Directive Number 1093/2025

Pesticide registration Directive

In order to mitigate the adverse effects of pesticide products on human health and the environment while enhancing their efficacy; to have a detailed implementation directive which is legally binding; to response to complaints and disputes related to pesticides service delivery clearly and based on a legal framework , ministry of agriculture issued this directive in accordance with the authority given to it in accordance with Article 34 Sub-Article 2 of Pesticide Registration and Control proclamation No. 674/2002.

Part One
General

1. **Short Title**
   This Directive may be cited as the "Pesticide Registration Directive No. 1093/2025"

2. **Definition**

Unless the context otherwise requires, the following terms shall have the meaning ascribed to them hereunder this directive:-

1) "Pesticide registration" means the process by which the quality, efficacy and safety of a pesticide is verified in the field and in the laboratory and the data provided is evaluated and registered;.

2) "Pesticide registrant" means a person who is a manufacturer or a formulator of pesticides and provides information on the effectiveness, quality and safety of pesticides and other important information;

3) "Certificate of Registration" means a certificate issued to the manufacturer of a registered pesticide for a period of five years confirming that the registration requirements are met;

4) "Pesticide Dossier" means a collection of document containing necessary information for pesticide registration to be submitted by the registrant to the registering authority ;

5) "Pesticide with New Active Ingredient" means a pesticide with minimum negative effect on the environment and health and used for Integrated Pest Management services and its effectiveness and benefits are verified in the country but is not yet registered;

6) “Primary Information Source” means a pesticide test result or report that is related to the effectiveness and efficiency of pesticides provided by local research institutions directly submitted to the Authority;

7) “Secondary Information Source” Means the effectiveness and efficacy test report, research paper, articles, papers, public domain documents and related materials documents ,which have been produced without the prior consent of the authority;

8) ‘’Target crop" means the type of crop that the pesticide is intended to protect against a specified pest;
9) “Adjacent Crop” means when a targeted crop is sowed or grown at the same time on plots of farmland next to each other ;
10) “Successive Crop” means a crop sowed or grown on a farmland from which the targeted crop was collected during the previous harvest season;
11) “Pre-verification Test” means a type of test assessment through which benefits and side effects of a pesticide is analyzed so as to verify the minimum efficacy standard;
12) Physical properties of the active ingredient" means the pesticide’s active ingredient physical properties depending on the type of formulation, such as physical state, color, smell, size, vapor barrier content, volume limit percentage, pressure, water and carbonic solvents. , the separation and decomposition temperatures, increase the melting point and boiling point;
13) "Chemical properties of the active ingredients " means are the characteristics that describe their behavior, interactions, and stability, including solubility, pH, melting and boiling points, density, reactivity, polarity, hydrophobicity, and specific functional groups. the pesticide’s active ingredient composition; It includes specifying percentages of image and driver content and size limits;
14) ‘’verification test" means a test that is used to compare the pesticide’s efficacy with other registered pesticides or any pest control mechanisms after passing the pre-verification test;
15) "Experimental control" refers to a test conducted to compare the uniformity of ecological conditions of the neighboring field to the testing field without the application of pesticides on the neighboring field;
16) "Minor use pesticide" refers to a pesticide applied to a crop or against a pest that has a limited economic impact at the national level;
17) ‘Reference pesticide" refers to the pesticide used for comparison during efficacy testing;
18) ‘’Testing protocol" is the test procedure prepared by the authority to be followed by the practitioner or researcher for testing pesticide efficacy;
19) ‘’Primary score" means a test point used primarily to measure the efficacy of the pesticide;
20) ‘’A minor criterion score’’ is an additional and auxiliary point used alongside the primary score to measure the efficacy of the pesticide;

21) "OECD" means the Organization for Economic Co-operation and Development;
22) "An accredited laboratory" is one that adheres to OECD principles and holds a certificate of good laboratory practice from an internationally recognized body, or a laboratory with a certificate of competence issued by the government of the country where the laboratory is located;
23) "Batch" is a quantity of pesticide product produced during a specific period of time;
24) ‘’A Certificate of Analysis’’ is a document that shows the results of testing a sample of the pesticide product to verify its content;
25) "Low-risk pesticide" means a pesticide that has low side effects on humans and the environment and is proven to be effective;
26) "Material Safety Data Sheet" is a document that provides detailed information about a pesticide's chemical content, potential risks to humans and the environment, handling instructions, safety precautions, and emergency procedures;
27) "Label" is a document created by the manufacturer or formulator and attached to the smallest package of a product. It provides essential information about how to use the product safely;
28) "Leaflet" is a document prepared by the manufacturer or formulator that provides information on how to use, handle, and dispose of a product, along with safety precautions;
29) "Technical manual" is a document that provides detailed technical information and usage instructions for a pesticide. It is designed to be understood by experts such as pesticide specialists, agricultural researchers, chemists, and environmental protection professionals;
30) "Administrative documents" are the documents related to ownership, representation, good manufacturing process and other related permits that are required when registering a pesticide;
31) "Research plan" is a formal document prepared by an authorized researcher according to the protocol established by the authority for testing efficacy;
32) "Authority" means the Ethiopian Agricultural Authority ;
33) "Proclamation" means Pesticide Registration and Control Proclamation 674/2010;
34) The definitions given to the terms used in Article 2 of Decree No. 509 issued by the Proclamation to determine the powers and organization of the Agricultural Authority shall also apply to this directive.

