RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING LICENSING TO MANUFACTURE, TO STORE, TO OPERATE AS WHOLESALE AND RETAIL SELLER OF PROCESSED FOODS AND RELATED PRODUCTS

(Rwanda FDA Law Nº 003/2018 of 09/02/2018, article 9)

ADOPTION AND APPROVAL OF THE REGULATIONS

In exercise of the powers conferred upon Rwanda Food and Drugs Authority under Article 9 of the Law N° 003/2018 of 09/02/2018 Establishing the Rwanda FDA and determining its mission, organization, and functioning, hereby ADOPTS and ISSUES these regulations N° CBD/TRG/028 Rev.0 governing licensing to manufacture, store, operate as a wholesale and retail seller of processed foods and related products, as approved this 21st day of January 2022.

21/01/2022

Dr. Emile BIENVENU
Director General

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	**09th July 2021**
ADOPTION BY RWANDA FDA	**04th November 2021**
STAKEHOLDERS CONSULTATION	**08th November 2021**
ADOPTION OF STAKEHOLDERS`COMMENTS	**12th November 2021**
DATE FOR COMING INTO EFFECT	**21st January 2022**

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ABBREVIATIONS AND ACRONYMS

FEFO : First expiry/First out
GDP : Good Distribution Practice
GMP : Good Manufacturing Practice
GSP : Good Storage Practices
HVAC : Heat, Ventilation and Air Conditioning (HVAC)
Rwanda FDA : Rwanda Food and Drugs Authority

CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these Regulations is to provide for a detailed framework for the effective and efficient licensing of the manufacture, storage, wholesale and retail of processed foods and related products.

Article 2: Citation

These Regulations may be cited as the "Regulations CBD/TRG/028 Rev. Nº 0, Governing licensing to manufacture, store, operate as a wholesale and retail seller of processed foods and related products."

Article 3: Application and Scope

These Regulations apply to premises involved in the manufacture, storage, sale, distribution, and dispensing of food products as stipulated under Article 3 of the Law Nº 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization, and functioning.

Article 4: Definitions

In these Regulations, unless the context otherwise requires:

"Applicant" means a person, company or their representative manufacturing or selling food products or food supplements applying for inspection for suitability of premises licensing of products.

"Approval" means official consent by the Authority as an acceptance of a licensing premises of processed food products and food supplements or practices related to that in the Rwandan market;

"**Authority**" means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Article 2 of the Law Nº 003/2018 of 09/02/2018.

"Authorization" means a legal document providing a right to manufacture, store, operate as a wholesale and retail seller of processed foods and related products, granted by Rwanda Food and Drugs Authority to an applicant under the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization, and functioning; it includes premise licenses, site approval notification letters, and any other documents deemed as such by the authority.

"Complaint" External information claiming a product does not meet defined acceptance criteria.

"Counterfeit product" A product which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, with the wrong ingredients, with an incorrect quantity of ingredients or with fake packaging.

"**Minor/Other Deficiency:** A deficiency that is not classified as either "Critical" or "Major", but indicates failure to meet the standards of premises suitability. A deficiency may be judged as **"Minor"** because there is insufficient information to classify it as "Critical" or "Major".

"Major Deficiency": A deficiency that is not a "Critical" deficiency, but could have major effects on the overall safety, efficacy and quality of the processed foods and related products. This consists of several **"Minor/Other"** related deficiencies, none of which on its own may be "Major", but which may together represent a "Major" deficiency or systems failure and should be explained and reported as such.

"Critical Deficiency": When the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to patients (personnel or environment) is highly probable, including life threatening situation, the deviation is categorized as Critical requiring immediate action, investigated and documented. A "Critical" deficiency may consist of several related deficiencies, none of which on its own may be "Critical", but which may together represent a" Critical" deficiency, or systems' failure where a risk of harm was identified and should be explained and reported as such.

"Critical equipment": means any piece of the equipment, instrumentation, or systems, whose malfunction or failure may cause variation in the quality and safety of the medical products.

"Distribution" The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products.

"Dormant" means inactive applications on which no response from the applicant is provided in a period of two (2) weeks to three (3) months from the date of reception of the feedback from the authority.

"Expiry date" The date given on the individual container (usually on the label) of product and including the period within which the product is expected to remain within specifications, if stored correctly.

"**Fee**" includes any charge made or levied in connections with services rendered by the Authority;

"First expiry/First out (FEFO)" means a distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date.

"Good Distribution Practice (GDP)" means that part of quality assurance that ensures that the quality of a product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, substandard, falsified or misbranded products.

"Good Manufacturing Practice (GMP)" means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation, or product specification. Good Manufacturing Practice is concerned with both production and quality control.

"Good Storage Practices (GSP)" means the part of quality assurance that ensures that the quality of a product is maintained by means of adequate control throughout the storage thereof.

