sheha, Mr. Abrahman Hamad Musa, Mr. Abdulmatin Yassin Mkubwa, Mr. Mohamed Shadhil Shauri, Ms. Khadija Abdalla Abass, Ms. Aisha Suleiman Mubandakazi, Mrs. Fatma Taha Makame, Mrs. Fatma Said Masoud and Ms. Amina Ramadhan Salim. The administrative and secretarial support provided by Mrs. Salma Yussuf is highly appreciated.

I would also like to sincerely thank all those who reviewed and made constructive comments and inputs to the guidelines including staff in the Department of Food Safety Control.

Dr. Khamis Ali Omar
DIRECTOR
DEPARTMENT OF FOOD SAFETY CONTROL
FOREWORD

The Zanzibar Food, Drugs and Cosmetics Agency is a regulatory body established under section 3(1) of the Amendment Act No.3 of 2017 of the Zanzibar Food, Drugs and Cosmetics Act, No. 2 of 2006. It is the sole Authority empowered by the Act for its enforcement. The Act provides for regulation and control of quality, safety and efficacy of food, drugs, herbal drugs, medical devices and cosmetics. Therefore, the Act aims at ensuring that Zanzibaris get products that are safe, of good quality and effective for their intended use.

The achievement of this goal depends on the awareness and adherence to the law by all key players dealing in one way or another with products regulated under the Act. The Act stipulates clearly in sections 16 and 18 the requirements for registration of premises and licensing of food business respectively.

All dealers in food business should have their prime concerns on the welfare of the members of the public they serve. Therefore, dealers should take reasonable steps to ensure that the food supplied to the community is safe, of good quality, and at the same time they should ensure that registered premises for selling, storage and distribution are well constructed, secured and maintained in a way that the safety and health of consumers is assured.

It is my sincere belief that you find these guidelines very useful and that you will commit yourselves and cooperate with us and we highly appreciate to receive your comments and experience gained from the use of these guidelines for the future improvement.
CHAPTER ONE

1. INTRODUCTION

1.1 General

Registration of premise for dealing in food business is a prerequisite requirement prior to commencing of such business. This requirement is stipulated under section 16 of the Zanzibar Food, Drugs and Cosmetics Act (ZFDCA) No. 2 of 2006 which prohibits the use of any premise for the manufacture for sale, sell, supply or storage of food unless the premises have been registered by the Zanzibar Food, Drugs and Cosmetics Agency (ZFDA) for that purpose. Furthermore to this, section 18 of the same Act requires all dealers in such business to apply to the Agency for permit and obtain such permit before starting operation.

Registration of premises and permit of food business shall not be considered as the sole means of controlling operations of such premises. However, there are other valuable means of aid in enforcing relevant legislation, such as adherence to good hygienic practices, good storage practices and good distribution practices that ensure day-to-day operations of these premises are in line with the Law and Regulations. Basing on these grounds, the Agency is empowered to suspend or revoke the registration certificate and permit of any premises found operating contrary to the law.

Food dealers should note that the requirements stipulated in these guidelines are considered to be minimum. In view to that all dealers should adhere to these requirements.

1.2 Objective

These guidelines have been developed to guide food dealers on the requirements for registration, permit and operation of their businesses as per the ZFDCA and its associated Regulations.

1.3 Scope

This document outlines the requirements and procedures governing the registration and permits of food premises upon compliance.
1.4 Terms and Definitions

For the purpose of these guidelines, the following definitions applied;

**Agency**
Means the Zanzibar Food, Drugs and Cosmetics Agency or the acronyms ZFDA
Under section 3(1) of ZFDC Amendments Act No. 3/2017.

**Business**
Includes professional practice and any activity carried on by person or a body of
persons in relation to products regulated under Zanzibar Food, Drugs and Cosmetics

**Equipment**
Means machines, instrument, apparatus, utensil or appliance, other than a single
use item, used or intended to be used in or in connection with food handling and
include any equipment used to or intended to be used to clean food.