3. Scope

This directive applies to both domestically manufactured or formulated and imported pesticides.

Part Two
Pesticide Registration System

4. Registration

The Authority:-

1) The pesticide registration service shall be carried out online and, as necessary, the information may be submitted in person by the applicant;

2) The Authority shall conduct a preliminary assessment of the information submitted in accordance with Sub-Article 1 of this Article;

3) If the preliminary assessment is accepted in accordance with Sub-Article 2 of this Article, it shall conduct a technical assessment of the pesticide;

4) It shall process applications on a first-come, first-served basis and may process applications for a newly discovered pesticide, a pesticide with low risk to humans or the environment, a pesticide with a specific use, or a pesticide that is sought to be registered on its own initiative, based on its importance and usefulness, provided that it meets the conditions specified in this guideline, in a priority or expedited manner as necessary;

5) To ensure the reliability of the information provided in accordance with this guideline, the registrant must complete the form in Appendix 1 attached to this directive;

5. Minor use pesticide

A pesticide of minor use may be registered:

1) When it is proven that safety equipment is provided with the product to help reduce the potential harm caused by the pesticide;

2) When it has complete pesticide safety information;

3) If it is registered in the country of production and meets the criteria for the control of pesticides of minor use issued by the Food and Agriculture Organization of the United Nations or the World Health Organization.

6. Low-risk pesticides

A low-risk pesticide may be registered:

1) If it is registered in the country of production and meets the requirements of the Low-Risk Pesticide Control Guidelines issued by the Food and Agriculture Organization of the United Nations or the World Health Organization,

2) If the producer can provide sufficient evidence to demonstrate that it is a low-risk pesticide;

7. **Preliminary evaluation**

1) Before conducting a technical evaluation, the authority will perform a preliminary evaluation to ensure the following information is provided:-

a) Study report on the physical and chemical properties of the pesticide or the substances used in its preparation;
b) Compliance with relevant international agreements;
c) Study on human health toxicology ;
d) Study on environmental toxicology ;
e) Results of local efficacy testing ;
f) Administrative documents ;
g) Document outlining disposal methods ;
h) Information on first aid and poisoning treatment ;
i) Labels and leaflets;
j) Manufacturer's description and manufacturing license;
k) Certificate of Good Manufacturing Practice issued by the authority;
a) Certificate of analysis detailing the contents of the pesticide formulation;
b) Studies related to storage of the pesticide ;
c) A copy of the agency agreement between the manufacturer and the local representative;
d) Evidence of Registration in country of formulation or manufacturing;

2) Pesticides that pass the preliminary evaluation will move on to a technical evaluation. If a pesticide fails the preliminary evaluation, the applicant must submit the missing information or documents within 10 consecutive days. Failure to do so will result in the application being completely rejected.

8. Technical Evaluation

Before a pesticide registered, the authority carries out a comprehensive technical evaluation. This includes reviewing studies on the pesticide's physical and chemical properties, its toxicological risks to human health and the environment, and its safety data. The evaluation also involves checking the certificate of content from batch testing and analysing the results of local efficacy research.

9. Physiochemical properties Technical Evaluation

The authority should made technical evaluation on physiochemical properties of the pesticide provided in Annex 2 regarding the following details:-

1) The generic name of the pesticide and the scientific name of the active substance, along with any specific details about ingredient processing enhancers;
2) The chemical category, chemical formula, physical form of the pesticide, and the brand name of the product;
3) Analysis details of the main active ingredient and the method used in the preparation of the product;

4) A certificate of results from five rounds of testing, conducted by a recognized laboratory, detailing the physical and chemical properties of both the main ingredient and the formulated product;
5) Data on the stability of the substance at high and low temperatures 54°C and 0°C.
6) The shelf life of the product, density and relative density, and potential interactions with other pesticides;.
7) pH level ;
8) Method of analysis used to measure pesticide residues;
9) If the product's shelf life exceeds two years, an authenticated study report from a recognized body ;
10) A report and certification of the physiochemical properties of the product, as tested in the laboratories of the authority or in institutions designated by the authority.

