RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING LICENSING OF PESTICIDES, LABORATORY AND HOUSEHOLD CHEMICALS PREMISES

(Rwanda FDA law N° 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	30/08/2021
ADOPTION BY RWANDA FDA	10/09/2021
STAKEHOLDERS CONSULTATION	15/09/2021
ADOPTION OF STAKEHOLDERS' COMMENTS	20/09/2021
DATE FOR COMING INTO EFFECT	15/09/2022

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
25/08/2022	0	First Issue

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations No.: FDISM/FDIC/TRG/004 Rev_0 governing licensing of pesticides, laboratory and household chemicals premises made this 15/09/2022.

Dr. Emile BIENVENU
Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER ONE: GENERAL PROVISIONS

Article One: Purpose of these Regulations

The purpose of these regulations is to enforce the legal and regulatory framework to ensure effective and efficient licensing of pesticides, laboratory and household chemicals premises and to provide an open, transparent and non-discriminatory licensing process.

Article 2: Citation

These regulations may be cited as the "Regulations FDISM/FDIC/TRG/004 Rev_0, Governing licensing of pesticides, laboratory and household chemicals premises".

Article 3: Scope

These regulations shall apply to premises involved in the manufacture, import, storage, exhibit, sale, dispensing and distribution of pesticides, laboratory and household chemicals. The premises include but not limited to manufacturers, wholesalers, importers and retailers of pesticides, laboratory and household chemicals.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

"**Applicants**" means a person, company or their representative manufacturing or selling pesticides, laboratory and household chemicals applying for inspection for suitability of premises licensing of the product.

"**Authority**" means the Rwanda Food and Drugs Authority or the acronym "Rwanda FDA" established by Law N° 003/2018 of 09/02/2018.

"**Authorization**" means a legal document 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 registration certificate and licenses.

"**Chemicals**" means laboratory chemicals, industrial chemicals and cleaning chemicals.

"**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, or with the wrong ingredients, without active ingredients, with insufficient/incorrect active ingredients or with fake packaging.

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

"**Good Distribution Practice (GDP)**" is a 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 Practices (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, Clinical Trial Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control.

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

"**Household Chemical Substance** "means a substance or mixture of substances packaged for use in a domestic or office setting as a germicide, an antiseptic, disinfectant, pesticide, insecticide, vermicide, rodenticide, detergent or any other substance or mixture of substances declared by the competent Authority to be a chemical substance.

"Importer" means a person or body corporate permitted and authorized to import under the laws and regulations in Rwanda pertaining to pesticides, laboratory and household chemicals not for sale purposes. e.g. Raw materials importers used in the factory, other products imported for in-house use (e.g.: in hotels, etc.)

"Manufacturer" means a person or corporation, or other entity engaged in the business of manufacturing Pesticides and laboratories or Household Chemicals.

"Online shop" means a premise that delivers, distributes, or dispenses pesticides, laboratory and household chemicals by means of the internet.

"**Pesticide**" means any substance, or a mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth.

"Premises" means any plot of land, buildings or boats, aircraft, vehicles, a part of a building, a place of storage, manufacturers, wholesalers, importers, retailers of pesticides, laboratory and household chemicals whether open or closed.

"**Qualified personnel**": means an individual who by possession of a recognized degree, who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter.

"**Retailer**" means a person or body corporate permitted and authorized to store and sell under the laws and regulations in Rwanda pertaining to pesticides, laboratory and household chemicals to the public in relatively small quantities for use rather than for resale.

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

"Substandard products" refer to products that fail to meet specifications stated in recognized international standards or the manufacturer's approved product dossier submitted for registration.

"Substantial modification" means a change to the premises, equipment, personnel, procedures, and processes that is likely to have significant impact and affect the quality, safety and the integrity of the products manufactured, stored, distributed, and used.

"**Wholesale**" means a person or body corporate permitted and authorized to import, store, and supply under the laws and regulations in Rwanda pertaining to pesticides, laboratory and household chemicals to authorized retailers.

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

CHAPTER II: LICENSING REQUIREMENTS AND INSPECTION

Article 5: Obligation to obtain an Authorization

No person shall manufacture, import or export, store, sale, exhibit, package, and distribute, pesticides, laboratory and household chemical products without prior authorization from the Authority.

Article 6: Registration of activities and premises

Any activity related to the manufacture, storing, import or export, sale, packaging, distribution of pesticides, laboratory and household chemical products shall be registered. The registration of activities and premises shall be proven by a certificate issued by the Authority.