**Premises**
Includes land, building structures, basements and vessels and in relation to any
building includes a part of a building and any cartilage, forecourt, yard or places of
storage used in connection with building or part of that building, and in relation to
vessel means ship, boat, and aircraft includes a carriage or receptacle of any kind.

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

**Handling**
Includes the making, manufacturing, producing, collecting, extracting, processing,
storing, transporting, delivering, preparing, treating, preserving, packing, cooking,
thawing, serving or displaying of food.

**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 possess for the purpose of sale and batter or exchange supply or
dispose of to any person whether for a consideration or otherwise.

**Executive Director**
Means the Chief Executive of the ZFDA appointed under section 6(1) of the ZFDC
amendments Act No. 3/2017.

**Inspector**
Means any officer appointed, authorized or recognized under section 106(1) of the
CHAPTER TWO

2. REQUIREMENTS FOR PREMISE REGISTRATION AND PERMIT

2.1 General Requirements

2.1.1 Any person who intends to carry out a business of food for human consumption shall apply to ZFDA for registration of premises and permit of carrying out such food business.

2.1.2 In order to adhere to the legal requirements, the applicant is obliged to follow the instructions prescribed in these guidelines.

2.1.3 The food business shall include but not limited to the following categories:

a) Food Processing Facilities
   i. Food Manufacturing Facilities.
   ii. Food Caterers
   iii. Bakery.
   iv. Grain Mills.
   v. Kiosks.
   vi. School and Institution Canteens.
   vii. Restaurants.
   viii. Hotels.
   ix. Abattoirs, slaughterhouse and butchers.

b) Food Outlets
   i. Retail and Wholesale food outlets.
   ii. Mobile food catering facilities and Food Carriers.
   iii. Supermarket.
   iv. Godowns/ Warehouses/Cold rooms for storing food products.

2.2 Payment of Fees

2.2.1 All applications shall be accompanied by relevant non-refundable fees as prescribed in the ZFDA Fees and Charges Existing Document, made under the Zanzibar Food, Drugs and Cosmetics Act No.2/2006.

   i. For local Currency in Tshs, payment of fees may be made to: Zanzibar Food and Drug Agency Account No. 021103000579 (Forodhani Branch), Account No 041103000230 (Wete Branch), THE PEOPLE'S BANK OF ZANZIBAR LIMITED, ZANZIBAR.

   ii. For foreign currency in USD, payments may be made to A/c No. 0221010000015 THE PEOPLE'S BANK OF ZANZIBAR LIMITED, ZANZIBAR (Forodhani Branch), Swift Code: PBZATTZT or by bank draft in favour of Zanzibar Food and Drug Agency.
2.2.2 All bank charges shall be borne by the applicant.

2.3 Language

All the prescribed information and communications regarding the application shall be made either in English or Kiswahili.
CHAPTER THREE

3. PROCEDURES FOR PREMISE REGISTRATION AND BUSINESS PERMIT

3.1 Application Procedures for Premise Registration

3.1.1 All applications for registration of food premises shall be made to the ZFDA Executive Director in prescribed application form (Annex 1).

3.1.2 The application shall be submitted to the ZFDA Head Office and Sub office(s).

3.1.3 Application form for registration of food premises to operate food business shall be obtained from Food Safety Control Department at ZFDA or through the ZFDA website www.zfda.go.tz.

3.1.4 Applicants shall furnish their applications for registration of food premises before any construction/renovations of the proposed premises.

3.1.5 Authorized food inspector(s) shall conduct pre-inspection of the site and the proposed premises plan/design according to the type of business and shall give his advice and/or instructions in writing to the applicant on the suitability for the intended business.

3.1.6 When the construction or renovation is complete, the inspector(s) shall conduct a thorough inspection using appropriate inspection checklist for that particular business and give his observations and recommendations on the suitability of the premises in the Inspection report.