10. Human Health Toxicology Risk Study Technical Evaluation

The authority should made technical evaluation on A human health toxicology study of the pesticide provided in Annex 3 regarding the following details:-

1) Evidence confirming that the study was conducted in accordance with OECD guidelines and followed good laboratory practice principles, or was performed by a laboratory recognized by the relevant authority in the country where the experiment took place;
2) A study report on acute toxicity conducted on mice, rabbits, and guinea pigs;
3) A study report on the short-term and long-term toxicity of the pesticide, including potential risks associated with Carcinogenicity, Neurotoxicity, fetotoxicity, Mutagenicity and reproductive Toxicity ;
4) A residue testing report from the authority's laboratory or an institution designated by the authority, detailing the pesticide residue levels and the recommended pre-harvest interval.

10. Environmental Toxicological Risks studies Technical Evaluation

The authority should made technical evaluation on The environmental toxicology study of the pesticide provided in Annex 4 regarding the following details:-

1) A toxicological study conducted on two species of fish, two species of birds, daphnia, bees, algae, and soil microorganisms;

2) Studies on the behavior of the pesticide in soil and water, including the process of its degradation and the properties of the resulting Degradation Products and Metabolites;

3) A study on pesticide mode of action.

12. Material Safety Data Sheet Technical Evaluation

Any pesticide safety data sheet should include at least the following:

1) The name of the pesticide formulation and active ingredient;
2) Contents of the pesticide formulation;
3) Physical and chemical properties,
4) The potential health and environmental damage of the pesticide.
5) Measures taken to reduce the risk of poisoning or exposure to the pesticide.
6) Actions to reduce the risk of fire or accidental pesticide spills.

13. Batch Certificate of Analysis Technical Evaluation

1) 1. For the formulated product include at list the following information:

    a) Manufacturer's name;
    b) Sample label;
    c) Date of sampling;
    d) testing date;
    e) Name of the performing laboratory;
    f) Name ,signature and potion of the personnel who conducted the test;
    g) Color;
    h) Physical state ;
    i) Weight and Percentage of the active ingredient;
    j) Type and percentage of the carrier;
    k) Type and percentage of fillers;

2) The laboratory providing the result certificate mentioned in sub-paragraph 1 of this article must hold a qualification certificate from the authorized body to conduct the test.

14. Pesticide Efficacy Report

1) Pesticide efficacy evaluation is based on primary or secondary data sources. If necessary, the authority may request additional data from the registrant, manufacturer, or researcher;
2) Local pesticide efficacy test results submitted at the time of registration will only be accepted if conducted with the prior approval of the authority;

3) To obtain pesticide trial authorization, applicants must fill out the form provided in Annex 5 and submit material safety data sheet and Technical manual prepared by the manufacturer;
4) The authority must verify that any sample submitted for testing originates from the manufacturer and oversee the process to ensure the sample reaches the research office;
5) The registrant must complete the form provided in Annex 6 to request sample import permit, and must provide a Memorandum of understanding with the research institution and trial research plan prepared by the researcher;
6) Registrant must submit an analytical comparison sample of the active ingredient for comparison with the pesticide being registered;
7) Trial inspection on the field and on the laboratory will be conducted by the authority's staff ;
8) Any pesticide or pest control method used for comparison without the prior approval of the authority will not be accepted;
9) Research institution or researcher conducting an experiment must follow the testing protocols issued by the authority.

15. Efficacy evaluation using primary data sources is conducted in the following situations:

1) When the manufacturer or place of manufacture is new;
2) When the pesticide substance is new or has not been used in the country before;
3) When the substance content changes;
4) When the pesticide is combined with one or more other substances;
5) When registration is requested for a new crop or a new type of pest.

16. Efficacy evaluation using a Secondary Data Source is conducted in the following situations:

1) If there is convincing evidence that the pesticide can control multiple crops or pest types;
2) If there is scientific evidence that prove the pesticide can control for biologically closely related crops or pests;.
3) If it is confirmed that the pesticide will be used only for crops grown in small quantities in limited areas;
4) If the authority deems the use of the pesticide urgent for various reasons.

17. Criteria for efficacy Evaluation

1) The following criteria shall be the primary points during the evaluation of pesticide efficacy:
    a) yield;
    b) Percentage of pest eradication or control;
    c) adverse effects on non-target crops;

2) In addition to the primary points outlined in article 15 Sub-article (1) the following conditions shall serve as a minor criterion points:
    a) Economic viability;
    b) Contributions to integrated pest management;
    c) Pest resistance status;
3) If a pesticide scores higher on the primary scores but lower on the minor criterion, it will be registered with pre-conditions and as a restricted use pesticide.

