GUIDLINE FOR REGISTRATION OF PESTICIDAL PRODUCT IN ETHOPIA

DRUG ADMINSTRATION AND CONTROL AUTHORITY

ADDIS ABABA, EHTIOPIA

OCTOBER,2003

CONTENT

ANNEX

INTRODUCTION

The Drug Administration and Control Authority of Ethiopia has issued this guideline for the registration of pesticides with the objective of providing applicants with information concerning documentation to be submitted for registration.

The guideline consists of three sections namely, Requirements for registration of pesticide other than biological (section I), requirements for registration of biological pesticides (section II) and requirements for registration of various other forms of application (section III).

One of these types of applications in section III, which necessitate special mention, is re-registration application. After a pesticides product is registered its registration is valid for five years only. It is, therefore, mandatory for manufacturers to apply for re-registration by submitting the required documents before the due date.

Samples for various standard formats have been annexed to the three sections of the guideline and applicants are advised to use these standard formats whenever they apply. Moreover all applications to be submitted should be in the English language. When any part of the document, except the packaging is originally written in another language, a legalized translation in to the English language must be submitted with the original version.

The guideline is subject to revision in the light of current development in science and technology. Therefore, comments and suggestion are welcomed and can be sent to the Drug Administration and Control Authority of Ethiopia, P.O. Box 5681 Addis Ababa, Ethiopia.

DEFINITIONS

For the purpose of this guideline the following have the meanings hereby assigned to them

1. Sprays- sprays are solutions, emulsions or suspensions of one or more active ingredients that are delivered in the form of aerosols (particle size ranging from 0.1 - 50µ with 80% being under 30µ) by the actuation of an appropriate valve or by a means of a suitable atomizing device.

2. Active Ingredient (a.i.) a substance or compound that is intended to be used in the manufacture of pesticide product as active part of the pesticide present in a formulation
3. Branded Generics:- Are un patented products sold under a brand name.

4. Change in Formulation- Designates a qualitative and quantitative Change inactive ingredient(s) and in the product process of the finished pesticide.
5. Change of Origin-Includes change of the country of origin or change of the manufacturing site.
6. Closure- is a part of a container is a part of the container.

7. Common Name: The name assigned to a pesticide active ingredient by the International standards organization or adapted by national standards authorities to be used as a generic or nonproprietary name for that part ingredient only.

8. Container Is that which holds the article and is or may be in direct contact with the Pesticide

9. Environment:- Surroundings, including water, air, soil and their interrelationship as well as all relationships between them and any living organisms.
10. Formulation: The combination of various ingredients designed to render the product useful and effective for the purpose claimed: the form of the pesticide as purchased

11. Hazard: The likelihood that a pesticide cause an adverse effect (injury) under the conditions in which it is used

12. Household insecticide product: a range of ready-to-use products which are effective against specific target insects and are readily accessible to the general population in supermarkets, shops, pharmacies and other retail outlets in the cities and in the countryside.

13. Immediate Container: is part of container closure which has a direct contact with the product

14. Labeling: All labels and other written printed or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container.
15. Package material: Container –Closure

16. Proprietary Name: A pesticide sold or supplied under a special name (A brand or trade name) rather than the generic name of the ingredient alone.

17. Pesticide: Any substance or mixture of substances intended for preventing, destroying or controlling any pest, including Vectors of human or animal diseases, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities wood and wood products or animal feed stuffs or which may be administered to animals for the control of insects, arachnids or other pest in or on their bodies.

18. Reference /standard Substance**:** Authentic specimen that has been verified for suitability for use as comparison standards tests and assays.

19. Registration: The process where by 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 purposes intended and not unduly hazardous to human health or the environment

20. Residue: Any specified substances in food, agricultural commodities, or animal feed resulting from the use of a pesticide.
21. Toxicity: a degree of a substance to do harm or produce injury to a living organism by other than mechanical means

Section I Requirements for Pesticide Registration

1. Application Form

1.1. The Application form for pesticide registration (Annex I) should be filled out completely by the applicant (Manufacturer or Agent).

