RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR THE REGISTRATION OF HOUSEHOLD PESTICIDES

MAY, 2020

Doc. No.: DHT/GDL/014	Revision Date: 04/05/2020	Review Due Date: 04/05/2023
Revision No.: 0	Effective Date: 04/05/2020	

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of pesticides in order to improve access to essential and harmless vector controls in Rwanda.

Rwanda FDA has referred to the globally harmonized system (GHS) of classification and labeling of chemicals to develop these guidelines to provide guidance to the applicants and Rwanda FDA in managing applications for registration of household pesticides.

Rwanda FDA acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr. Charles KARANGWA
Ag. Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	23 January 2020
ADOPTION BY RWANDA FDA	14 February 2020
STAKEHOLDERS CONSULTATION	20 February 2020
ADOPTION OF STAKEHOLDERS`COMMENTS	04 March 2020
DATE FOR COMING INTO EFFECT	04 May 2020

TABLE OF CONTENT

ABBREVIATIONS AND ACRONYMS

AI:	Active Ingredient
CAS:	Chemical Abstract Service
CBI:	Confidential business information
FAO:	Food and Agriculture Organization
FDC:	Fixed Dose Combination
FP	Finished Product
GHS:	Global Harmonization System
GMP:	Good Manufacturing Practice
ISO:	International Organization for Standardization
IUPAC:	International Union of Pure and Applied Chemistry
LD50:	Lethal Dose
MAH:	Market Authorization Holder
SDS:	Safety Data Sheet
SOPs:	Standard Operating Procedures
STOT:	Specific Target Organ Toxicity
UN:	United Nations
WHO:	World Health Organization

GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. The following definitions are provided to facilitate interpretation of the guidelines. Detailed information can be found in the Rwanda FDA glossary of terms.

Active substances (S)/ Active Ingredient (AI)/ Active pharmaceutical ingredient (API)

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. Detailed information can be found in the Rwanda FDA glossary of terms.

Agent/ Local Technical Representative (LTR)

Every applicant who is not resident in Rwanda shall appoint a person or a company in Rwanda and authorized by Rwanda FDA to deal in medicinal products to be an AGENT Local Technical Representative (LTR). The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin, and registered with registrar of Companies in Rwanda.

Applicant

An applicant is a person who applies for registration of a medicinal product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured.

The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person to register the medicinal product on his behalf, then Powers of Attorney, duly notarised in the country of origin, and registered with the Registrar of Companies in Rwanda shall be provided. After the product is registered, the applicant shall be the Marketing Authorisation Holder (MAH).

Appropriate fee/fee

The fee prescribed in the regulation n° CBD/TRG/004 related to the regulatory services tariff/ fees and charges in Rwanda FDA.

Approve / Approval

Official consent by the Authority as an acceptance of a registration of the pesticide or practices related to that in the Rwandan market;

Authority

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.

Authorized person

A person responsible for the release of batches of finished product for sale or distribution. The batch documentation of a batch of a finished product must be signed by an authorized person from the production department and the batch test results by an authorized person from the quality control department for batch release.

Batch (or lot*)*

A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.

Batch number (or lot number)

A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.

Batch records

All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.

Certification

The final review and formal approval of a validation or revalidation, followed by approval of a process for routine use.

Container

Any form of packaging of pesticide 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.

Finished product (FP)

A finished dosage form of a product, which has undergone all stages of manufacture, including packaging in its final container and labelling. Detailed information can be found in the Rwanda FDA glossary of terms

Good Manufacturing Practices

Measures or practices undertaken to ensure that the pesticide produced, or manufactured is of good quality for pest control and safe for human.

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).

Importer

Any person or body corporate permitted by the Authority to import product regulated by Rwanda FDA.

In-process control

Checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

License

An instrument for official approval of an outlet for the commence of business

Manufacture

All operations of purchase of materials and products, production, packaging, quality control, release, storage, shipment of finished products, and the related controls.

Manufacturer

A manufacturer is a natural or legal person with responsibility for manufacturing of a medicinal product or active ingredient. It involves operations such as production, packaging, repackaging, labelling and relabelling of product. Detailed information can be found in the Rwanda FDA glossary of terms

Manufacturing process

The transformation of starting materials into finished products (drug substances or product dosage forms) through a single operation or a sequence of operations involving installations, personnel, documentation and environment.

Marketing authorization (product license, registration certificate)

A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

On-going stability study

The study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected retest period (or shelf-life) of the AI, or confirm or extend the shelf-life of the FP. Detailed information can be found in the Rwanda FDA glossary of terms

Packaging

All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.

Packaging material

Any material, including printed material, employed in the packaging of a product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Primary batch

A batch of an AI or FP used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a retest period or shelf-life. (*WHO Glossary of Terms*)

Production

All operations involved in the preparation of a product, from receipt of materials, through processing and packaging, to completion of the finished product.

Production batch

A batch of an AI or FP manufactured at production scale by using production equipment in a production facility as specified in the application.

QT interval prolongation

A measure of delayed ventricular repolarisation, which means the heart muscle takes longer than normal to recharge between beats. It is an electrical disturbance which can be seen on an electrocardiogram (ECG). Excessive QT prolongation can trigger tachycardias such as Torsades de Pointes (TdP).