"Import" means the act of Bringing regulated products into the Republic.

"Importer" means person or body corporate permitted and authorized under the laws and regulations in Rwanda pertaining to import food products for distribution, or not for sale purpose e.g. Raw materials used in the factory, other products imported for in-house use in hotels, etc…

"Labeling" Process of identifying a product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

"License" means an instrument for official approval of manufacturing premises, storage, wholesale and retail premises for the commencements of business.

"**Manufacturer**" means a person or corporation, or other entity engaged in the business of manufacturing, processing food products, whether engaging in full or partial processing.

"Person" A physical human being or moral entity.

"**Food product**" means any animal or plant products that have been processed or transformed from their original state and are intended for human or animal consumption with the exception of pharmaceutical products, tobacco, food additives and food fortificants. These may be products including but not limited to any powders, liquids, fruits, vegetables, grains, minerals, or commercially produced foods made for human or animal consumption.

"**Food additive**" means any substance added to food to maintain or improve its safety, freshness, taste, texture, or appearance.

"**Food fortificant**" means a substance, in a chemical or a natural form, added to food to increase its nutritive value.

"Food supplement" are concentrated sources of nutrients (i.e. *mineral* and vitamins) or other substances with a nutritional or physiological effect that are marketed in "dose" form (e.g. pills, tablets, capsules, liquids in measured doses). A wide range of nutrients and other ingredients might be present in food supplements, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.

"**Food supplement shop**" An entity providing food supplements on request. These may be distributors, or traders, and should be authorized by a competent authority.

"Premises" means any buildings or boats, aircrafts, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed, intended for manufacturing, storing, wholesale or retail activities of food products and related products.

"Qualified personnel": means an individual who by possession of a recognized bachelor's degree/advanced/diploma or its equivalent, who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter and technical responsibilities within an enterprise.

"Recall" A process for withdrawing or removing a product from the distribution chain because of defects in the product, consumer complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor, or a responsible agency.

"Storage" The storing of products up to their point of use.

"Supplier" An entity providing food products on request. Suppliers may be agents, brokers, distributors, manufacturers, or traders. Where possible, suppliers should be authorized by a competent authority.

"Wholesale" Supplying food products to a person or entity who obtains the product for the purposes of supplying it further to another person or entity.

In these Regulations, the following verbal forms are used:
"**shall**" indicates a requirement;
"**should**" indicates a recommendation;
"may" indicates a permission; and
"**can**" indicates a possibility or a capability.

CHAPTER II: LICENSING AND INSPECTIONS

Article 5: Obligation to obtain an Authorization

No person shall manufacture, process, import, store, sell, exhibit, distribute or retail food products, food additives, and food fortificants without prior authorization from the Authority. Failure to comply shall result in administrative sanctions.

Every premise, facility, establishment and company that is involved in the manufacture, processing, importing, storing, selling, exhibition, distribution or retailer of food products, food additives, and food fortificants must possess a valid license to operate issued by the Authority.

Article 6: Prohibitions

For purposes of public health interest, any food products, that do not meet quality requirements are prohibited.

No person shall manufacture, sell, donate, import, store, distribute or exhibited food products that:

1º Contain or consist of substances likely to adversely affect human or animal health when Consumed.
2º Are derived from diseased or infected animals.
3º Are manufactured, prepared, preserved or stored under unsanitary conditions.
4º Contain toxic substances.
5º Unsafe for human or animal consumption.
6º Are rotten, spoiled, expired, or contaminated.
7º Contain additives that may cause a disease.
8º Are associated with effects on human health.
9º Are not conform to quality standards or provisions of food product regulations.
10º Are counterfeited, recalled or manufactured, stored, distributed, exhibited, repackaged without Authorization.

Article 7: Types and Purpose of inspections

There shall be four types of licensing inspections which are divided into the following categories:

1º Routine inspection.
2º Enforcement inspection.
3º Follow-up inspection.
4º Special inspection; and
5º Any other types as the Authority may designate.

The inspection should be conducted as follows:

The routine inspection is a full inspection of all applicable components of licensing provisions. Routine inspection of the premises is mandatory. Inspection should be conducted as follows:

It may be indicated when the establishment:

1º Is newly established or intending to be established.
2º Requests for renewal of an operational license.
3º Has a history on non-compliance with regulations.
4º Has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, among others.

Enforcement through regular inspection is the execution of the process of ensuring compliance with laws, regulations, and guidelines. The Authority attempt to effectuate successful implementation of policies by enforcing laws and regulations.

Follow-up inspections (reassessment or re-inspection) are made to monitor the result of corrective measures. They are normally carried out from two (2) weeks to three (3) months after the initial inspection, depending on the nature of the defects and the work to be undertaken. They are limited to specific licensing requirements that have not been observed or that have been inadequately implemented.