3.1.7 The food registration officer shall make sure that the necessary applicant informations are accurately provided as requested in the application form and all informations required in the inspection checklist are properly filled.

3.1.8 Upon receipt of duly filled in application forms, inspection report and all other necessary documents from the food registration officer, the Executive Director shall scrutinize the status of each application, followed by acknowledging the receipt.

3.1.9 The Executive Director may approve, withheld or reject any application and provide reason(s) for his/her decision of withhold or rejection.

3.1.10 All applicants whose application have been approved, withhold or rejected as the case may be, shall within one week from the day which the decision was made, sent with an official letter informing them on the status of their application.

3.1.11 Applicants whose applications have been withheld for any reason shall be required to carry out rectification or give a clarification before they are legible for consideration in the following meeting.
3.1.12 The Executive Director shall before issuing premises registration certificate (Annex 2) to which the application relates, consider if the following requirements have been met;

a) The proposed premises have been inspected by the authorized food inspector and complied the required specifications.

b) For the food manufacturing facilities, the premise layout, process flow chart and certificate of qualified persons are attached in the application form.

c) Payment of application fees as prescribed in the Food, Drugs and Cosmetics (Fees and Charges) existing document that has been made to the Agency.

3.2 Application Procedures for Business Permit

3.2.1 All applications for permit to operate food business or renewal of permit shall be made to the ZFDA Executive Director in prescribed application form (Annex 3).

3.2.2 The application shall be submitted to the ZFDA Head Office and Sub office(s).

3.2.3 Application forms for permit to operate food business shall be obtained from Food Safety Control Department at ZFDA or through the ZFDA website www.zfda.go.tz.

3.2.4 Applicants shall furnish their applications for permit to operate food business after registration of premises.

3.2.5 Upon receipt of duly filled in application forms and all other necessary documents from the applicant, the Executive Director shall scrutinize the status of each application, followed by acknowledging the receipt.

3.2.6 The Executive Director may approve, withhold or reject any application and provide reason(s) for his/her decision of withhold or rejection.

3.2.7 All applicants whose application have been approved, withhold or rejected as the case may be, shall within one week from the day which the decision was made, sent with an official letter informing them on the status of their application.

3.2.8 Applicants whose applications have been withheld for any reason shall be required to carry out rectification or give a clarification before they are legible for consideration in the following meeting.

3.2.9 The Agency shall before issuing business permit (Annex 4) to which the application relates, consider if the following requirements have been met;

a) The applicant premises has been registered by ZFDA;

b) For renewal of permit, current premise inspection report should be submitted.
c) Payment of annual permit fees as prescribed in the Food, Drugs and Cosmetics (Fees and Charges) existing document.

3.3 Validity of Food Premises Registration and Business Permit

3.3.1 The registration of premises shall be valid provided that the following conditions are met.

a) The business permit is renewed.
b) The premises complies with conditions under which it was registered;
c) There is no change of ownership, business name, location or any alteration of registered premises.
d) The Agency has not suspended, cancelled, revoked or amended premises registration.
e) Premises registration holder has no wish to terminate his/her registration.

3.3.2 The permit shall be annually renewed unless suspended, cancelled or revoked by the Agency.

3.3.3 Every Food business permit issued by the Agency shall expire on the 30th Day of December every year.

3.3.4 The Agency shall start to receive applications for renewal of permit one month before 30th December.

3.3.5 Renewal of permit shall be done through the ZFDA headquarter and sub office(s) by filling in application form.

3.3.6 Dealers who shall delay to renew their permits beyond 30th January every year shall be required to pay the Agency the prescribed fee together with 25% penalty. Contrary to that, premises registration certificate shall be revoked.

3.4 Notification for Shift of Premises, Change of Ownership or Any Alteration and Termination of Premises Registration by Holder of Registration Certificate

3.4.1 Any change of location (shift of premises), trade name of the premises, ownership or any other change of registered premises, shall be made to the Executive Director.

3.4.2 Premises registered by Agency shall cease to have effect upon the expiration of thirty days from the date of changing the ownership of the business.