Rwanda FDA

The Rwanda Food and Drugs Rwanda FDA or its acronym "Rwanda FDA", established under Article 2 of the Law;

Reprocessing

The reworking of all or part of a batch of product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.

Re-validation

Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements

Specification

A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

Standard operating procedure (SOP)

An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection).

Validation

The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

Validation report

A document in which the records, results and evaluation of a completed validation program are assembled. It may also contain proposals for the improvement of processes and/or equipment.

CHAPTER 1: INTRODUCTION

1.1 Scope

The purpose of this document is to provide guidance on pest and pesticide management policy development in support of pesticide risk reduction and sustainable vector control. These guidelines will assist industries and applicants to know adequate substances allowed in pesticides used in Rwanda and requirements for the pesticide to be on the Rwandan market.

These guidelines apply to Product dossier applications for pesticides containing Active Substances of synthetic or semi-synthetic origin. The principles in these guidelines would also apply to chemical combinations and complexes that comprise more than one active ingredients including Fixed Dose Combination (FDCs).

1.2 Objective of registration

The purpose of the registration of pesticides is to ensure that the registered product;

- Is efficacious
- Is used in accordance with label instructions
- Safeguard human health, animal health and the environment
- Meets both national and international standards
- Is properly documented for regulatory purposes

Registration enables authorities to safeguard society from the adverse effects of pesticides without denying access to the benefits of their use. It also enables the authority to exercise control over quality, use levels, claims, labeling, packaging, advertising, and disposal of pesticides, thus ensuring that the interests of end-users are properly protected.

1.3 Responsibility

The Rwanda FDA in collaboration with REMA (Rwanda Environment Management Agency), RAB (Rwanda Agriculture and Animal Resources Development Board) and other related institutions are responsible for Pesticides Control and Management in Rwanda. In that capacity, the Rwanda FDA has the sole authority and responsibility to register all pesticides imported,

exported, manufactured, formulated, distributed, advertised, sold or used within Rwanda. Pesticides registration is the process whereby the responsible national government authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or to the environment.

Applicant shall be responsible for facilitating communication with the Authority and when the product is registered, (s) he shall assume all responsibilities regarding the safety, quality, performance or efficacy of product on the Rwanda market as a Registrant.

1.4 Submission of application

An application for product registration for either locally manufactured or imported, shall be made in writing via a cover letter and application form dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The local agent shall be a registered wholesale company or an accredited manufacturer's representative. All application documents shall be in English

The application should be submitted to Rwanda FDA through the authorized local technical Representative to the following address:

Director General
Rwanda Food and Drugs Authority
P. O. Box 84
Kigali- Rwanda

1.5 Categories of certificate for registration

a) **Full registration** is one that has fulfilled all Rwanda FDA registration requirements

b) **Conditional registration** is a registration conditioned upon the completion of certain specified data requirements. Examples might be a 1-year storage stability study or additional efficacy data. Once conditions of registration have been met, the conditions are removed and a full registration can be granted.

c) **Experimental Use Permit** is a permit that allows a person/company to test an unregistered pesticide product or an unregistered use of a currently registered product, to develop the data necessary to register the product.

d) **Emergency Exemption from registration** is the use of an unregistered pesticide in a state for a limited time due to specific emergency situation.

1.6 Types of Applications

For the purposes of submission of Product Dossier to Rwanda FDA, applications are classified into three categories as follows:

1. **New applications for registration:** an application for registration of product that is intended to be placed on the Rwanda market for the first time or product which was on the market without registration certificate.
2. **Renewal of product registration:** Applications for renewal of a registered product. The application shall be made at least 3 months before the expiry of existing registration.
3. **Variation of a registered product:** an application for any change in the registered products. All applications for variation to a registered product shall be made according to requirements as stipulated in the Rwanda FDA Guideline for Variation of Registered products.

1.7 Application requirements

An application for pesticide product registration in Rwanda shall include the following:

1. Signed and dated original hard-copy of cover letter ***(refer to the annex I, document N^{o} DHT/FMT/31)***
2. Signed and dated Product registration application form ***(refer to the annex II, document N^{o} DHT/FOM/044)***
3. Proof of payment of non-refundable registration fee at the time of submission
4. Two CD-Rom or external driver virus free containing all information on safety, quality and efficacy of the product.
5. Two commercial samples of the products with certificate of analysis.

6. Two (2) coloured artwork/Label of the product and leaflet insert of the product (where applicable)

A separate application shall be submitted for each product or product variant.

1.8 Receiving of applications for household pesticides registration

An application consists of electronic copies, online submission or specified hard copies where applicable. The application of product registration is only received by the Authority when the payment of prescribed registration fees is made. After receiving a product registration application, a reference number is assigned according to SOP for assigning reference number for product registration and it will be used in all subsequent correspondences relating to the application. An acknowledged receipt will be issued.

1.9 Retention of household pesticides on the register

The registered household pesticide is retained on the register annually. The household pesticides shall be removed from the register if application and payment of fees is not effected

Application for retention on the register shall be submitted one (1) month before the due date.

The application shall be accompanied by:

a. A covering letter
b. Non-refundable fees as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff/fees and Fines d fees

1.10 Restricted and banned products in pesticides

Certain active substances are banned from use in Rwanda and products containing these active substances shall not be registered: These include product listed as banned in international conventions that Rwanda has signed and ratified. Refer to the list of banned products as determined in the ministerial order **N^{o} 27/10/2008** in official Gazette and the list of banned products on Rwanda FDA website.