1.2. The date of application should correspond to the date of the application to the Drug Administration and Control Authority of Ethiopia (DACA).

2. Agency Agreement

2.1. An agency agreement should be made between the manufacturer of the pesticide in question and the Agent responsible for the import, distribution and sale of the pesticide in Ethiopia.

2.2. The agreement should be signed by both parties and such is what is to be presented. The seal/stamp of both parties should also be affixed to the document.

2.3. The agreement should specify that the representative chosen is the sole agent in Ethiopia.

2.4. The agent representing the manufacturer should hold a certificate of competence issued by Authority and a license issued by the Ministry of Trade and Industry.

3. Product Certificate

3.1 The certificate of the product must be issued by the national competent authority (Sample of the certificate is attached as Annex II).

3.2. The certificate should be original and current

3.3 The certificate should be authenticated by the Ethiopian Embassy in the country of origin . Where this may prove to be difficult consultation with the Drug Administration and Control Authority of Ethiopia is necessary.

4. Chemical and Pharmaceutical Documentation

4.1. Chemical Data on Active Ingredient

4.1.1. Data about the identity of active ingredient

4.1.1.1 Source of the active ingredient (Manufacturers full name and address

4.1.1.2 Generic or common name proposed or accepted by ISO and synonyms; Chemical name (IUPAC)

4.1.1.3 Structural formula, Empirical formula and molecular weight;

4.1.1.4. Chemical group

4.1.2 Physico- chemical Properties of the active Ingredient (indicate test methods).

4.1.2.1. Organo leptic properties (appearance, physical state, colour, odour etc);
4.1.2.2. Melting /Decomposition/Boiling points
4.1.2.3 Vapor pressure
4.1.2.4. Solubility in water and organic solvents
4.1.2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol),
4.1.2.6. Acid/Base dissociation constants (when applicable)
4.1.2.7. Density (for liquid only),
4.1.2.8. Hydrolysis rate under stated relevant conditions:
4.1.2.9. Photolysis under stated relevant conditions;
4.1.2.10. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.
4.1.2.11 The minimum (and maximum) active ingredient content in g/kg or g/l
4.1.2.12. Identity and amount of isomers, impurities and other by-products, together with information on their possible range expressed as g/kg.

4.2. Data on Packaging Materials (Container and Closures)

Detailed information is required about the packaging material, which comes in to such contact with the pesticide. Information required is:

4.2.1. Materials of which the pesticide containers are made
4.2.2. Technical properties of the finished packaging materials
4.2.3. Quality requirements and test methods

4.3. Formulation Report

4.3.1 . Data on Composition

Complete quantitative and qualitative composition of the formulated pesticide (both active and inactive ingredients); including quality specifications (requirements) and control methods.

4.3.2 Data on Manufacturing and Packaging Procedure

4.3.2.1. Concise description of the method of preparation of the formulated pesticide mentioning the quality and quantity of each ingredient (both active and inactive ingredients) used including the final packaging and labeling

4.3.2.2. Description on the precautions and in-process controls that are made in connection with different stages in the pesticide manufacturing process, that are of importance in ensuring the quality of the formulated pesticide.

4.4. Analytical Report

The manufacturer should submit:(2 copies)

4.4.1. Analytical procedure for the formulated pesticide,

4.4.2. Quality specifications (requirements) of the formulated pesticide. The quality specifications should include at least the following test parameters wherever they are applicable:

4.4.2.1. Content of the active ingredient

4.4.2.2. Identification of the active ingredient

4.4.2.3. Physical/Chemical properties of the formulated product such as:

- Organoleptic properties (appearance, physical state, color, odour)
- Density (for liquids only);
- Bulk density;
- Flammability: liquids- flashpoint; solids-a statement must be made as to whether the product is flammable
- pH
- Wettability (for dispersible powder)
- Persistent foam formation (for formulations to be applied in water)
- Suspensibility (for dispersible powders and suspension concentrates)
- Dry sieve test (for granules, dusts)
- Wet sieve test (for dispersible powders and suspension concentrates);

- Corrosiveness
- Other relevant parameters.