3.4.3 Whenever a Premises registration holder wishes to terminate the registration, he/she shall notify the Agency in writing at least thirty (30) days prior to date of termination, giving reasons thereof.
3.5 Appeals

3.5.1 An applicant who is aggrieved by the decision of the Agency regarding rejection of his/her application shall submit his grievances to the Minister responsible for health within 60 days from the date of the decision.
CHAPTER FOUR

4. SPECIFIC REQUIREMENTS

4.1 Location

4.1.1 The food premises shall be located away from sites or activities that emit obnoxious material like fumes, dust, smoke, offensive trade or breeding sites for vermin.

4.1.2 Physical and postal address of the premises where the business is to be carried out shall be clearly indicated in the application form to include plot and house numbers, street, district and region as this will facilitate easy reach during supervision and inspection.

4.1.3 The Agency shall have final say on the location and name of the proposed premises.

4.2 Premises design

4.2.1 The food premises shall be designed for the intended purpose and shall have no direct link with any business or occupation that may lead to contamination of food.

4.2.2 The premises shall be of suitable layout and constructed to facilitate easy maintenance and sanitation.

4.2.3 The food premises and facilities installed shall have;

   a) Sufficient space for placement and storage of materials, which are necessary for sanitary operations.
   b) Adequate space, either by partition, location or other effective means for those operations, which may cause contamination of food.
   c) Sufficient lighting and ventilation to enable all operations to be carried out satisfactorily and safely.
   d) Maximum protection against rodents, birds, vermin, etc.

4.2.4 The floor, walls and ceiling of food premises shall be adequately cleanable and maintained in a clean and good state of repair.

4.2.5 The fixtures, ducts and pipes shall not be suspended over areas where drips or condensate may contaminate food and raw materials or food contact surfaces.

4.2.6 Aisles or working spaces between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contaminating the food or food contact surface with their clothing or personal contact.
4.3 Equipment, Utensils and Food Contact Surfaces

4.3.1 Every utensil and equipment used in food premises shall be suitable for their intended use; well designed and adequately cleanable and proper maintenance of cold chain for frozen products.

4.3.2 Every food contact surface shall be smooth and impervious, free from pits, crevices and loose scale, non-toxic; and capable of withstanding repeated cleaning, disinfection and sanitization.

4.3.3 Utensils, crockery, cutlery and other equipment coming in contact with food shall be sufficient in number to enable adequate sanitization before reuse. Single service articles shall be stored in appropriate containers and handled, dispensed, used and disposed off to prevent contamination of food or food contact surfaces.

4.4 Personnel

4.4.1 Persons suffering from communicable diseases shall not be involved in handling of food or food contact surfaces.

4.4.2 Thorough medical examination for Food handlers shall be carried out prior to employment and after every six months.

4.4.3 Medical examination records for each worker shall be kept properly and accessible for inspection. The records shall be kept and maintained for not less than two years.

4.4.4 There shall be qualified personnel from a recognized Institution to identify sanitation failures.

4.5 Storage Facilities

4.5.1 Storage facilities shall protect products from deterioration and the specified storage conditions shall be monitored and maintained accordingly.

4.5.2 Controlled storage environment/facilities e.g air conditions, refrigeration for cold chain products shall be made available and monitored using suitable temperature recording devices and records reviewed and filed.

4.5.3 All food products shall be stored off the floor in well-fitted shelves or pallets

4.5.4 Storage facilities for grains should be monitored for humidity, temperature and pests and in addition records should be kept properly.

4.6 Sanitation and Hygiene

4.6.1 All food premises shall be provided with adequate and easily accessible sanitary conveniences to cater separately for both genders, for employees and/or customers.
4.6.2 There shall be adequate and readily available potable water supply; hot and cold running water to be used for the intended operation or use.