18. Pesticide efficacy test results may be rejected under the following conditions:

1) If the pesticide's positive impact on crop yield and pest control is not statistically significant compared to a control experiment.
2) If the pesticide's positive effect is not statistically equal to or better than)that of the Reference pesticide or pest control method;
3) If the pesticide's negative impact on the target crop, adjacent crops, and subsequent crops is not significantly less than that of the reference pesticide;
4) If there is evidence of a conflict of interest between the registrant and the research institute or researcher.
5) If there are unsatisfactory answers to questions raised by the Authority experts during or after the field visit, or if the results are ambiguous ;
6) If the pesticide’s sample is not received by the researcher through the proper confidential chain;
7) If the pesticide effectiveness test does not follow the prescribed test procedures issued by the authority.

Part three
Registration Decision, Registration renewal, and Registration certificate

19. Registration Decision

1) The authority ensures that the pesticide is evaluated based on internationally accepted practices, laboratory test results, and recommendations from technical evaluators, and then makes a decision to approve or reject the registration;

2) If necessary, the submitted documents may be verified through an Ethiopian consulate or embassy in the country of origin;
3) If the pesticide passes preliminary and technical evaluations, and the administrative review confirms it does not pose significant risks to people or the environment and demonstrates superior efficacy, it will receive a registration certificate valid for five years;
4) If the pesticide fails to meet technical requirements, if its efficacy is not accepted, or if administrative documents confirm it poses high risks to people or the environment compared to its benefits, the registration will be rejected;
5) If the pesticide requires additional involvement from other institutions or stakeholders for handling, use, storage, transportation, or disposal, the registrant will be given up to six months for further evaluation and consultations. This will be managed according to article 19 sub-articles (3) and article 19 sub-articles (4) ;
6) Pesticides with significant positive or negative effects will be registered as a restricted used pesticide;
7) Temporary registration for up to one year may be granted to allow the completion of any outstanding criteria or documentation, provided it does not affect the overall registration outcome.

20. Registration Certificate

1) Upon approval of the registration, the authority will issue a certificate to the registrant, provided that the service payment has been successfully completed ;
2) The pesticide registration certificate should include the following information:-
    a) Trade name of the pesticide;
    b) Common name ;
    c) Quantity and composition of the active ingredient ;
    d) chemical abstract number of the product;
    e) Registrant's name and address ;
    f) Purpose of registration , limitations and other conditions of the registration;
    g) Duration of the registration ;
    h) Legal seal of the authority, including signature and date;
3) As required by sub article (2) of this article, the registration certificate may include information about intellectual property ownership if necessary;
4) In addition to the information specified in sub article (1) of this article, the registration certificate will also include the name and address of the first registration agent, along with a copy of the approved label and package details, and will be provided to the registrant;

5) A list of registered pesticides will be made publicly available through publication, a database, and the official website of the authority;
6) Changes to the information on the registration certificate will not be allowed unless the applicant requests an amendment or re-registration, in which case an amended certificate will be issued according to the system outlined in this directive.

21. Renewal of Certificate of Registration

1) An applicant may request renewal of registration by submitting the form provided by the authority at least 90 days before the registration period expires;

2) The authority will consider the following when renewing a registration:-
    a) Verifying the accuracy and relevance of the information provided in the form;
    b) Ensuring that no complaints have been made during the post-registration period regarding the pesticide's efficacy, quality, safety, or any illegal activities;
3) Despite the conditions in sub article 2(b), if the pesticide has not been used at least once during the registration period, the applicant may apply for renewal by conducting local efficacy and residue tests;
4) Renewal requests will not be accepted if they are not submitted within the time frame specified in sub article (1) ;
5) If the authority denies the renewal request, the applicant will be notified in writing;
6) If the applicant disagrees with the decision, they must submit an appeal within 30 days.

22. Amendment of Registration

1) An applicant may request a registration amendment under the following conditions:
    a) Minor changes to label or package;
    b) Changes to the registrant's information, such as address or personal details;
    c) If the change does not alter the risks or benefits associated with the pesticide;
2) If the requested amendment meets the following criteria, the authority will review the application and issue an amended registration certificate:-
    d) The change does not affect the pesticide itself or its intended use;
    e) The pesticide's efficacy, health, environmental risks, or toxicity remain unchanged;
    f)The amendment does not conflict with the legality of the pesticide or the label contents;

g) The modification does not introduce new handling risks or inconvenience;

3) If the authority rejects the request for a registration amendment, the applicant must be informed of the reason within seven days of the decision;
4) If the applicant disagrees with the decision, they may submit an appeal within 30 days