Note: Should the manufacturer use the quality specifications contained in well-known compendia references can be made to these

4.4 The stability data sheet

The study data sheet must show

4.5.1. The formulation

4.5.2 The Batch number and size (minimum two)

4.5.3 Date of manufacturing,

4.5.4 Storage conditions

4.5.5 Type and chemical nature of the packaging materials (Test should be performed in the proposed market container closure systems).

4.5.6 Analytical methods that will quantitatively measure the characteristic structure and chemical properties of each active ingredient of a dosage form and distinguish them from their degradation products so that active ingredient content can be measured.

4.5.7 Initial and all subsequent results of chemical, physical and /or biological testing. The data must include the result of studies at suitable test intervals. The following is an example of 0,6,12,18 and 24 months.

4.5.8 Data on the degradation products found under various stress condition and a description of the degradation pathway. The data submitted should contain at least the following information.

(a) Chemical Structure

(b) Cross-reference to any available information about biological effect and any significance at the concentration likely to be encountered.

(c) Mechanism of formation, including order of reaction

(d) Physical and chemical properties

(e) Procedure for isolation and purification

(f) Specification and direction for testing for their presence at the level of concentrations expected to be present

4.5.9 Stability and compatibility test results and reconstituted solution or suspension

4.5.10 The summary should consist of proposed shelf life, which should coincide with the length of study at the recommended storage conditions (e.g. if the proposed shelf- life of a product is 2 years then the result of tests performed at the recommended storage conditions to account for 2 years should be supplied)

4.5.11 Storage recommendation based on the data generated

5. Sample of Package Labeling

Package labeling includes package leaflet and label of the immediate container. The language for the labeling must be in English and Amharic and must appear conspicuously so that the ordinary individual will understand it.

5.1. Package Leaflet and Label of the immediate Container

The package leaflet and Label of the immediate Container should consist of factual and scientific information consistent with the information indicated in the document submitted for registration. The information to be indicated on the leaflet and label of immediate container include:

5.1.1. Name of the product; brand and common or generic name/INN
5.1.2. Formulation type
5.1.3. Qualitative and quantitative composition of active ingredient and other ingredients that require precaution in their use
5.1.4. Indication, mode of action and use category
5.1.5. Technical direction for use
5.1.6. Warnings, precautions
5.1.7 Safety period
5.1.5. First aid and other emergency procedures in case of accidental exposure, ingestion, inhalation, skin contact or poisoning.
5.1.6. Description of the symptoms of human poisoning and a note to the physician
5.1.7. Antidote (if any)
5.1.8. Harmful effects on non-target species,
5.1.9. Handling and Storage instructions
5.1.10. Warning against the re-use of containers,
5.1.11. Symbols and pictograms including WHO classification in words;
5.1.12. Method of disposal for the used containers
5.1.13. Quantity in the container (packing)
5.1.14. Batch number

5.1.15. Manufacturing and Expiry date
5.1.16. Name and address of manufacturer.

5.4. General Note

The titles for batch number, manufacturing and expiry dates should be part of the printing (type written material stickers etc are not acceptable) If the labeling technology of the manufacturer is such that this information is to be printed on the label on production line using inkjet laser printing, rubber stamp etc. written commitment to show all the required information on the label of the finished product must be submitted.

6. Sample of Actual Products and /or Reference Substance

6.1. Sample of actual products and reference standard substance (active ingredients) will be requested only after document approval by the Authority. Applicants are, therefore, advised not to submit samples along with registration documents.

