RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING THE REGISTRATION OF PESTICIDES, LABORATORY AND CLEANING CHEMICALS

(Rwanda FDA law N° 003/2018 of 9/02/2018, Article 8)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	15 August 2019
ADOPTION BY RWANDA FDA	13 February 2020
STAKEHOLDERS CONSULTATION	19 February 2020
ADOPTION OF STAKEHOLDERS`COMMENTS	25 February 2020
DATE FOR COMING INTO EFFECT	20 April 2020

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 N° CBD/TRG/013 Rev_0 Governing Registration of pesticides, chemicals and poisonous substances, made this 20th day of April, 2020.

Dr. Charles KARANGWA
Ag. Director General

ARRANGEMENT OF REGULATION

CHAPTER 1: GENERAL PROVISION

Article 1: Purpose of these Regulations

The purpose of these Regulations is to enforce the legal framework to ensure effective and efficient registration of pesticides, chemicals and poisonous substances, and to provide an open, transparent and non-discriminatory process for the manufacture, registration, importation & exportation, as well as post marketing surveillance of these products in Rwanda.

Article 2: Citation

These regulations may be cited as the *"Regulation N° CBD/TRG/013 Rev_0, Governing registration of pesticides, laboratory and cleaning chemicals in Rwanda".*

Article 3: Application

These regulations apply to all pesticides, laboratory and cleaning chemicals to be marketed in Rwanda.

Article 4: Definitions

In these regulations, unless the context otherwise requires-

1. **"Address"** means where the business of manufacture or sale or distribution or storage or display of product is carried out which includes the house number, plot number, street name, Town/City, State, Country, website, email, phone number etc.
2. **"Advertisement"** is a form of communication through the media about products, services or ideas paid for by an identified sponsor. It is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action.
3. **"Advertising"** means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, digital and social media, and any other documents) made orally, online or otherwise or by means of projected light and sound recordings;
4. **"Applicants"** means a person or company manufacturing product or their representatives applying for inspection for suitability of premises and licensing of registering the product.

5. **"Appropriate fee"** means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services and charges;
6. **"Approve" or "approval"** means official consent by the Authority as an acceptance of an registration of the product or practices related to that in the Rwandan market;
7. **"Authority"** means the Rwanda Food and Drugs Authority or the acronym "Rwanda FDA" established by Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization, and functioning.
8. **"Chemicals"** means laboratory chemicals and cleaning chemicals;
9. "**Container**" means any form of packaging of product for sale as a single item whether by completely or partially enclosing the pesticides and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer;
10. **"Distributor"** means any person or body corporate that sells goods on behalf of a principal
11. **"Good Manufacturing Practices"** or the acronym GMP means measures or practices undertaken to ensure that the product produced or manufactured is of good quality for pest control and safe for human.
12. **"Household pesticide"**

    (A) any material or mixture of substances used for the control of pests (e.g. flies, mosquitoes, cockroaches, ants, rodents) found in places of human habitation, work and recreation.

    (B) products that are intended for use in domestic or commercial establishments for the control of flying, crawling and structural insect pests (e.g. termiticides, rodenticides and wood preservative).
13. **"Importer"** means any person or body corporate permitted and authorized under the laws in Rwanda pertaining to product to import pesticides and laboratory and cleaning chemicals.
14. **"License"** means an instrument for official approval of an outlet for the commencement of business.
15. **"Manufacturer"** means a person or body corporate or other entity engaged in the business of manufacturing product;

16. **"Poisonous substances"** means substances which cause death, injury or harm to organ, usually by chemical reaction or other activity by molecular scales, when an organism absorbs sufficient quantity.
17. **"Premises"** means any place that includes a vehicle, vessel, railway carriage, aircraft and building;
18. **"Product"** means pesticides, chemicals and poisonous substances regulated by these regulations
19. **'recall'** means any measure aimed to return product that has been already made available to the end user for assessment;
20. **"Rwanda FDA"** means the Rwanda Food and Drugs Rwanda FDA or its acronym "Rwanda FDA", established under Article 2 of the Law;

CHAPTER 2: ASSESSMENT AND REGISTRATION OF PESTICIDES, CHEMICALS AND POISONOUS SUBSTANCES

Article 5: Application for registration of product

a. All products shall be registered with the authority before they are placed on Rwanda market. A person who intends to manufacture, import or export a product shall apply to the Authority for registration of the product.

b. An application for registration of the product shall be made to the Authority in writing by the Marketing authorization holder, the manufacturer or local technical Representative.