23. Re-registration

1) If the re-registration request involves changing the trade name, the application must include a certified document from the Ethiopian consulate or embassy in the country of origin;
2) If the re-registration request involves changing the content of the pesticide's active ingredient or altering its intended use, new local efficacy report, toxicological studies, environmental risk studies, residue, or any relevant documents upon request must be submitted with the application;
3) If the re-registration request involves transferring the registration to another individual, the application must include a certified document from the Ethiopian consulate or embassy in the country of origin, along with a certified copy;
4) The authority must make a decision within 90 days of receiving the re-registration request;
5) The decision made under sub article 2 of this article must be communicated to the applicant within seven days of the decision;
6) If the authority rejects the re-registration request, the reason must be provided to the applicant within seven days of the decision;
7) If the applicant disagrees with the decision, they may submit an appeal within 30 days.

Part Four
Pesticide Trade Name, label and Leaflet, and Confidentiality

24. Trade name of Pesticides

Pesticide registration is conducted using the trade name and mark provided by the registrant. However, a trade name or mark may be rejected for the following reasons:-

1) If the trade name is contrary to public peace and morals;
2) If the trade name is widely used in economic or commercial activities or is recognized as a common term by the public;
3) If the trade name or label misleads the public or business community regarding the type or nature of the pesticide;
4) If the trade name or label includes, without proper authorization, military symbols, flags, or other emblems, names, acronyms, or abbreviations of any state,

intergovernmental organization, or other entity established under international agreements, including official marks or emblems of honor;

5) If the trade name contains personal names;
6) If the trade name or label is similar or confusingly similar to a pesticide trade name or label previously registered by another individual or organization for the same or a similar pesticide;
7) If the trade name or label is identical or misleadingly similar to the trade name or label of another product that is well-known or widely used in Ethiopia;
8) If the trade name is inconsistent with the trademark registration laws in force in Ethiopia.

25. Pesticide Product Label and Leaflet

1) Pesticide labels and leaflets, as specified in Annex 7, must include the following details:-

a. The name of the pesticide manufacturer or formulator, and importer;
b. The trade name and generic name of the pesticide;
c. The target pests and the specific crops or application methods;
d. Direction for use, safety warnings, and precautions;
e. Use preparation method;
f. The expiration date;
g. Color codes, pesticide's classification, along with graphics for usage and safety instructions;

2) In addition to English and Amharic, the pesticide label may also be written in the working languages of each region when necessary;
3) The label design for pesticide containers should comply with the specifications provided in Annex 7;
4) A pesticide leaflet must be accompanied with the pesticide smaller packages containing additional information that cannot be fully detailed on the label due to space limitations.

26. Confidentiality

1) If an applicant wishes to keep certain information submitted for registration confidential, they must clearly identify and mark this information as "confidential";
2) For a pesticide with an active patent, all submitted information will remain confidential from the initial registration until the patent expires;
3) Non-proprietary information must be kept confidential for up to 10 years from the date of submission;

4) The information identified as confidential will not be disclosed to another applicant unless the original registrant provides written consent during the confidentiality periods outlined in sub-article(2) and (3);
5) Except for the confidential information specified in sub-article (2) and (3) of this article , the regulatory authority may disclose any other information it deems appropriate, including:

a) Applicant's address;
b) Pesticide labels, active ingredient, formulation type, and any additives that could be of concern due to their toxicity or environmental impact;
c) Intended benefits of the pesticide;
d) Information on toxicity and environmental impact;
e) The behavior and fate of the pesticide on crops and in the environment;
f) Any physical damage the pesticide may cause;
g) Recommended disposal methods;
h) First aid instructions in case of poisoning.

6) Subject to the provisions outlined in this article, when there is a significant public interest in the submitted dossier, and upon the applicant's request, the authority may release the following information to the public

a) Pesticide formulation composition ;
b) Details of the manufacturing process;
c) A list of crude chemicals present in the main ingredient;
d) The analytical method used to detect crude chemicals in the original substance;
e) Test results for each product type or batch of the main ingredient, including any unwanted chemicals found;

f) Relationship between the manufacturer or formulator and the applicant or their agent;
g) Information on studies conducted to assess the effects of the pesticide on vertebrate animals, including the names and addresses of the individuals involved on the study.

Part Five:
Miscellaneous Provisions

27. Prohibition

1) Registering a product manufactured by the same manufacturer or formulator under different trade names is strictly prohibited;

2) An applicant who receives a prohibition decision may file a complaint within 60 days of the decision or pursue a complaint in accordance with the administrative procedure law.

28. Transitional Provision

Pesticide registrations that were carried out before the issuance of this Directive in a manner inconsistent with the provisions of this Directive must be registered within 18 months from the date of approval of this Directive.