CHAPTER 2: GENERAL REQUIREMENTS FOR REGISTRATION

2.1 Data requirements for new application

Data requirements for a new application contain administrative requirements and technical data requirements. This chapter provide a guidance of component expected in each section (***Refer to the Annex-IV for the Arrangement of data requirements for pesticides registration***).

2.1.1 Section A: Administrative requirements

All administrative documents (for example, application forms, certifications …), general correspondence and annexes should be provided in part of administrative requirements as follow:

2.1.1.1 A.1 Cover letter

Applicants should include a cover letter with all applications. A copy of the letter should be placed at the beginning of Administrative data. The cover letter for product registration shall be dated and signed by the applicant (***Refer to the annex-I document N^{o} DHT/FMT/31***) downloadable from Rwanda FDA website in list of annexes to the guidelines for registration of pesticides.

2.1.1.2 A.2 Application form

An application to register a pesticides must be accompanied by a completed product application form (***refer to the annex II, document N^{o} DHT/FOM/044***) downloadable from Rwanda FDA website. The application form should be duly filled with relevant information and attachments, dated signed and stamped appropriately.

2.1.1.3 A.3 Contract Manufacturing Agreement

(where applicable)

2.1.1.4 A.4 Manufacturing license

The applicant should submit proof of manufacturing authorization granted by competent authorities in the country of manufacturing.

2.1.1.5 A.5 Valid GMP Certificate or other applicable internationally recognized Quality Management System certification

For all products, irrespective of the country of origin, all key manufacturing and/or processing steps in the production of active ingredient, ingredients and finished products must be performed in plants that comply with Rwanda FDA GMP guidelines. Therefore, to the submission, a valid GMP Certificate or other applicable internationally recognized management system certification must be enclosed in the application.

2.5.1.6 A.6 Product samples

Two pictures of commercial samples of the product and two coloured artwork/Label of the product as well as leaflet insert of the product where applicable must be submitted in the product dossier.

2.5.1.7 A.7 Local technical representative

Appointment letter of the local technical representative with original copy of Power of must be enclosed in this section attorney from the product manufacturer if it is imported. For local manufacturer, they must specify the information of the person in charge of post marketing surveillance.

2.1.1.9 A.8 Commitment letters

For ongoing stability studies, the applicant must submit the commitment letter indicating when the final data on stability will be available.

2.1.1.10 A.9 Product license or approval in other countries

1. Registration status within EAC and SRAs/WLAs

The applicant should provide a list of countries in EAC and countries with SRAs/WLAs in which a similar application has been submitted, dates of submission (if available), the status of these applications and valid certificates.

1. Statement on rejection or withdrawn application

Applicant must declare whether a marketing application for the product has been rejected prior to submission of the application in Rwanda. If the medicine has been rejected, repeatedly deferred, withdrawn or suspended then reasons must be stated. If rejection occurs during the Rwanda FDA evaluation process, Rwanda FDA should be informed.

2.1.1.11 A.10 Proof of payment of non-refundable registration application fee

A scanned copy of the proof of payment must appear on the CD drive.

2.1.2 Section B: Technical requirements

Application technical requirements clarify all product information and should contains 2 main parts defining the detailed pesticide product dossier which are Safety data sheet and Technical data sheet.

2.1.2.1 B.1 Chemical analytical data of raw materials

The applicant shall indicate the following for raw materials:

B.1.1 Name for each ingredients

B.1.2 Name and address of manufacturer for each ingredients and manufacturing license

B.1.3 Copies of certificate of analysis for each ingredient should be submitted

B.1.4 Safety Data Sheet for each raw material and mixture (where appropriate). The SDS should contain the following headings:

1. Identification
2. Hazard (s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures

7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information.

2.1.2.2 B.2 Data on final product

2.1.2.2.1 cturing process

1. Flow chart and narrative of manufacturing process.
2. References used
3. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

2.1.2.2.2 B.2.2 Product efficacy

a. Type of formulation (e.g. soluble concentrate, wettable powder, emulsifiable concentrate)
b. Function of the product (e.g. insecticide, insect repellent, rodenticide, …) and target pest species
c. Application rate per unit treated and concentration of active ingredient in the material as applied (for example, if the product is diluted before application)
d. Comprehensive Certificate of Analysis.

Duly signed and dated referring to the same batch/lot number of the sample submitted; written/translated in English on the letterhead of manufacturer shall include the following:

1. Name and batch number of sample submitted
2. Complete specifications, methods and limits stated on technical specifications of the finished product
3. All test results based on technical specifications of finished product stating actual numerical value (when applicable)

e. Method of analysis and references

f. Application and mixing instructions, including method of application, type of equipment used, application techniques and rates for each use site, and type and volume of diluent per unit of area or volume

g. Number, frequency and timing of applications (e.g. per year, per month) and duration of protection expected

2.1.2.2.3 B.2.3 Manufacturing process

a. The applicant shall provide flow chart and narrative of manufacturing process, mentioning the quality and quantity of the raw materials used including the final packaging and labelling procedures.

b. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

2.1.2.4 B.2.4 Human health assessment

a. Re-entry periods (e.g. after space spray for mosquito control), waiting periods and other precautions to protect people, livestock and the environment.

b. Study data for adverse and chronic toxicity due to exposure

c. A statement about any risk arising from the recommended methods and precautions and handling procedures, in order to minimize those risks (e.g. precautionary statements of the Globally harmonized system of classification and labelling of chemicals)

d. Information on antidotes, if any, and medical treatment in the case of accidental exposure; names of co-formulants that may influence the toxicity of the product

2.1.2.5 B.2.5 General safety information

a. Procedures for cleaning application equipment, if relevant to the proposed use

b. Proposed hazard classification (according to WHO classification), labelling and safety phrases and symbols

2.1.2.6 B.2.6 Stability data

The applicant shall provide stability data supporting the proposed shelf life for at least two batches. The stability studies shall be conducted in the container closure system in which it will be marketed in Rwanda.