4.6.3 There shall be proper system of waste disposal.

4.6.4 There shall be provision of protective gears and occupation health facilities.

4.6.5 Food handlers shall be clean in person and shall avoid unhygienic practices such as smoking, sneezing and coughing over food, nose picking, finger licking, talking over food etc.

4.6.6 There shall be adequate provision for hand washing facilities with hot and cold running water, nail brushes and disinfectant liquid soap. To avoid re-contamination of hands there shall be automatic or elbow or foot operated water tapes.

4.6.7 Doors may be designed to open by pushing from all sides or self operating doors to avoid contaminating food handler’s hands.

4.7 Documentation and Record Keeping

4.7.1 Any person who owns a food business shall make available the following documents/records:

a) Food import permits and/or purchasing documents
b) Sanitation and fumigation documents
c) Ledger book or an appropriate inventory control system
d) Visitors book
e) Sales receipts (wholesalers)
f) Inspection register document
g) Medical examination records where applicable
h) Complaints handling document
i) Register for expired/recalled /rejected/withdrawn food products
j) Staffs Training Records

4.8 Recalls, Reject and Withdrawal

4.8.1 The applicant shall show capacity to prompt and effective system of traceability and recall from the market of products known or suspected to be defective or hazardous.

4.8.2 In case of recall of product initiated by the Agency, the Agency shall notify the food dealer and state the reason(s) of recall; the recalling exercise shall be executed within sixty (60) days.

4.8.3 In case of recall of product initiated by the dealer himself, the Agency shall be notified on the reason(s) of recall and the exercise shall be executed within sixty (60) days.
4.8.4 Recall operations shall be capable of being initiated promptly at least down to the level of retailers.

4.8.5 The distribution records shall be readily available to the person(s) responsible for recalls and they shall contain sufficient information related to the product, e.g. Name of product, Manufacturer, Dates of Manufacture, Dates of Expire and Batch Number/Lot Number.

4.8.6 The disposal of recalled/rejected/withdrawn products from the market shall be effected within one month after completion of exercise. Disposal exercise shall be carried out under supervision of ZFDA inspectors and representatives from other Government Institutions.
5. REFERENCES

Other important documents to be read together with these guidelines include;

(a) The Zanzibar Food, Drugs and Cosmetics Act No. 2 of 2006 and its Amendment Act No. 3/2017.

ANNEXES

Annex 1

APPLICATION FOR REGISTRATION OF PREMISES
Under Section No. 16(2) of the Zanzibar Food, Drugs and Cosmetics Act, 2006

PART I: APPLICANT DETAILS

I/We hereby apply for registration of my/our existing/new premises in accordance with the Zanzibar Food, Drugs and Cosmetics Act, 2006 and its Amendments No. 3/2017.

1. Name of applicant .................................................................
2. Postal address ................................................................. Tel No: .................................................................
3. Full name of partner(s) and/Director(s)........................................ Tel No: .................................................................
4. Situated at ................................................................. Street/Village, Plot No: ................................................................. District ................................................................. Region .................................................................
5. Premises to be registered for a business of .................................................................
6. The business will be under the direct supervision of .................................................................
7. The proposed name of the premises is .................................................................
8. My/our financial resources committed for this business amount to ................................................................. and my/our annual projected turnover is Tshs .................................................................

PART II: APPLICANT DECLARATIONS

1. If my/our premise is registered and licensed I/We shall keep it in hygienic condition and good state of repair under the above mentioned Act and Regulations made there under.
2. I/We have not been convicted of any offence relating to provision of the Zanzibar Food, Drugs and Cosmetics Act 2006 and Regulations made thereunder within 12 months immediately proceeding this application and have not been disqualified from holding a licence/certificate and my/our license is/is not suspended.

N.B. False declaration constitutes an offence.

.................................................................  ................................................................. Signature of applicant and stamp

Date  

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Fees ................................................................. Receipt No: ................................................................. of .................................................................
Registration granted/not granted because .................................................................
Registration No: ................................................................. Approved by Management Meeting No: ................................................................. of .................................................................