29. Effectiveness of the directive

This directive will be effective from the date it is registered by the Ministry of Justice and posted on the website.

Addis Ababa, June 17, 2025

Girma Amente (PhD)

Minister of Agriculture

Annex 1

APPLICATION FOR THE REGISTRATION OF A PESTICIDE

Indicate where appropriate:

A. Pesticide containing a new active ingredient:

B. Pesticide where source of active and/or formulation is not identical to that of a registered product:

C. Registration transfer:

D. Amendments to existing registration:

E. Other:

1. APPLICANT		
1.1 Identification	Name / Corporate name of company Reg. no.: (of registration holder)	Name of distributor/agent in country: (if different from registration holder)

1.2 Status: (Importer/formulator/distributor)		
1.3 Physical Address:		
1.4 Postal Address:		
1.5 Telephone: (and area code)		
1.6 Fax: (and area code)		
1.7 e-Mail:		

2. PRODUCT		
2.1 Designation	Trade name:	
	Trade mark:	
	Trade mark holder:	
2.2 Function of product:		
2.3 Intended use: (veterinary, public health, industrial, agriculture, forestry, etc.)		
2.4: Target pest(s) and host(s):		

2.5: Method, dosage rates and frequency of application: (if required)				
2.6 Type of formulation:		GCPF code:		
2.7 Existing reg. no.: (if relevant)		Customs Tariff Code: (Brussels Tariff Nomenclature)		
2.8 Registration in SEARCH country/ies:				
2.9 Registration in other country/ies:				
2.10 Registration in country of manufacture and formulation:			submit evidence:	

3. ACTIVE INGREDIENT (S) (Technical grade) (may be attached in sealed envelope)

Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Min a.i. % purity:	Range %:

4. FORMULATION

4.1 Formulator: (Name)	Address:
4.2 Composition (may be attached in sealed envelope)	

Ingredients and Function:	g/l	g/kg	Range

5. TOXICOLOGY (formulated product)

5.1 RAT:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} mg/kg)	Inhalation LC_{50} (mg/l /hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated

5.2 RABBIT:	Skin irritation	Eye irritation
None		
Mild		
Moderate		
Severe		

5.3 Sensitisation in guinea pig:	None	Mild	Moderate	Severe

5.4 WHO class:	Ia	Ib	II	III	

5.5 Summary of other Mammalian Toxicological Studies:
5.6 Summary of Environmental Effects:
5.6.1 Toxicity to bees:
5.6.2 Toxicity to fish and other aquatic organisms:
5.6.3 Toxicity to birds:
5.6.4 Toxicity to earthworms and soil micro organisms:
5.6.5 Toxicity to other non-target organisms:
5.6.6 Persistence in environment:
5.6.7 Other effects:

6. PACKAGING	
6.1 Packaging material / container:	
6.2 Pack size(s):	
6.3 Disposal of empty container(s):	

7. DECLARATION	
I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	

..... Name in full (printed)	..... Signature
..... Date	..... Official Title
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks: .... Signed: Date:

Annex 2

ACTIVE INGREDIENT (TECHNICAL GRADE)

1. DESIGNATION

REQUIREMENTS:	REMARKS:
a. Common name (ISO)	Specify accordingly
b. Manufacturer code	
c. Chemical name (IUPAC)	
d. Chemical group	
e. Structural formula	
f. Empirical formula	
g. Patent status Is the a.i. under patent Who is patent holder Expiry date	**Patent situation:** If the product is under patent and the application is not by the patent holder, a letter of authorization from the patent holder must be included in the dossier.

2. PHYSICAL AND CHEMICAL PROPERTIES

(active ingredient – technical grade)

REQUIREMENTS:	REMARKS:
a. Physical state	Where relevant indicate method/test used and give value.
b. Colour	
c. Odour	
d. Density at 20°C	
e. Vapour pressure at 20/25°C	
f. Volatility	
g. Hydrolysis	Give the DT 50 of the active ingredient, with mention of temperature and pH parameters employed during the determination. Indicate specific method used.
h. Photolysis	Give the DT 50 of the active ingredient (in days) and method used.
i. Solubility in water	PH solubility
j. Solubility in organic solvents	Indicate value
k. n-octanol/water partition coefficient	Indicate value
l. Boiling point °C	Indicate value
m. Melting point °C	Indicate value
n. Decomposition temperature °C	Indicate value
o. Method of Analysis and Impurities	Full Study report and method of analysis

GUIDELINE: FORMULATED PRODUCT DOSSIER

1. PHYSICAL AND CHEMICAL PROPERTIES OF THE FORMULATED PRODUCT.

Clearly state method used to determine properties under the appropriate section of the dossier. CIPAC methods are recommended.