The applicant shall provide stability data supporting the proposed shelf life for at least two batches. The stability studies shall be conducted in the container closure system in which it will be marketed in Rwanda.

Stability study reports critically examine the method used to determine the established product shelf life including:

i. Study design (protocol);

ii. Test conditions (humidity and temperature), testing interval and Duration:

Storage conditions	**Duration**	**Testing interval (Months)**
Long term stability studies at $4^{o}C$	Shelf life	0, 3,6,9,12,18,24,36,48
Long term stability studies at $25^{o}C$ / ambient Relative Humidity	Shelf life	0, 3,6,9,12,18,24,36,48
Accelerated stability studies at $37^{o}C$/ ambient Relative Humidity	6months	0,3,6
Accelerated stability studies at $37^{o}C$ / 80 % Relative Humidity	6 months	1

iii. Type of container used (Testing should be conducted using containers and closures intended for marketing of products);

iv. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product. They shall at least cover appearance (clarity, color, homogeneity and odor) for product form, levels of characteristic ingredients, physicochemical properties (such as pH, purity, and consistency), average weight or volume, assay of active ingredient and microbial limits depending on the nature of the product.

v. Test results from item (IV) above.

2.1.2.7 B.2.7 Packaging and Labelling information

a. The applicant shall provide information on packaging material. This shall be made of substances/materials which are safe and suitable for its intended use and which shall preserve its hygienic, safety and quality.

b. The label must contain the following:

1. Signal words

A signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in the GHS are “Danger” and “Warning”. “Danger” is mostly used for the more severe hazard categories (i.e. in the main for hazard categories 1 and 2), while “Warning” is mostly used for the less severe. The tables in the individual chapters for each hazard class detail the signal words that have been assigned to each of the hazard categories of the GHS.

2. Hazard statements

(i) A hazard statement means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard. The tables of label elements in the individual chapters for each hazard class detail the hazard statements that have been assigned to each of the hazard categories of the GHS;

(ii) Hazard statements and a code uniquely identifying each one are listed in section 1 of Annex 3. The hazard statement code is intended to be used for reference purposes. It is not part of the hazard statement text and should not be used to replace it.

3. Precautionary statements and pictograms

(i) A precautionary statement means a phrase (and/or pictogram) that describes recommended measures that should be taken to minimise or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product. The GHS label should include appropriate precautionary information, the choice of which is with the labeller or the competent authority. Annex 3 contains examples of precautionary statements, which can be used, and also examples of precautionary pictograms, which can be used where allowed by the authority;

(ii) Precautionary statements and a code uniquely identifying each one are listed in section 2 of annex 3. The precautionary statement code is intended to be used for reference purposes. It is not part of the precautionary statement text and should not be used to replace it.

4. Product identifier

(i) A product identifier should be used on a GHS label and it should match the product identifier used on the SDS. Where a substance or mixture is covered by the UN Model Regulations on the Transport of Dangerous Goods, the UN proper shipping name should also be used on the package;

(ii) The label for a substance should include the chemical identity of the substance. For mixtures or alloys, the label should include the chemical identities of all ingredients or alloying elements that contribute to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitization, or specific target organ toxicity (STOT), when these hazards appear on the label.

(iii) Where a substance or mixture is supplied exclusively for workplace use, the competent authority may choose to give suppliers discretion to include chemical identities on the SDS, in lieu of including them on labels;

(iv) Confidential business information (CBI) take priority over the rules for product identification. This means that where an ingredient would normally be included on the label, if it meets the competent authority criteria for CBI, its identity does not have to be included on the label.

5. Supplier identification

The name, address and telephone number of the manufacturer or supplier of the substance or mixture should be provided on the label.

2.2 Data requirement for Variation

a. If for any reason the applicant changes any matter related to pesticide

Pesticide including but not limited to change of packaging, labeling or any other change, shall before selling the changed product, notify and obtain the Authority's approval of the change. The application shall be accompanied by:

1. A duly signed covering letter
2. Documentation in support of variation
3. Product samples reflecting the variation
4. A non – refundable variation fee as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees

b. The Authority will evaluate reasons provided in the notice and if satisfied with such reasons it will approve the changes by issuing approval notice and if it is not satisfied the applicant will be notified by stating the reasons thereof.

c. Changes involving product(s) composition and manufacturing sites shall be treated as new application.

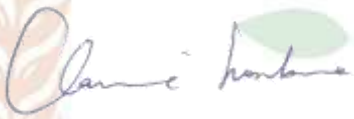
2.3 Renewal of product registration

An application for registration renew shall be made 3 (three) months before expiration of the last registration.