.................................................................  ................................................................. Responsible Registration Officer  Signature

Date  

.................................................................  ................................................................. Signature of Executive Director and stamp


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Annex 2

Zanzibar Food and Drug Agency

Registration Certificate of Premises
Under Section 19(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006

Certificate No.
ZFDA/CP/01281/2018

This is to certify that the premises owned by
M/S Yakub Salim Kombo of P.O. Box ---, Zanzibar,
which is located at Darajani street / village in Urban
District / municipality, Urban West Region,
has been registered to be used for preparation / selling / packing / carrying / advertising / storing
/ manufacturing of food with
registration number ZFDA/RC/01281/2018.

Subject to the following conditions:
a) The premises and the manner in which the business is to be conducted must conform to the
requirements of the Zanzibar Food, Drugs and Cosmetics Act, 2006 related to premises
registration at all times failing of which this certificate shall be suspended or revoked.
b) Any change in the ownership of the registered premises shall automatically invalidate this
certificate.
c) This certificate is not transferable to other premises or to any other person.
d) This certificate shall be displayed conspicuously in the registered premises.

Issued on
04 – 05 – 2018

Executive Director

28 Nov 2018
Original Copy
Annex 3

APPLICATION FOR PERMIT

Under Section 18(1) of the Zanzibar Food, Drug and Cosmetic Act, 2/2006

PART I: APPLICANT DETAILS

I/We hereby apply for renewal/a new license to manufacture, sell, pack, store or distribute Pre-packaged food.

1. Name of applicant .................................................................
2. Postal address ........................................Tel No .................................................................
3. Full names of Partner(s) and/Director(s): .................................................................
4. Premises situated at ........................................Street/Village, Plot No ........................................District ........................................Region ........................................
5. Premises registered for a business of .................................................................
6. Registration No. ........................................Date: .................................................................
7. Existing Business Permit No........................................Dated ........................................Expiring on ........................................
8. My/our financial resources committed for this business amount to ........................................and my/our annual projected turnover is T.Shs ........................................

PART II: APPLICANT DECLARATIONS

1. If my/our business is licensed I/We shall keep the premises in hygienic condition and good state of repair as required under the mentioned Act and Regulations made thereunder.

2. If I/We have not been convicted of any offence relating to provision of the Zanzibar Food, Drugs and Cosmetic Act, ........................................

N.B. False declaration constitutes an offence.

........................................ .................................................................

Date Signature of applicant and stamp

FOR OFFICIAL USE ONLY

Fees ........................................Receipt No ........................................of .................................................................
Registration granted/not granted because .................................................................
Registration No. ........................................Approved by Management Meeting No. ........................................of .................................................................

........................................ .................................................................

Date Responsible Registration Officer Signature

........................................ .................................................................

Date Signature of Executive Director and stamp

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Appendix 4

BUSINESS PERMIT

*Under Section 19(2) of the Zanzibar Food, Drugs and Cosmetics Act, 2006*

Permit No.

**ZFDA/BP/0529/2017**

Permit is hereby granted to

M/S LAZULI CAFE of P.O. BOX -, Zanzibar
to operate/ manufacture/ prepare/ pack/ sell/ store/ carry/ advertise

RESTAURANT

at the premises situated at SHANGANI street/ village in URBAN

District/ Municipality in URBAN WEST region having the premise’s registration No. ZFDA/RC/01064/2017.

This Permit shall have and continue to have effect from and including the day when it is issued until it ceases to have effect on **30-December, 2017**.

**Issued on**

**12 – 10 – 2017**

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**EXECUTIVE DIRECTOR**


**CONDITIONS**

1. This permit does not exempt the holder from complying with the business and trade requirements on the Ministry of Trade, Marketing and Tourism and the Municipal Authority.

2. It does not authorize the holder to operate business in an unregistered premise or during the period of suspension, revocation or cancellation of registration of the premises in respect of which it was issued.

3. It is not transferable without a written approval of Board.

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