Requirements:	**REMARKS:**
a. Physical state / formulation type	Description
b. Colour	Description
c. Odour	Description
d. Storage stability	Indicate the stability of the preparation after storing at 54°C for 14 days. Other durations and/or other temperatures (e.g. 8 weeks at 40°C, 18 weeks at 30°C) if the preparation is thermo-sensitive, may be provided in this case, the new parameters have to be specified. (method and value)
e. Shelf life	The shelf life of the product at room temperature (30°C) is given in years if it is more than two years, and in months if it is less than two years; the appropriate temperature specifications must be given.
f. Density	Indicate the density of liquids.

g. Bulk density	Indicate the density of solids after compression.
h. Compatibility with other pesticides	Summary report
i. pH	Value (if liquid)
j. pH of 1% aqueous dilution	Relevant to products to be diluted in water. Value
k. Oxidizing properties	Indicate information
l. Corrosiveness	Indicate information
m. Water content	Indicate relevant information
n. Wettability	
o. Solubility in water	
p. Foaming	
q. Particle size	
r. Emulsifiability	
s. Emulsion stability	
t. Volatility (Henry's Law constant)	Value
u. Viscosity	For formulations to be used at very low volume, it is necessary to know the viscosity.
v. Other properties (where applicable)	For example: dry/wet sieve test
w. Method of Analysis	Full Report

Annex 3

1. TOXICOLOGY (ACTIVE INGREDIENT-TECHNICAL GRADE)		
	Annex. No	**Official use only**
a. ADI		
b. Acute oral LD_{50} mg/kg rat/rabbit		
c. Acute dermal LD_{50} mg/kg rat		
d. Inhalation LC_{50} mg/li hour (rat)		
e. Skin irritation (rabbit)		
f. Eye irritation (rabbit)		
g. Sensitisation (guinea pig)		
h. Reproduction (specify species		
i. Subchronic toxicity 90 day NOEL mg/kg/day		
j. Chronic toxicity NOEL mg/kg/day		
k. Carcinogenicity (life time) NOEL mg/kg/day		
l. Neurotoxicity NOEL mg/kg/day		
m. Teratogenicity NOEL mg/kg/day		
n. Mutagenicity Genotoxicity		
o. Metabolism (rat)		
p. Other studies	26	

2. TOXICOLOGY (formulated product)		
a. Rat Acute oral LD mg/kg		
b. Acute dermal LD mg/kg		
c. Inhalation LC mg/l hour		
d. Rabbit Skin irritation		
e. Eye irritation		
f. Sensitisation in guinea pig		
g. WHO classification		
h. Other studies		

FORMULATED PRODUCT	**Annex. No. in dossier if study included**	**Official use only**
3. **EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING**		
a. Symptoms of human poisoning		
b. First aid treatment		
c. Skin contact		
d. Eye contact		
e. Inhalation		

f. Ingestion		
g. Antidote		
h. Note to physician		
i. MRL Codex		
j. Residue analysis method		
k. Residue data and pre-harvest interval		

ANNEX 4

Active ingredient	Attached is the number given in the dossier if the study is attached	
1. Environmental toxicity For the main ingredient (technical grade)		
1.1 For Birds (2 Species)		
1.2. Fish (2 Species)		
1.3. daphnia		
1.4. Algae		
1.5 For Bees		

1.6 Soil worms		
1.7 Soil micro-organisms		
2. Behavior in the environment For the main ingredient (technical grade)		
Soil conditions, size reduction and ways to reduce size		
2.1 Major Other Chemicals Caused by Chemical Change		
2.2 DT_{50} (days)		
2.3 Mobility		
2.4 Ability to stick to solid material		
2.5 The nature of the chemical in water, its reduction in size and ways of reducing		
2.6. Major Other Chemicals Caused by Chemical Change		
2.7 DT50 (days)		
2.8 Ground water		
2.9 Hole water		
3 Residues formed in plants		
3.1. Major Other Chemicals Caused by Chemical Change		
3.2. Metabolism		
3.3. Behaviour of residues		
3.4. Crop type		

Annex 5

ETHIOPIAN AGRICULTURE AUTORTY
PESTICIDE EFFICACY TRIAL PERMIT

Ref.No----------
Date: ----------

Name Address of Applicant _____

Role of applicant (manufacturer, Importer, Agent, representative etc.)