The application shall be accompanied by:

a. A covering letter
b. Supporting documentation for any variations since the product was last registered
c. Samples of the product in the final package
d. Non-refundable application fee as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees
e. The registration renew shall be approved by the Authority

ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Drugs and Health Technologies	Head of Food and Drugs Assessment and Registration	Director General
Names	**Irasabwa Clarisse**	**Kabatende Joseph**	**Dr Charles Karangwa**
Signature			
Date	**04/05/2020**	**04/05/2020**	**04/05/2020**

ANNEXES

Annex I: Cover Letter

Letter header of the applicant

< Applicant>

< Address>

<Postal Code>

< Town>

<Country>

<Date>

<Rwanda FDA>

<P.O.BOX 84> <Kigali>

< Rwanda >

Dear Sir/Madam,

Subject: Submission of application for registration of pesticide <Brand Name(s), Common Name (s) and product form(s)

We are pleased to submit our Application Dossier(s) for a registration of pesticide that details are as follows:

Name of the pesticide product as follow:

Brand name (s): ……

Proprietary (Common Name (s): ……

Active ingredient(s) IUPAC name: ……

……

Product form: ……

Intended use(s): ……..

Manufacturer: …….

You will find enclosed the submission dossier as specified hereafter:

□ The relevant fees for this application have been paid.

□ Two CD rom/external driver that contains product information in word format and in PDF

□ Two commercial samples of the product

□ The electronic submission contains the following sections:

Section 1: Administrative requirement information

Section 2: Technical requirements

We confirm that the electronic submission has been checked with up-to-date and state-of-the-antivirus software.

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

Annex II: Application form for pesticide registration

Applicant Information **Important: Read instructions on page 3 before completing this form**

1. Applicant Name

2. Applicant address **City:** **Country:**

3. Name of Local technical Representative **City** **Country**

4. Physical address of Local technical Representative

5. Telephone Number of LTR **6. Fax Number** **7. E-mail Address**

8. Proprietary name of the product and Brand name (exactly as shown on label):

9. Type of registration action requested

- ☐ New registration
- ☐ Variation
- ☐ Renewal

10. Container Type(s), and Size(s)

11. Liquid Products Only:

Specific Gravity:

12. **Solid Products Only (Density):** lbs. per cubic foot

13. WHO Hazard class (For pesticides):

- ☐ **Class Ia** ("DANGER-POISON")
- ☐ **Class Ib** ("DANGER - POISON")
- ☐ **Class II** ("WARNING")
- ☐ **Class III** ("CAUTION")

I certify, under penalty of perjury, that all information submitted on this application for registration is accurate and complete. All data that we submitted to the Rwanda FDA to support this product are enclosed in this submission or have previously

been submitted to Rwanda FDA.

Type or Print Name/Title

Signature of applicant and date Signed

Product Characterization Information

Information about your product and its intended uses is required to allow the Authority to correctly process and prepare notices for this application.

1. **a) This pesticide is a:** ☐Microbial (product itself is composed of microbes) ☐ Biochemical ☐ Chemical

b) Type of pesticide,

☐ Vector control products ☐ Pesticides/ Fungicide ☐ Mosquito coil ☐ Mosquito spray ☐ Odor prevention

2. **a) Is this product applied** ☐aerial ☐ground, ☐both (aerial and ground), or ☐Topical

b) Application methods, check all boxes that apply:

☐ Ant / Wasp / Rodent Mound	☐ Fumigation	☐ Spray	☐ Rub on, wipe on	☐Wash, Soak, Dip, or Mop
☐ Additive	☐ Dust	☐ Water Application	☐ Trap / Device	
☐ Attached (e.g., collar, ear tag)	Evaporating Solid	☐Paint or Coating	☐ Smoke	☐ Other (specify):

3. **Type of Formulation,** check **one** box that best describes the product formulation:

Solids

☐ Dust / Powder	☐ Pellet, Tablet, Cake or Briquet	☐ Pressurized Dust	☐ Pressurized Gas (Dry)	☐ Wettable Powder
☐ Soluble Powder	☐ Dry Flowable	☐ Other (Dry)		

Liquids

☐ Emulsifiable Concentrate	☐ Oil (ready-to-use) Liquid	☐Solution /	☐ Suspension	☐ Aqueous (Liquid) Concentrate
☐ Flowable Concentrate	☐ Pressurized Gas	☐ Pressurized Liquid/Sprays/ Foggers	☐ Other (Specify)	
☐ Paint or Coatings				

4. **Intended use**

Label Signal Word

Poison / Toxic ☐ Danger ☐Warning ☐Caution ☐ None

Does this product require child-resistant packaging**?** ☐Yes ☐No

Flash point/flame extension of products containing more than 70% petroleum distillates:

Instructions for Application for Pesticide Registration

INCOMPLETE FORMS WILL NOT BE PROCESSED

If any section does not apply to your product, please mark it N/A. A separate application form must be completed for each product and each product brand name. If you require further assistance, consult the guidelines.