Article 6: Application requirement for registration of product

a) Application for registration of the product shall be made in hard or electronic copies as detailed in *guidelines on submission of documentation for registration of pesticides*, and *guidelines on submission of documentation for registration of cleaning and laboratory chemicals*

b) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or administrator any product unless the product is registered and the person holds the appropriate licence required and issued under these Regulations.

c) All products that are manufactured, imported, distributed, sold and used in Rwanda shall be packed and labeled in accordance to this regulation.

d) Products containing substances that are prohibited or suspended from use in Rwanda or listed as banned or suspended in international conventions that Rwanda has signed and ratified shall not be registered.

Article 7: Data requirement for registration of product

All applications for registration of product shall comply with the technical requirements as determined by the Authority in *guidelines on submission of documentation for registration of pesticides* and *guidelines on submission of documentation for registration of cleaning and laboratory chemicals* and shall be accompanied by data to demonstrate quality, safety and efficacy.

Article 8: Language

All applications and supporting documents shall be in **English.**

Article 9: Authenticity of document

a. Any document submitted shall be authentic when approved by the applicant or by the authorized person.
b. The Authority shall reject an application for registration of product if it is satisfied that the submitted documents are not authentic or integrity of data is questionable.

Article 10: Accountability of the applicant and marketing authorization holder

The applicant shall be accountable for all information supplied in support of his application for registration of the product and variations thereof.

The marketing authorization holder shall be accountable for:

a. Manufacturing the product in compliance with the specifications approved according to provisions of these Regulations;
b. Updating, when necessary, summary of product characteristics and package inserts for the purpose of enabling a correct and safe use of the product;
c. Communicating the variations to the Authority within the framework of the relevant provisions of the guidelines;
d. Providing responses to the issues raised/requested by the Authority, in relation to a registered product;
e. To carry out post market surveillance to monitor the safety of the product in the market and provide safety update reports to the Authority;
f. Ensuring that the product continues to comply with the safety, efficacy and quality requirements prescribed in the Law and Regulations.

Article 11: Safe custody and confidentiality of information

a. The Authority shall ensure safe custody of information related to the registration of product submitted by applicants.
b. All information submitted shall be treated confidential and shall not be disclosed to any third party without a written consent of the applicant.

Article 12: Assessment process of product

a. The Authority shall, upon being satisfied by the application, conduct assessment to verify the compliance with safety, quality and efficacy requirements of product. The authority shall set out guidelines, SOPs, forms, and tools for product assessment procedures.
b. The Authority may, during the assessment of the product, require the applicant to submit additional samples, documents, information, data or clarification to support the application for registration.

Article 13: Good Manufacturing Practices and Good Clinical Practices

During the assessment of product, the Authority shall as it may deem necessary conduct on-site inspection and causal inspection of the non-clinical studies (where applicable), clinical trials (where applicable), and production site inspection to confirm the authenticity, precision and integrity of information and data submitted.

Article 14: Requirement for pesticides, chemicals and poisonous substances

The authority shall issue a certificate of registration of product only if:

1. The product dossier is assessed and fulfil requirements of Safety, quality and efficacy
2. The manufacturing site of the pesticides, chemicals and poisonous substances is compliant to the Good Manufacturing Practices
3. Pesticides, chemicals and poisonous substances fulfil the requirements of laboratory quality tests

Article 15: Approval of product

Upon approval of registration of product, the Authority shall:

a) enter in the register the prescribed particulars of the product;
b) allocate a registration number to the product;
c) issue to the marketing authorization holder a certificate of full or conditional registration as per prescribed format.

Article 16: Conditional registration of product

Approval issued for conditional registration shall specify the conditions which need to be fulfilled by marketing authorization holder to acquire full registration.

Article 17: Publication of a registered product

The Authority shall publish a list of registered product on the authority's website. The information in the register shall be specified in appropriate guidelines for registration of the product.

Article 18: Validity of registration

a. A certificate of registration issued under Article 14 shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees, be valid for a period of five (5) years from the date of issuance and may thereafter be renewed.
b. Notwithstanding the provision in Article 18 a, a certificate of conditional registration shall be valid for a period specified in the certificate and that period shall not exceed three (3) years.

Article 19: Application for variation of a registered product

a. Any variation to registered product information shall be notified in writing to the Authority through an application in the approved format.
b. An application for variation shall be submitted as per the requirements set out in the Guidelines in force at the time of submission.

Article 20: Retention of product on the register

a. The registered product is retained on the register annually after payment of fees.
b. Application for retention on the register shall be submitted one (1) month before the due date.
c. The product shall be removed from the register if application and payment of fees is not effected

Article 21: Application for renewal of registration certificate

a. Application for renewal of registration shall be made to the Authority at least ninety (90) calendar days before its expiry.
b. A grace period for renewal shall extend to ninety (90) days after the specified expiry date.
c. Failure of renewal within the grace period, the application shall be considered as new.
d. The application shall be in the prescribed format as per Rwanda FDA guidelines for renew of registration of that product.