Special inspections may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports on food intoxication. Such inspections may be focused on one product, a group of related products, or specific operations including but not limited to mixing, sterilization, or labeling in the concerned premises.

Article 8: Requirements for authorization to manufacture, to operate as wholesale and retail seller of food products and food supplements

Every application for premise licensing shall comply with the technical requirements as determined by the Authority in the relevant guidelines. However, incomplete applications that will be dormant for a period exceeding three (3) months shall be rejected, and the applicant shall be required to reapply again, with prescribed fees applicable.

The Authority inspects the premises to determine the suitability thereof for manufacturing, wholesale and retail selling of food products. Premises that do not comply with the requirements for suitability shall not be eligible for the authorization to operate.

Article 9: Location approval prior to premise construction

For the food products manufacturers:

The Authority shall approve the site location for food product manufacturers after satisfactory review of the preliminary documents:

1º Letter of intent
2º Site master plan indicating the location /plan of the premise and the surrounding activities,

Article 10: Architectural Plan Approval

The applicant must demonstrate that following the approval letter for site location from the Authority, the building must have an Architecture plan showing but not limited to the following:

1º Production process flow chart. sanitation facilities (Clean water and waste water treatment system),
2º Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
3º Construction and process materials such as food grade material,
4º finishing materials food production floor, ceiling and walls should be seamless, easy to clean.
5º Environmental impact assessment.

Article 11: Premise licensing application

The requirements of premise licensing are detailed in the guideline for registration and licensing food premises. Prior to granting a premises license, the Authority ensures that:

1º Premises that do not comply with the requirements for suitability shall not be eligible for consideration for an authorization.

2º No person shall conduct the business of manufacturing, wholesale or retail outlet or offer for sale any food products, food additives, and food fortificants except in premises inspected and licensed by the Authority for the manufacture, importation, storage, packaging, distribution and sale of food products, food additives, and food fortificants.

3º Inspection fees for new premises shall be part of the application fee, and re- inspections carried out due to unsuccessful initial inspections will attract an inspection fee in addition to the application fee paid.

4º Food operators shall indicate at least bachelor's degree qualification of related food business to ensure food safety or employ qualified personnel meeting the qualification requirements. However, other relevant qualifications may be accepted after analysis and approval by the authority.

Article 12: Compliance with the Law on Occupational Health and Safety

The premises shall comply with the requirements of the Law N° 66/2018 of 30/08/2018 Regulating Labour in Rwanda, which elaborates the requirements for Occupational Health and Safety in Chapter V.

Article 13: Good Distribution Practices

Food product, food additives, and food fortificants distributors shall have systems, facilities and operations that comply with relevant guidelines, as adopted by the Authority.

Article 14: Good Manufacturing Practices

Food product, food additives, and food fortificants manufacturers shall have systems, facilities and operations that comply with relevant Guidelines, as adopted by the Authority. After commissioning the facility, and start of manufacturing, the company should apply for GMP inspection before the release of products on the market. All applications for GMP inspection shall comply with the technical requirements as determined by the Authority in relevant guidelines, as adopted by the Authority.

Article 15: Good Storage Practices

Areas where food products, food additives, and food fortificants are stored shall be regularly inspected to ensure that the premises and food products are in an acceptable condition, and monitoring of temperature and humidity shall be followed.

Food products, food additives, and food fortificants shall be stored/displayed separately and away from all other materials to avoid any possibility of their contamination and confusion with other materials.

Article 16: Establishment of Licensing and Inspection technical and advisory Committee

The Authority shall establish a technical and/or advisory committee comprising of internal and/or external experts from different fields and scientific research to advise the Authority on Licensing and inspection regulatory matters with clear terms of reference.

CHAPTER III: REFUSAL AND VALIDITY OF AN AUTHORIZATION

Article 17: Refusal to grant an Authorization

An authorization to manufacture food products, food additives, food supplements and food fortificants or to operate a wholesale establishment; or to operate a retail establishment of any food product, food additives, and food fortificants; shall not be granted where the Authority finds the applicant not complying with the minimum technical requirements prescribed in these regulations and relevant regulatory documents.

Article 18: Validity, Renewal, Expiry, Variation, and Transferability of an Authorization

An authorization shall be valid for twelve (12) months renewable from the date it is issued, but may be suspended or withdrawn/revoked, if any of the conditions under which it was granted, is violated.

Application for renewal of an authorization shall be made to the Authority within the validity period of the authorization, at least one month before the authorisation expires.

The establishment shall remain closed after the expiry of the license until the valid license is issued.

An authorization is issued to an applicant and shall not be transferable to another applicant without approval of the Authority.

Any change to the authorization information shall be notified to the Authority through an application, within a period of five (5) working days.