1. **Application mailing Address:** Correspondence, licenses, notices, etc. will be sent to this address.
2. **Name of Authorized Local Technical Representative:** The person who is authorized to answer any questions about your application for registration. Generally, this person prepares the application. If the person is an agent/consultant, a letter from the firm authorizing the agent/consultant to act on its behalf is required.
3. **Type of Registration Action Requested:**
   - **New Product:** A product is not yet registered in Rwanda FDA.
   - **Variation:** For a product already registered in Rwanda FDA.
   - **Renewal:** Registered product which has a certificate remaining few month of validation.
4. **Container Type(s), Composition(s), and Size(s):** Describe the actual container(s), which hold the formulated product. For example, 16 oz. plastic bottle; 1, 2, and 5 gallon plastic buckets; 55 gallon steel drum.
5. **Liquid Products Only:** List the density i.e., the pound weight of one gallon of the formulated product or list the specific gravity.
6. **Solid Products Only:** Total weight per cubic foot of the formulated material.
7. **WHO Hazard class:** refer to the WHO Class in the guideline for registration

The Application Package should contain the following:

☐ A cover letter describing the type of registration action requested and what is being submitted to Rwanda FDA.

A completed application form (pages 1, 2, 4).

☐ Two (2) copies of the product labeling. Typescript labeling may be submitted if printed labels are not yet available. Printer's proofs or final printed labels are required prior to issuance of a Certificate of Registration.

Information Available on the Internet

Information about the Rwanda laws and regulations governing pesticide registration, as well as Rwanda FDA notices, policies, and procedures is available on the Internet at <http://www.rwandafda.gov.rw>. Information on currently registered products, registrants, telephone numbers, and other information are also available at this site.

Certificate of Registration / Acceptance

If your product is registered, a Certificate of

Registration (license) will be issued to you, authorizing sales for the remainder of the calendar year. Pesticide products may not be offered for sale until a Certificate of Registration has been issued.

Product Formulation Information

See page 5 for instructions

1. Brand name:

2. Proprietary Name (Common name):

3. pH (if water soluble liquid):

4. Active Ingredient Give common chemical name for each active ingredient listed on the label. Microbials should show genus, species, and strain.	5. Chemical Abstracts Service (CAS) (or ATCC) No.	6. Brand name of **source product** for active ingredient	7. Percent by weight of **source product** in formulated product.	8. Percent by weight of **active ingredient** in formulated product.

9. Inert Ingredient (common chemical name)	10. Chemical Abstracts Service (CAS) No.	11. Brand name of **source product** for inert ingredient.	12. Purpose in formulation.	13. Percent by weight of **source product** in formulated product.	14. Percent by weight of **inert ingredient** in formulated product.

If space is not sufficient, attach additional pages. Inert ingredients information given on this form is considered to be confidential business information and is protected from disclosure under the Rwanda FDA Law).

Total 0.00
Columns 7 + 13
=100.00%

Total 0.00
Columns 8+14
=100.00%

Instructions for Product Formulation Information

Applications with **incomplete product formulation** information cannot be processed, and the first page **will be returned.**

1. **Active Ingredient:** List each active ingredient in this formulation as it appears on the label. Please list all active ingredients from one source product together for ease of calculation of percentages.
2. **CAS No.:** The CAS Number may be obtained from the Chemical Abstract Service of the American Chemical Society, P.O. Box 3012, Columbus, Ohio, 43210. Microorganisms should be identified by ATCC (American Type Culture Collection) or other recognized type culture collection number.
3. **Name of Source Product:** The name of the product which provides that active ingredient in the formulation.
4. **Percent By Weight of Source Product in Formulated Product:** Each source product listed in Column #6 must have a value in Column #8. For example, if active ingredient A and active ingredient B are both from the same source product which makes up 50% of the formulated product, the single entry in Column 8 is 50%.
5. **Percent By Weight of Active Ingredient in Formulated Product:** This percentage should be **identical** to that given on the labeling.
6. **Inert Ingredient:** List each inert ingredient component in this formulation. **NOTE:** If you do not know the identity of an inert ingredient in your product, have your supplier submit the chemical name of each inert ingredient, source product name, purpose in formulated product and percent by weight of the source product in the formulated product directly to the Authority, with reference to your firm name, your product brand name and Rwanda FDA Reg. No.
7. **Brand Name of Source Product:** The name of the product which is the source of the inert ingredient listed in Column #09.
8. **Percent by Weight of Source Product in Formulated Product:** Give the percentage by weight of each **SOURCE PRODUCT** in the formulated product. If the percent of a source product is already listed in column #7, do not list the same figure again in column #13.
9. **Percent by Weight of Inert Ingredient in the Formulated Product:** The percentage by weight of the inert ingredient in column #09 in the formulated product.

Example for filling formulation products

4. Active Ingredient Give common chemical name for each active ingredient listed on the label. Microbials should show genus, species, and strain.	5. Chemical Abstracts Service (CAS) (or ATCC) No.	6. Brand name of **source product** for active ingredient	7. Percent by weight of **source product** in the formulated product.	8. Percent by weight of **active ingredient** in formulated product.	
Pyrethrins	121-21-1	Pyrotech Concentrate	50.000%	0.010%	
piperonyl butoxide	51-03-6			0.005%	
9. Inert Ingredient (common chemical name)	10. Chemical Abstracts Service (CAS) No.	11. Brand name of **source product** for inert ingredient.	12. Purpose in formulation.	13. Percent by weight of **source product** in the formulated product.	14. Percent by weight of **inert ingredient** in the formulated product.
inerts from PyroTech Concentrate	-	Pyrotech Concentrate	inerts from technical	-	49.985 %
petroleum distillate	8002-05-9	SoluSolv	diluent	50.000%	50.000%

TOTAL Columns 7 + 13 =100.00%	**TOTAL** Columns 8 +14=100.00%

Annex III: Labelling of pesticides

Pesticides labeling must meet the minimum requirements specified in the Guidelines on Good Labelling Practice for Pesticides revised in 2015 by FAO and WHO [1]

1 Purpose of pesticide label

The pesticide label conveys to the end user the information needed to make decisions on how, when and how much of the product to use. It is therefore essential that end users understand the messages on the label sufficiently to motivate them to use the pesticide properly and to take the necessary precautions.