6.2. An adequate quantity of sample should be submitted for quality control analysis and the samples should be accompanied with the certificate of analysis.

6.3. Sample should be identical to the actual commercial product i.e. it should not be sample for detailing purpose.

6.4 An adequate quantity standard substance (s) should be submitted if the method of analysis calls for the use of these particulars.

6.5. Sample of any other ingredient that can be expected to be of importance in the control of the specialty should also be submitted

NOTE: If special requirements must be imposed on the storages of samples or standards, information about their storage should be affixed to the containers.

7. Toxicological Data

Toxicological studies carried out on different species / animals such as rat, rabbit should be presented in tables which indicate species, number, weight and strain of animals, information on dosage rate, formulation, mode of application, treatment required , duration of treatment, parameters evaluated, significant observations and conclusions.

The dates of studies and name(s) of the laboratories conducting the studies should be mentioned.

7.1. **Toxicological studies of the active ingredient should include**:

7.1.1. ADI- Acceptable Daily Intake in mg/kg body weight
7.1.2. Acute Oral LD_{50} mg/kg rat/rabbit
7.1.3. Acute dermal LD_{50} mg/kg rat
7.1.4. Inhalation LC_{50} mg/l /hour (rat)
7.1.5. Skin irritation (rabbit)
7.1.6. Eye irritation (rabbit)
7.1.7. Sensitization (guinea pig)
7.1.8. Reproduction (specify species)
7.1.9. Sub chronic toxicity 90 day NOAEL mg/kg/day
7.1.10. Chronic toxicity NOAEL mg/kg/day
7.1.11. Carcinogenicity (life time) NOAEL mg/kg/day
7.1.12. Neurotoxicity NOAEL mg/kg/day
7.1.13. Teratogenicity NOAEL mg/kg/day
7.1.14. Mutagenicity/Genotoxicity
7.1.15 Metabolism (rat)
7.1.16. Summary of the above toxicological studies preferably should be submitted.

7.2. Toxicological study for formulated product

7.2.1. Rat -Acute oral LD_{50} mg/kg
- Acute dermal LD_{50} mg/kg
-Inhalation LC_{50} mg/l/hour

7.2.2. Rabbit - Skin irritation
- Eye irritation

7.2.3. Sensitization in guinea pig

7.2.4. Other studies

Summary of the above toxicological study should also be included, preferably in tables as per the WHO's classification scheme.

7.3. Ecotoxicology

7.3.1. Active ingredient and/or formulated product

7.3.1.1. Birds (2 species) One land and one water bird
- LD_{50} mg/kg
- NOAEL
- Reproduction

7.3.1.2. Fish (2 species) - LD50 mg/kg
- NOAEL
- Reproduction
- BCF (bio concentration factor of the a.i .in the tissues)

7.3.1.3. Daphnia
- LC50 mg/l
- NOAEL

7.3.1.4. Algae
- LC50 mg/l
- NOEL

7.3.1.5. Bees
- LC50 µg/bees
- NOAEL

7.3.1.6. Earthworms
-LD_{50} mg/kg

7.3.1.7. Soil micro- organisms

7.4. Behavior in Environment

(Active ingredient-Technical grade)

7.4.1. Behavior, ways of degradation, degradation products in soil.

7.4.1.1. Major metabolites
7.4.1.2. DT_{50} (days)
7.4.1.3. Mobility
7.4.1.4. Adsorption
7.4.1.5. Mobility of metabolites

7.4.2. Behavior, ways of degradation, degradation products in water:

7.4.2.1. Major metabolites
7.4.2.2. DT_{50} (days)

7.4.2.3. Behavior, ways of degradation, degradation products in surface and
ground water
7.4.2.4. Adsorption/desorption on sediments.

8. Residual Effect of the Pesticide

Residual effect study results showing
8.1. Major metabolites
8.2. Metabolism- principles of destabilization of the active ingredient in the plant and degradation products formed
8.3. Behavior of residues (action) and persistence of the residue or its metabolite in the plant and plant products
8.3. Method of residual analysis.