The following classes of variations are allowable under a licensed premise. Note that the listed variations may not be exhausted enough to cover all possible variations as such clients are advised to contact the Authority for any guidance in this respect.

1º Major Variation:

a. Relocation or additional storage space of the licensed premise
b. Change of the qualified personnel
c. Additional production line
d. Expansion of establishment
e. Change of activity

2º Minor Variation

a. Change of the name of the establishment
b. Change of ownership of the licensed premise
c. Closure of the licensed premise

Article 19: Display of the Authorization and Display of Signpost

The authorization to operate shall be conspicuously displayed in the establishment.

Authorized establishment shall be identified by a clearly displayed signpost containing among others; the name of establishment, activities performed on the site and telephone number.

CHAPTER IV: ADMINISTRATIVE SANCTIONS AND FINAL PROVISIONS

Article 20: Administrative sanctions

Any person who contravenes any provisions of these regulations commits a fault and shall be liable to administrative sanctions as stipulated in the regulations related to regulatory service tariff/fee and fines in force, prescribed as follows:

1º Manufacturing, importation, sale, storage & distribution of substandard, unapproved, recalled, counterfeit/falsified, expired and fraudulent regulated products: the business is fined with twice the value of condemned products plus test related costs (when testing is compulsory),
2º Violation of closure by Rwanda FDA: the business is fined with a fine of five hundred thousand Rwandan Francs (500,000 FRW) and temporary closure of the premise until proof of compliance with the regulatory requirements,
3º Absence of responsible technical person in an authorized facility dealing with regulated products: the business is fined with a fine of one hundred thousand

Rwandan Francs (100,000 FRW),

4º Operating without operational license: the business is sanctioned with a fine of one million Rwandan Francs (1,000,000 FRW),

5º Operating without valid operational license: the business is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW),

6º Display of expired regulated products in shelves: the business is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW),

7º Production without production /quality control manager: the business is sanctioned with a fine of five hundred thousand Rwandan Francs (500,000 FRW)**,**

8º Transport of regulated products in unacceptable conditions: the business is sanctioned with a fine of two hundred thousand Rwandan Francs (200,000 FRW),

9º Any change to the authorization without notifying the Authority within the prescribed timelines: the business is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW).

Article 21: Warning, Suspensions and revocations

A warning letter may be issued to the applicant or the authorization be suspended or revoked where the Authority finds the applicant not complying with any of the requirements or conditions in these Regulations; or has ceased to be fit to carry on the business.

The Authority shall cancel, suspend or withdraw a license of a facility if the facility contravenes following licensing requirements:

1º Any of the conditions under which the license was issued no longer exist,

2º The information on which the approval was given is later found to be false,

3º The circumstances under which the approval was given no longer exist,

4º Repeated violation of the regulatory administrative sanction or decision.

Where the license is suspended, withdrawn or cancelled, the Authority shall issue a notice to the management of the facility. The Authority shall take steps including closure to ensure that the manufacturing, wholesale or distribution activity is stopped until otherwise decided by the Authority. Measures towards enforcing this article may include the publication of the Rwanda FDA's action on its website and other relevant media.

An authorization holder or applicant may notify Authority his or her grounds when he or she:

1º Objects to any suspension or revocation of authorization, or to any notice served,

2º Objects to the refusal of authorization or the imposition of any condition, may notify the Director General of its desire to make written representations to, or be or appear before and be heard by, a person appointed by the Director General for that purpose.

<u>Article 22:</u> Regulatory Action(s)

The Authority shall take the regulatory actions based on Minor, Major and Critical category of non-compliances as stipulated in relevant guidelines.

1° Minor non-compliances
   a. Corrective action within a given timeframe
   b. Request for compliance report

2° Major non-compliances
   a. issue warning letter
   b. request for corrective action within a given timeframe
   c. temporary withdrawal or suspension of the authorization
   d. Request for comprehensive compliance report
   e. Follow-up inspection to verify implementation of corrective action within a given timeframe

3° Critical non-compliances include
   a. Permanent withdrawal of the authorization in case of registered products.
   b. Suspension of the authorization in case of registered products
   c. Not eligible to be granted the authorization for new application.

<u>Article 23</u>: Appeals and Review

The manufacturer, distributor, wholesaler and retailer of food products, food additives, and food fortificants or any other person responsible for the regulated premises, if not satisfied with the decision of the Authority, may submit his/her appeal to the management of the Authority for the review within thirty (30) working days from the date of the reception of the decision.

The Authority shall within 30 working days from the date of appeal application review, vary or reject its own decision.

If a person is dissatisfied with a decision after review, he/she may appeal to the supervising Authority of Rwanda FDA or the Minister having Health in his or her attributions whose decision shall be final.

Article 24: Commencement

These Regulations shall enter into force upon their approval and publication on the Authority's website.

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