2 Comprehensibility and comprehensiveness of label content

The five principles to adhere to in preparing a label are clarity, completeness, comprehensiveness, conformity and consistency.

2.1 Clarity

is achieved by avoiding complex or excessively technical explanations and by using a clear layout with a prominent display of key words, phrases, symbols, and pictograms. Thus it is important to:

1. attract the user's attention;
2. tell the user what he/she needs to know in brief and precise terms;
3. use locally familiar expressions and symbols; and,
4. avoid ambiguous statements.

2.2 Completeness

[1] http://www.fao.org/3/I4854E/i4854e.pdf

is ensured by u sing a checklist of all essential information, so that no important information or advice is omitted.

2.3 Comprehensiveness

is achieved by providing training and information on what pictograms, colour codes and other label elements mean and how to read a label, as well as by conducting user surveys which may result in label improvements.

2.4 *Conformity*

is achieved by following existing regulations, standards and guidelines, both national and regional/international.

2.5 Consistency

is assured by the standardization of label components, such as hazard statements and precautionary texts, so that label texts and layout of different labels will be as similar as regulatory requirements and user needs allow.

3 Label content information

3.1 Product information content

The following information identifying the contents of the container should appear on all labels:

a) **Product name**

b) **Product category** (e.g. herbicide, insecticide, fungicide, etc.).

c) **Type of formulation** – name and code, according to the International Formulation Coding System[2].

d) **Active ingredient name** (according to ISO[3]) or other locally used common name, or, in the absence of either, the chemical designation according to IUPAC [4]). If the active ingredient is a microbial agent, it is best identified by genus and species (and if appropriate, also by subspecies and/or isolate/strain number).

e) **Active ingredient content.** This should normally be expressed as "contains X g AI per kg" (for solids (including mosquito coils), viscous liquids, aerosols or volatile liquids) or "contains X g AI per litre" (for other liquids). For vaporizing mats, contents are expressed as mg/mat If the active ingredient is a microbial agent, content may be expressed as International Toxic Units (ITU) per mg product or as the number of viable units (spores, cells, colony forming units (cfu), etc.) per unit weight or volume of product. For specific types of pesticides or formulations, other appropriate units for active ingredient content may be applicable (e.g. % w/w or % w/v for certain household pesticides).

f) **Name/identity and concentration of hazardous co-formulants.** (i.e. all substances [e.g., solvents, adjuvants] in the formulation that contribute to the classification of the formulated product) (if any). For example, petroleum distillates must be listed and highlighted to promote effective medical treatment.

g) **Net contents of the pack.** This should be expressed in metric units (e.g. litre, gram, kilogram, which can be abbreviated to L, g and kg), or in number (e.g. for the pheromone dispensers),

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[2] CropLife. 2008. Catalogue of pesticide formulation types and international coding system. 6th edition, revised May 2008. Technical Monograph n°2. Crop Life International, Brussels. [Available at: http://croplife.org/wp-content/uploads/2014/05/Technical-Monograph-2- Revised-May-2008.pdf]

[3] ISO. 1981. Common names for pesticides and other agrochemicals. ISO Standard 1750 (including amendments). International Organization for Standardization, Geneva.

[4] IUPAC. Various dates. Nomenclature of Organic Chemistry (the "Blue Book"), and Nomenclature of Inorganic Chemistry (the "Red Book"). International Union of Pure and Applied Chemistry, Research Triangle Park, North Carolina. [Links at: http://old.iupac.org/publications/books/seriestitles/nomenclature.html]

unless the country does not use, or only partly uses, metric units. In such situations, local units should take precedence, but metric units should also be given.

h) **Batch number**

i) **Registration number (if any).**

3.2 Hazard and safety information

a) **Hazard symbol(s)** (if any)

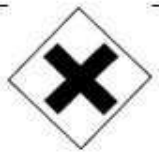
b) **Signal word** (if any)

c) **Hazard statement(s)** (if any)

d) **Precautionary statements or warnings** The advice to minimize any risks of using the product must cover the following:

1. General precautionary statements or warnings.
   The following statements must appear, as a minimum, on all labels1 :
   KEEP LOCKED AWAY AND OUT OF REACH OF CHILDREN and
   WASH AFTER USE and DO NOT EAT, DRINK OR SMOKE WHEN USING THIS PRODUCT, etc.
2. Product specific precautionary statements or warnings.
3. Relevant personal protective equipment.
4. Precautions when handling the concentrate (if applicable).
5. Precautions during and after application.
6. Environmental precautions during and after application
7. A warning against the reuse of containers Much of the safety advice may be put on the label in the form of standard precautionary statements or warnings.