Article 7: License to practice

The license to operate premises used for carrying out activities under Article 6 of these regulations is granted according to the types of licenses and other conditions required by the Authority in the guidelines for licensing of medicated cosmetics, pesticides, laboratory and household chemicals premises.

The licensee may have his/her license revoked if he/she contravenes the provisions of these regulations. A license is issued to an applicant and shall not be transferable to another applicant without the approval of the Authority.

Article 8: Validity of an application

All applications for premise licensing shall comply with the regulatory requirements. All applications shall be valid for a period of ninety (90) calendar days from the date of application.

If the applicant fails to comply with premise licensing requirement (s) within a period of ninety (90) calendar days unless otherwise authorized by the Authority, the application shall be closed. If the applicant wishes to re-submit the application, it shall be considered as a new application and the prescribed fees shall be paid.

Article 9: Validity of a license

A license to operate shall be valid for one-year renewable from the date it is issued. The validity of the renewed license to operate shall refer to the date of the first issuance of the operational license. Application for renewal of a license to operate shall be made to the Authority one month before the end of the validity period of the license to operate.

The premise shall be closed after the expiry, suspension or revocation of the license to operate. An applicant who fails to submit all the requirements before the expiry for renewal of the license is considered to operate without valid operational license.

Article 10: Online Shop

An online shop dealing with pesticides, laboratory and household chemical products shall be granted an authorization and all applications shall comply with the requirements as determined by the Authority in the guidelines for licensing of medicated cosmetics, pesticides, laboratory and household chemicals premises.

Article 11: Requirements for authorization to manufacture, operate as a wholesale, importer and retail of pesticides, laboratory and household chemicals

All applications for premise licensing shall comply with the technical requirements as determined by the Authority in the guidelines for licensing of medicated cosmetics, pesticides, laboratory and household chemicals premises.

An authorization to manufacture, to operate as a wholesale, importer; and or a retail premise of pesticides, laboratory and household chemicals shall not be granted where the Authority finds the applicant not complying with the minimum technical requirements as determined by the Authority in guidelines relating to licensing of pesticides, laboratory and household chemicals premises.

Article 12: Substantial modification

Any substantial modification to registered and licensed premise information shall be notified in writing to the Authority through an application and the applicant shall wait for the written approval of the Authority before the implementation of the requested substantial modification. The types and

conditions for substantial modifications shall be provided in the guidelines for licensing of medicated cosmetics, pesticides, laboratory and household chemicals premises.

Article 13: Inspection of premises for suitability

The Authority shall, prior to issuing a premise registration certificate and license, inspect the premises to determine that the premises are suitable for the purpose for which the premise registration certificate and license are to be issued.

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

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

Article 14: 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 on the requirements for Occupational Health and Safety in Chapter V.

Article 15: Good Distribution Practices

Pesticides, laboratory and household chemical products distributors shall have systems, facilities and operations that comply with the International Code of Conduct on Pesticide and Household Chemicals distribution and Guidelines on good distribution practices as adopted by the Authority.

Areas, where pesticides, laboratory and household chemicals are distributed shall be regularly inspected to ensure that the premises and pesticides, laboratory and household chemicals are in an acceptable condition.

Article 16: Good Storage Practices

Pesticides, laboratory and household chemicals shall be stored/displayed separately and away from all other materials to avoid any possibility of a source of fire, contamination and confusion with other materials.
Areas, where pesticides, laboratory and household chemicals are stored, shall be regularly inspected to ensure that the premises and pesticides, laboratory and household chemicals are in an acceptable condition.

Article 17: Good Manufacturing Practices

Pesticides, laboratory and household chemical product manufacturers shall have systems, facilities and operations that comply with guidelines on good manufacturing practices as adopted by the Authority.

Areas, where pesticides, laboratory and household chemicals are manufactured shall be regularly inspected to ensure that the premises and pesticides, laboratory and household chemicals are in an acceptable condition.

Article 18: Safety Precautions

The precautions for handling and use of pesticides, laboratory and household chemicals shall be read carefully with respect to each active ingredient as stated on the label. Warnings and cautionary statements should be strictly observed, and first-aid measures noted before handling.

CHAPTER III: PROHIBITIONS AND ADMINISTRATIVE SANCTIONS

Article 19: Prohibitions

For purposes of public health interest, any pesticides, laboratory and household chemicals ingredients that do not meet quality requirements are prohibited.

No person shall manufacture, import, store, sell, exhibit, and distribute pesticides, laboratory and household chemicals products that:

1º Contain or consist of substances likely to adversely affect health when used;
2º Were manufactured, prepared, preserved or stored under unsanitary conditions;
3º Are substandard or falsified/counterfeited;
4º Are prohibited or banned.