9. Pesticide Efficacy Data

9.1. An application form for Experimental clearance (Annex III) should be filled out completely by the applicant.

9.2 Test protocol of the efficacy trial should be attached with the experimental application.

9.3 The applicant has to submit detailed data generated through appropriate efficacy trial on the pesticide to be registered.

9.5 The study must be conducted under the environmental condition of Ethiopia

9.6 Efficacy assessment data should indicate;

9.6.1 Laboratory and Operational field-tests

9.6.2 Dose efficacy relationships

9.6.3 Level, duration and residual effect

9.6.4 Compatibility with other chemical control measures

9.6.5 Information on use in IPM

Section II Requirements for Biological Pest Control Agents

1. Application Form as indicated in section I No. 1.
2. Agency Agreement as indicated in section I No. 2.
3. Product Certificate as indicated in section I No. 3.
4. Sample of Package Labeling as indicated in section I No.5.
5. Sample of Actual Products and/or Reference Standard Substance (Active Ingredients) as indicated in section I No. 6.
6. Pesticide efficacy Data as indicated in section I No.9.
7. Chemical Documentation of bio-Chemical Pesticide

7.1**. Identity of the Product**

7.1.1. Active agent

7.1.1.1 Chemical or systematic name

7.1.1.2 General description and morphological structure of the agent

7.1.1.3 Method of development and isolation

7.1.1.2. Physical and chemical properties of the isolated preparation

7.1.1.3. Mode of action and degree of specificity

7.1.1.4. Analytical methods of the isolated product

7.1.1.5. Information on the formation of unintentional ingredients

7.1.2. Finished Product

7.1.2.1. Formulation type, composition of formulation, nature and quantity of diluents, purpose and identity of non-active ingredients.

7.1.2.2. Physical and chemical properties

7.1.2.3. Stability of product and storage conditions

7.1.2.4. Method of preparation (manufacturing)

7.1.2.5. Analytical methods

Note

The requirement for toxicological, residual effect and environmental fate study are as indicated in section I of this guideline

Section II Requirements for various other types of applications

1. Re-registration Application

An application for re-registration should consist of:

1.1. An application form for re-registration (Annex II)
1.2. Product certificate, as indicated in section 1.No.3
1.3. Samples of packaging materials or a statement from the manufacturer confirming that the type of packaging materials and the labels are identical to the one submitted during the time of the previous registration
1.4. Samples of actual products with certificate of analysis, as indicated in section 1.No.4.4.

2. Application for Change of Origin

Change of origin includes change of the country of origin or change of manufacturing site Application for change of origin should consist of:

2.1. An application form for change of origin (Annex III)
2.2. Product certificate, as indicated in section I.No.3
2.3. Accelerated stability study data demonstrating compatibility with the previously approved pesticide product, plus standard commitment to continue the stability study. The results of the on-going stability study should be submitted every 6-month until the final shelf life is determined.
2.4. Sample of packaging labeling as indicated in item No.5, section I
2.5. Sample of actual product as indicated in item No.6, section I.
2.6. A statement confirming that product formula, manufacturing process, quality control standards are not changed. If this is not so, the new data on each of these components should be submitted as indicated in their respective item numbers of section I.

3. Application for Change of Pack Size or Additional Pack Size

3.1. Application form for change of pack size (Annex IV)
3.2. The requirements indicated in section I, No.5

4. Application for Change in Container-Closure

Application for change in container-closure should consist of:

4.1. Application form for change in container closure (Annex V)
4.2. A statement from the manufacturer stating the reason (s) for the change.
4.3. Accelerated stability data demonstrating compatibility with the previously approved product, plus standard commitment to continue the stability study under normal recommended storage conditions.