e) **Precautionary pictograms** reinforcing the safety text should be included

 1 - The product is very toxic/toxic to human beings and to animals	 2 - The product is dangerous to human beings and to animals	 3 - Keep locked away and out of reach of children	 4 - Use the recommended quantity of the product which is a liquid concentrate
 5 - Use the recommended quantity of the	 6 - Precautions to take for the application of the	 7 - Wear gloves	 8 - Wear boots

f) **Hazard colour band** may be printed at the lower part of the label to indicate the acute toxicity of the formulated product

g) **A tactile warning for the blind and visually impaired**. The word **PESTICIDE** should be printed in Braille on all labels of products which a resupplied to the general public. In addition, a tactile warning of danger, in the form of a raised triangle or three raised dots placed in a triangle, is required for pesticide products supplied to the general public which are classified as dangerous.

h) **First aid and medical advice Labels** should carry first aid and medical advice, where relevant. Additional information regarding symptoms and antidotes may be added, where appropriate, for particular products. The following statements should appear, as a minimum, on all labels: If medical advice is needed, have product container or label at hand

i) **Product or user category,** pesticide products are classified by product or user categories (e.g. professional use products, restricted use products, household products/pesticides (also referred to as domestic-, consumer- or amateur products), public health pesticides). If that is the case, the appropriate product or user category should appear on the label.

j) **Accidental spills advice,** instructions for containing and/or cleaning up spills of the pesticide should be provided.

3.3 Direction for use

Clear directions or instructions for use should appear on the label. These generally encompass the following elements: Field of use, Directions for use, and Storage and disposal.

3.4 Other information

In addition to the contents, hazard and safety information and directions for use discussed above, the following information may also appear on all labels: The release date of the product should always appear on the label; Shelf-life or expiry date; Legal responsibility and/or warranty statement; a Quick Response code (QR-Code) and supplier information.

Annex IV: Arrangement of data requirements for pesticides registration

This arrangement is subdivided in two sections: administrative requirement, and technical data requirements.

Note: All sections and subsections of this document must be presented on the CD as directed and if, due to the form of the product, there are information which cannot be completed, N.A must be indicated on that part.

a) The application and supporting document should be submitted in CD-ROM or External driver addressed to Rwanda FDA

b) The application form should be typed in English. Any document which is in any language other than English must be accompanied by a certified or notarized English translation.

c) Application Form and part three should be in both PDF and word format

d) The PDF documents should be selectable and searchable

e) All pages of the application should be numbered in the style: ***page x of y***.

Therefore, the applicant shall prepare and present the product dossier information in the following format.

Section A. Administrative requirement

A.1 Dated and signed cover letter

A.2 Application form

A.3 Contract Manufacturing Agreement (where applicable)

A.4 Manufacturing license

A.5 A valid GMP or other applicable internationally recognized Management System certification

A.6 Two (2) samples of commercial product(s)

A.7 Two (2) coloured artwork of the product and leaflet insert of the product (where applicable).

A.8Appointment letter of the local technical representative with original copy of Power of attorney from the product manufacturer (if imported)

A.9 Commitment letters (Ongoing stability studies) where applicable

A.10 Product license or approval in other countries

A.11 Proof of payment of non-refundable registration application fee

Section B. Technical requirements

B.1 chemical analytical data of raw materials

B.1.1 Name for each ingredients

B.1.2 Name and address of manufacturer for each ingredients

B.1.3 Certificate of Analysis (COA) for each ingredient

B.1.4 Safety Data Sheets (SDS) for each ingredient

B.2 Data on final product

B.2.1 **Manufacturing process**

B.2.1.1 Flow chart and narrative of manufacturing process.

B.2.1.2 References used

B.2.1.3 Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

B.2.2 **Product efficacy**

B.2.2.1 Type of formulation (e.g. soluble concentrate, wettable powder, emulsifiable concentrate)

B.2.2.2 Function of the product (e.g. insecticide, insect repellent, rodenticide, …) and target pest species

B.2.2.3 Application rate per unit treated and concentration of active ingredient in the material as applied (for example, if the product is diluted before application)

B.2.2.4 Comprehensive Certificate of Analysis.

B.2.2.5 Method of analysis

B.2.2.6 Application and mixing instructions, including method of application, type of equipment used, application techniques and rates for each use site, and type and volume of diluent per unit of area or volume

B.2.2.7 Number, frequency and timing of applications (e.g. per year, per month) and duration of protection expected

B.2.3 **Human health assessment**

B.2.3.1 Re-entry periods (e.g. after space spray for mosquito control), waiting periods and other precautions to protect people, livestock and the environment.

B.2.3.2 Study data for adverse and chronic toxicity due to exposure

B.2.3.3 A statement about any risk arising from the recommended methods and precautions and handling procedures, in order to minimize those risks (e.g. precautionary statements of the globally harmonized system of classification and labelling of chemicals)

B.2.3.4 Information on antidotes, if any, and medical treatment in the case of accidental exposure; names of co-formulants that may influence the toxicity of the product

B.2.4 **General Safety Information**

B.2.4.1 Procedures for cleaning application equipment, if relevant to the proposed use

B.2.4.2 Proposed hazard classification (according to WHO classification), labelling and safety phrases and symbols

B.2.5 **Stability studies data**

B.2.6 **Packaging and Labelling information**

B.2.7 **Other supportive documents for quality, safety and efficacy information**