Article 20: Warning letter

The Authority may issue a warning letter to the licensed premise under the following conditions:

1° If non-related and non-licensed activities are found to be performed in the licensed premise.
2° Minor malpractices or non-conformances that may not affect the quality and safety of the products manufactured, stored, or distributed.

Article 21: Suspension of the license

The Authority may suspend a licensed premise if it is satisfied that:

1° Repeated violations of the conditions that triggered a warning letter as stated in article 20.

2° The licensed premise made a false or misleading statement or misrepresentation in the application;
3° Alteration or modification of the premises and/or equipment after approval by the Authority.
4° The premises in which the product or part thereof is manufactured, packaged or stored are unsuitable for the manufacturing, packaging or storing of the product;
5° It is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.
6° Failure of the licensee to cooperate with the Authority's inspectors.

The suspension of the license shall set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it shall be taken. The suspension of the license shall not exceed six (6) months.

Article 22: Revocation of license/certificate

The Authority may revoke the license/certificate of the licensed premise if:

1° Repeated violations of the conditions that triggered a suspension as stated in article 21.
2° The suspended premise fails to provide the corrective actions within the timeline stated during the suspension of the license.
3° License has been suspended for a period of more than 12 months.
4° It is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.
5° Abandonment of the licensed activities
6° Bankruptcy or liquidation of the licensee

Article 23: Reinstatement

A licensee whose license/certificate is revoked may be reinstated in registered/licensed premises after three (3) years from the day his or her revocation was issued. However, in the interests of the service, a licensee whose revocation has been issued may be reinstated in registered/licensed premises before the expiration of three (3) years.

Article 24: Administrative Faults

Without prejudice to provisions in articles 19, 20, 21 and 22; any person contravening any provision of these regulations commits an administrative fault and shall be liable to administrative sanctions and penalties as stipulated in **Annex A**:

1° Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.
2° Illegal opening of premises closed by the Rwanda FDA.
3° Absence of an authorized personnel in an authorized premise dealing with regulated products.
4° Operating without operational license.

5° Operating without valid operational license.
6° Production without production manager or/ quality control manager.
7° Transport of regulated products in unacceptable conditions.
8° Any change to the authorization without notifying the Authority within the prescribed timelines.
9° Relocation without notifying the Authority.
10° Obstruction of inspectors from Rwanda Food and Drugs Authority.

CHAPTER IV: MISCELLANEOUS PROVISIONS

Article 25: Display of the Authorization

The premise registration certificate and license to operate shall be conspicuously displayed in the establishment.

Article 26: Display of Signpost

The registered and licensed premise shall be identified by a clearly displayed sign post containing the name of the establishment and the registration number of the premise, names and telephone number of the qualified personnel where applicable.

Article 27: Appeals and Review

The manufacturer, distributor, wholesaler and retailer of pesticides, laboratory and household chemicals 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 thirty (30) working days from the date of appeal application review, vary or reject its decision.

If the appellant is not satisfied with the decision of the Authority, he/she may appeal to the Supervising Authority of Rwanda FDA in accordance with the law relating to Civil, Commercial, and Administrative procedures.

Article 28: Publication of authorized premises

Premises that are granted authorizations shall be published on monthly basis on the Rwanda FDA Website, and on any other media, as the Authority may decide from time to time.

Article 29: Commencement

These regulations shall enter into force on the date of signature and publication.

End of Document

ANNEX-A: FAULTS AND ADMINISTRATIVE SANCTIONS

Fault	Administrative sanction
1. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products	25% to 50% of the product value found in violation.
2. Illegal opening of premises closed by the Rwanda FDA	500,000 Frw
3. Absence of an authorized personnel in an authorized premise dealing with regulated products	500,000 Frw
4. Operating without operational license	1,000,000 FRW
5. Operating without valid operational license	100,000 Frw Note that for each delay, a 25% increment, on the original fine will be applied monthly from the second month after expiry of the license. This charge of 25% increment shall not go beyond 24 months after expiry of the license
6. Closure of the pharmacy which is officially on duty	100,000 Frw
7. Production without production manager or/ quality control manager	500,000 Frw
8. Transport of regulated products in unacceptable conditions	200,000 Frw
9. Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard	100,000 Frw
10. Failure to provide prescriptions/reports for distribution of narcotics and controlled products at the time of inspection	100,000 Frw
11. Any change to the authorization without notifying the Authority within the prescribed timelines	100,000 Frw
12. Relocation without notifying the Authority	100,000 Frw
13. Obstruction of inspector from Rwanda Food and Drugs Authority	100,000 Frw for each day of obstructions