For significant changes of products known to be relatively unstable, six month's data at the normal recommended storage temperature as well as the data from accelerated condition.

The result of the on-going stability study should be submitted every 6 month until the final shelf-life is determined.

5. Application for Change in Formulation

Change in formulation means a qualitative and quantitative change in inactive ingredients and in the production process of the finished product.

5.1. Change in Inactive Ingredient(s)

5.1.1. An application form for change in formulation (Annex VI)
5.1.2. All requirements as indicated in section I No.3,4.3, 4.4 (if there is any change in analytical procedure and/or specification)
5.1.3 If there is a change, which is known to affect the stability of product, accelerated stability data and commitment to continue the stability study under normal recommended storage conditions should be submitted. The results of the on-going stability study should also be submitted every 6-month until the final shelf life is determined.
5.1.4 If the change affects either its toxicity or its biological efficacy, the necessary data should be submitted.

5.2. Change in the Production Process

An application for making major change in the earlier reported production process of a finished product shall include:

5.2.1. An application form for change in formulation (Annex VI)
5.2.2 All requirements as indicated in Section I, numbers 4.3, 4.4 and section III No.5.1.3.

6. Application for Change in the Quality Control Process and/or Specifications

An application for making a change in the quality control method (both in-process and finished product Q.C.) and specifications leading to a change in the limits or to major changes in the control methods shall include:

6.1. An application form for change in quality control process and/or specifications (Annex VII)
6.2. The new quality specifications and control methods with adequate information on accuracy, precision, and suitability of the methodology.
6.3. Sample of actual product as indicated in section I, No.6

Annex I

Application Form For Pesticide Registration
Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILLED IN BY APPLICANT

1. Date of Application _____
2. Name of the pesticide to be registered: Common Name _____
   Brand Name _____
3. Pesticide formulation type /EC;.WP; etc..._____
4. Concentration_____
5. Pack size /presentation _____
6. Shelf-life or expiry date of product from the date of manufacture _____
7. Registration No of product in the country of origin _____
   _____
8. Name and address of manufacturer _____
   _____
   _____
9. License No. of the manufacturer in the country of origin
   _____

10. The name and physical address manufacturer

_____

_____

_____

11. Name and address of the agent in Ethiopia
    _____
    _____
    _____
    _____

12. Complete composition of the product (use non proprietary)

A) Active Constituents	**Concentration**
_____	_____
_____	_____
_____	_____

B) In Active constituents	**Concentration**
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

13. Proposed Legal Sales Category (Functions of product- intended use, veterinary, Public health, industrial, agriculture, fishing e.t.c)

_____

14. Target pest(s) (Main indications) method, dosage rates and frequency of application:

_____
_____
_____
_____

15. Regulatory status in other countries (indicate also the date)

- Marketed without Approval
- Approved and Marketed
- Under trial with phase
- Withdrawn, if any with reasons

Restrictions on Use, if any, in Countries where marketing is approved

_____

19. Supporting Documents or Materials Attached

Name, Official Designation and professional status of Applicant

_____

Signature _____

Date _____

Annex II

Exporting (Certifying) country
No of Certificate _____ Importing (requesting) country

Certificate of a Pesticidal product[1]

Proprietary name (if applicable):_____
Active ingredient(s)[2] and concentrations_____

1. Is this product licensed to be placed on the market for use in the exporting country?[4] If yes, complete box A, If no, complete box B.

A

Product license holder_____

Status of license holder[5] a)☐ b☐ c)☐ d)☐

Number of product licence[6] and date of issue: _____

Is an approved technical summary appended"[7]

Yes ☐ No ☐

If the attached product information Complete and consonant with the license?

Yes ☐ No ☐ Not approved ☐

Applicant for certificate if different from the license holder[8]

B

Applicant for certificate _____

Status of applicant[5] a)☐ b)☐ c)☐ d)☐

Why is authorization lacking?