_____

Name and Address of manufacturer formulator _____

_____

Name and address of Manufacturer technical product_____

_____

Name contact person _____**tel:**_____

Item description

NO	Trade name	A.I. and Concentration	Target pest	Host

Trial types

Insecticide trial ☐ **Fungicide trial** ☐ **Herbicide trial** ☐ **Aerosol trial** ☐ **Storage pesticide trial** ☐ **Anti-mosquito trial**

☐ **Preferred performing Institutions**_____ **Preferred location** _____

Responsible researcher_____ **Co researchers (if any)** _____

Estimated date of trial starting_____ **Attached Documents**

☐ **MSDS** ☐ **MOU** ☐ **Technical Manual** ☐ **agency agreement** ☐

Name and Signature

Annex 6

ETHIOPIAN AGRICULTURE AUTORTY
SAMLE IMPORTATION PERMIT APPLICATION

Ref.No----------
Date: ----------

Name Address of Applicant _____

Role of applicant (manufacturer, Importer, Agent, representative etc.)

_____

Name and Address of manufacturer formulator _____

_____

Name and address of Manufacturer technical product _____

_____

Name contact person _____ **tel:** _____

Item description

No.	Trade Name	Common Name A.I content	Quantity		
			Volume (litter)	Net weight in (kg)	Number of packing (no.)

Performa Invoice no (if any) _____

Formulation type _____

Package type _____ **Country of Origin/supply**

☐ **MSDS** ☐ **MOU** ☐ **Technical Manual** ☐ **agency agreement** ☐

Name and Signature

ANNEX 7 Pesticide Product Label and Leaflet

1. Content of the label on the container should include:
   - Product name:- Trade name
   - Concentration of active ingredient and formulation type:-
   - Description of the product and Summary of its use:- Includes the target pest and host and the rate of application indicated on the application form and on the efficacy data.
   - Product group code according to mode of action:- Fungicide Resistance Action Committee (FRAC), Insecticide Resistance Action Committee (IRAC),
   - Warning phrase : " **Read the label before use**" and " **Keep locked out of the reach of children**"
   - The name of manufacturer
   - The name of primary agent or importer
   - The pesticide registration number
   - Date of manufacture
   - Shelf life
   - Batch number
   - The net content of the package
   - Pictogram
   - Color band:- Red to WHO class I, Yellow to WHO class II and Blue to WHO class III
   - Hazard symbol
   - Hazard statement

2. Leaflet prepared should be attached and it should include:
    - Safety precautions:- Disposal methods and storage conditions
    - Symptoms of poisoning
    - First aid
    - Advice to doctor
    - Direction for use: Mixing instructions, Application rate, Compatibility,
    - Ground application and Arial application (when applicable).
    - F. Resistance warning
        - Waiting period for follow-up crops (when applicable)
        - Environmental hazards
    - i Crop tolerance
    - j. Mode of action
    - Re-entry period (when applicable)
    - Pre-harvest interval
    - Legal responsibilities

3. Label Requirement for one panel label

English version	Amharic version
Before using this product **READ the LABEL CAREFULLY!**	
PRODUCT NAME Concentration of active ingredient and formulation type	
Description of product and summary of uses	
Product Group Code according to mode of action (according to IRAC, FRAC Or code system	
KEEP LOCKED UP OUT OF REACH OF CHILDREN	
Registration number:	
Manufacturer:	
The name of primary agent or importer:	
Manufacturing date:	
Expiry date:	
Batch number:	
Net content:	
Pictogram Hazard symbol according to WHO hazard classification Hazard statement (WHO Hazard classification color band; should not be less than 15% of label area)	Pictogram

4. Ethiopian Minimum Label Requirement for three panel label

Before using this product READ the LABEL CAREFULLY!		
SAFETY & PRECAUTIONS: Disposal methods Storage conditions **WARNING PHRASES:** **SYMPTOMS OF POISONING:** **FIRST AID:** **ADVICE TO DOCTOR:** (specify antidote if available) **RESISTANCE WARNING:** **USE RESTRICTIONS:** **WAITING PERIODS FOR FOLLOW-UP CROPS:** (when applicable)	**PRODUCT NAME** Concentration of active ingredient and formulation type. Description of product and summary of uses. Product Group Code according to mode of action (according to IRAC, FRAC or HRAC code system). **KEEP LOCKED UP OUT OF REACH OF CHILDREN** **Registration number of Act no xxx of xxx** **Manufacturer:** **The name of primary agent or importer** **Manufacturing date:** **Expiry date/Shelf life:** **Batch number:** **Net content:** Trade mark acknowledgement(s)	**DIRECTION FOR USE:** Mixing instructions: Application Rate: Compatibility: Ground Application: Aerial application (when applicable): **RE-ENTRY PERIOD**: (when applicable) **PRE-HARVEST INTERVAL:** **LEGAL RESPONSIBILITY/WARRANTY:**

Pictograms &