Article 22: Suspension of registered product

The Authority may suspend registered product if it is satisfied that:

a) A registered product has been advertised in manner which is false or misleading or does not comply with the provisions of these Regulations currently enforced by the Authority;
b) The marketing authorization holder has contravened these Regulations;
c) The marketing authorisation holder made a false or misleading statement or misrepresentation in the application;
d) the marketing authorisation holder has failed to comply with the terms and conditions of the registration as provided in certificate of registration;
e) the marketing authorisation holder has failed to pay the prescribed retention fees within the prescribed time;
f) the marketing authorisation holder has failed to submit periodic post-marketing surveillance reports;
g) the marketing authorisation holder, intentionally and without justifiable reasons has failed to submit reports on adverse effects; and
h) Renewal of registration has been defaulted beyond the specified grace period.

Article 23: Notice of suspension

Any suspension shall be effected upon a written notice thereof.

The notice for suspension of registered product shall:

a) Set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
b) Require the marketing authorisation holder to show reasons as to why the suspension should not be effected.

Article 24: Suspension or cancellation of registration without notice

a. The Authority may cancel or suspend the registration of a product without prior notice if it is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.
b. The marketing authorization holder may apply to the Authority, in writing, requesting that the cancelation or suspension be uplifted.
c. The Authority may, within thirty (30) days after the date of receiving the application review its decision.

Article 25: Restoration of a cancelled or suspended registered product

The Authority may, upon satisfaction that the reasons of the suspension or cancellation of registered product has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the registered product

Article 26: Refusal to register a product

The Authority shall refuse to grant marketing authorisation of a product if it is satisfied that:

a) the application for registration or the label of the product does not comply with these regulations;
b) The information that the applicant provides to the Authority is not sufficient to enable the product to be assessed and evaluated;
c) The use of the product would lead to an unacceptable risk or harm to untargeted population or to the environment.
d) The product contains prohibited active ingredients stated in the Ministerial Order N° 26/03 of 23/10/2008 determining the list of chemicals and other prohibited pollutants
e) the application for registration does not comply with these regulations;
f) The information the applicant provides to the Authority is not sufficient to enable the product to be assessed and evaluated;

g) Product was manufactured, prepared, preserved, packaged or stored under unsanitary condition

h) The information on product label does not comply with these regulations

i) Contain substance that may cause harm to the health of the user,

j) Consists in whole or in part of any filthy or decomposed substance or of any foreign matter;

Article 27: Cancellation or revocation of marketing authorisation

a. The Authority may cancel or revoke the marketing authorization of a registered Prime if:
   1. it is not in the public interest that the registered a product should be made or continue to be made available;
   2. A product has been banned in Rwanda;
   3. A product no longer meets the quality, safety and effectiveness requirements; and
   4. The marketing authorisation has been suspended for a period of more than 12 months.

b. A written notice of cancellation shall then be issued to the marketing authorisation holder, stating the reasons for cancellation.

Article 28: Labelling information

a) The label of a product must contain the information specified in the *guidelines on submission of documentation for registration of pesticides* and *guidelines on submission of documentation for registration of cleaning and laboratory chemicals* depending on the type of the product.

b) The label must contain sufficient information to guide the user and necessary precautions.

Article 29: Exemption of product

Notwithstanding Article 5, The Authority may authorize the importation of unregistered product if:

a) the product is imported for experimental or research purposes and not for distribution;

b) the product is imported in the event of emergency;

c) the Minister in charge recommends for the importation of the product.

CHAPTER III: MISCELLENIOUS PROVISIONS

Article 30: Ownership of the certificate

No person to whom a certificate of registration has been issued under these Regulations shall lend, hire, sell, transfer or otherwise dispose of the certificate of registration to any other person without an approval of the Authority.

Article 31: Appeal and review

a. Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) days from the date of notice.
b. The Authority shall, within fifteen (15) days from the date of receiving the application, review, reject or vary its own decision.
c. Notwithstanding the provision of Article 29a the applicant shall not be barred from appealing to the Minister without applying to the Authority for review.
d. If a person is dissatisfied with the decision after review, he may appeal to the Minister whose decision shall be final.

Article 32: Offences and penalties

A person contravening a provision of these regulations commits an offence and shall be liable to any of the penalties as stipulated in the regulation related to regulatory service tariff/ fees and fines in force at the time of application issued by the Authority.

Article 33: Power to seal

The Authority shall have power to seal up any premises used or being used in connection with any offence under these Regulations until such time as the regulated product is removed or such time as the regulated product is removed or such reasonable time as the Authority determine

Article 34: Power to issue guidelines and Forms

The authority shall issue guidelines, forms necessary for the implementation of these Regulations

Article 35: Commencement and repealing

a. This regulation shall enter into force on date of its signature and publication.

b. All prior contrary provisions to these regulations are hereby repealed.

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