Not required ☐ Not requested ☐ Under consideration ☐ Refused ☐

Remarks[9]

2.Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced yes ☐ No ☐ If no proceed to question, 3

Periodicity of routine inspections (years):
Has the manufacture of this type of dosage form been inspected?
Yes☐ No ☐
Do the facilities and operations conform to GMP requirement?
Yes ☐ No ☐

3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party?[11]
Yes ☐ No ☐ If no explain

_____

Address of certifying Authority:

Telephone/fax numbers

Name of authorized person
Signature/stamp/date:

General instruction and explanatory notes overleaf

General instructions

Please refer to the guidelines for further information on how to complete this for and on the implementation of the Scheme.
Forms should be comp leted using a typewriter to ensure legibility.
A cross should be placed in squares as appropriate to indicate which options apply.
Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1]This certificate, which is in the format, establishes the status of the product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for differe nt dosage forms and different concentrations can vary.

[2]Use, whenever possible International Nonproprietary Names (INNs) or national nonproprietary names.

[3]A qualitative listing of other ingredients contained in the dosage form should be appended.

[4]When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is entered on the product license.

[5]Specify whether the person responsible for placing the product on the market:

(a) manufactures the active ingredients and the finished dosage form

(b) manufactures the finished dosage form

(c) packages and/or labels a finished dosage from manufactured by an independent company; or

(d) is involved in none of the above

[6]Indicate, when applicable, if the license is provisional, pending technical review.

[7]This refers to the document, prepared by certain national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[8]In this circumstance, permission for issuance of the certificate is required from the product license holder.

[9]please indicate the reason the applicant has provided for not requesting registration:

(a) the product has been developed exclusively for the treatment of conditions-particularly tropical diseases -not endemic in the country of export,

(b) the product has been reformulated with a view to improving its stability under tropical conditions

(c) the product has been reformulated to exclude excipients not approved for use in products in the country of import

(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient,

(e) any other reason, please specify.

[11]This section is to be completed when the product-license holder or applicant conforms to status (c) or (d) as describe note 5 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In t circumstances the applicant should supply the certifying authority with information to identify the contracting pa responsible for each stage of manufacture of the finished product, and to indicate the extent and nature of any con exercised over each of these parties

Annex III.

Application form for Re-Registration
Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILLED IN BY APPLICANT

1. Date of Application _____
2. Name of the product to be re-registered: Common name _____
   Trade name _____
3. Formulation type (EC, WP, etc…)_____
4. Concentration _____
5. Presentation (pack size) _____
6. Name and address of the manufacturer _____
   _____
7. Name and address of the agent in Ethiopia _____
   _____
8. Previous registration No. in Ethiopia _____
9. Supporting document (materials) attached _____
   _____

Name, Official designation and professional status of the applicant

_____

_____

_____

Signature _____

Date _____

Annex IV

APPLICATION FOR CHANGE OF ORIGIN

Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILIED IN BY APPLICANT

1. Date of Application _____
2. Name of the pesticide : Common Name _____
   Brand Name _____
3. Formulation type (EC,WP,etc…)_____
4. Concentration_____
5. Pack size (Presentation) _____
6. Previous registration No. in Ethiopia _____
7. Previous origin (country)_____
8. Planned new origin (country) _____
9. Reason for changing the origin _____
   _____
   _____
10. Name and address of the manufacturer _____
11. Name and address of the agent in Ethiopia _____
12. Supporting documents attached _____
    _____

Name, official designation and professional status of applicant

_____

Signature: _____

Date:_____

Annex V

Application For Change of Pack Size and /or Additional pack size

Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILIED IN BY APPLICANT

1. Date of Application _____
2. Name of the Pesticide: Common Name_____
   Brand Name _____
3. Formulation type (EC.WP.etc)_____
4. Concentration_____
5. Previous pack size (Presentation) _____
6. New Pack size (presentation)_____
7. Previous registration No. in Ethiopia_____
8. Does the change also involve change in container-closure?
   Yes ☐ No ☐
9. If yes to No 8 above please describe the type and nature of both the old and new container-closures_____
   _____
10. Name and address of the manufacturer _____
    _____
11. Name and address of the agent in Ethiopia _____
    _____
12. Supporting documents _____
    _____

Name, Official designation and Professional status of the applicant

_____

Signature _____

Date _____

Annex VI

Application For Change in Container Closure
Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILIED IN BY APPLICANT

1. Date of Application _____
2. Name of the Pesticide: Common Name _____
   Brand Name _____
3. Formulation type (EC,WP etc…)_____
4. Concentration_____
5. Previous pack size (Presentation) _____
6. Previous registration No. in Ethiopia_____
7. Type and nature of the new container-closure_____
8. Does the change also involve change in pack size?
   Yes ☐ No ☐
9. If yes to No 8 above please describe the new pack size _____
   _____
10. Name and address of the manufacturer _____
    _____
11. Name and address of the agent in Ethiopia _____
    _____
12. Supporting documents _____
    _____

Name, Official designation and Professional status of the applicant

_____

Signature _____

Date _____

Annex VII

Application For Change of Formulation
Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILIED IN BY APPLICANT

1. Date of Application _____
2. Name of the Pesticide: Common Name_____
   Brand Name _____
3. Formulation type (EC, WP.etc…)_____
4. Concentration _____
5. Pack size (Presentation) _____
6. Previous registration No. in Ethiopia_____
7. Does the change involve?
   (a) change in inactive ingredients? Yes ☐ No ☐
   (b) change in the manufacturing process? Yes ☐ No ☐
   (c) change in both of the above? Yes ☐ No ☐
8. If yes to No 7 (a) or 7 (b) above, please list the ingredients in the spaces provided below:

Previous inactive ingredients		**The New inactive ingredients**	
Name	Quantity/Unit	Name	Quantity/unit
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

9. Name and address of the manufacturer _____
_____

10. Name and address of the agent in Ethiopia _____
11. Supporting documents attached _____
_____

Name, Official designation and Professional status of the applicant

_____

Signature _____

Date _____

Annex VIII

Application For Change In The Quality Control Process and/or Specifications

Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILLED IN BY APPLICANT

1. Date of Application _____
2. Common Name _____

   Brand Name _____
3. Formulation type (EC,WP,etc…)_____
4. Concentration_____
5. Pack size (presentation)_____
6. Registration No. in Ethiopia _____
7. Name and address of the Manufacturer _____

   _____
8. Name and address of the agent in Ethiopia _____

   _____
9. Brief description of the change intended to be made _____

   _____
10. Reason(s) for changing the quality control process of specification _____

    _____
11. Supporting documents attached _____

    _____

    _____

    Name, Official designation and professional status of the applicant

    _____

    Signature _____

    Date _____

Annex IX

Application Form For Experimental Clearance
Drug Administration and Control Authority
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILLED IN BY GOVERNMENT RESEARCH ORGANIZATIONS

1. Date of Application _____
2. Name and Address of the applicant
   _____
   _____
3. Common name _____
4. Trade name _____
5. Formulation type (EC,WP,etc..)_____
6. Concentration_____
7. Name and Address of Active Ingredient manufacturer _____
8. Name and Address of formulator _____
9. Intended use:
   _____
   _____
10. Purpose of trials _____
11. Location of Trial _____
12. Name and address of institution responsible for trials
    _____
13. Total area covered by trial _____
14. Total amount of product needed _____
15. Duration of the experiment _____
16. Supporting documents (brochures, literature review etc)
    _____
    _____

I/we herby certify that the information given above is correct to the best of my/our knowledge using the information and scientific data available to me/us.

Signature

Name of Researcher(s)_____ _____
_____ _____
_____ _____

Head of Institution _____ _____
_____
_____

Date _____

Official Seal