Guideline to the Application for the Registration of a Plant Protection Product in Ethiopia (including the application forms)

Federal Democratic Republic of Ethiopia
Ministry of Agriculture
Plant Health Regulatory Directorate

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This document provides guidance on the information that is necessary for registration of a Plant Protection Product in Ethiopa, and also provides the forms that the applicant needs to provide upon request for registration (Annex V).

Contents

Introduction

The Pesticide Risk Reduction Programme (PRRP)-Ethiopia runs from the beginning of 2010 up to the end of 2014. It is funded by the State of The Netherlands (Ministry of Foreign Affairs/Development Cooperation), the Food and Agriculture Organisation of the United Nations (Technical Cooperation Programme) and the Federal Republic of Ethiopia (Ministry of Agriculture).

Its main objectives are:

1. To develop a legal framework for the registration and post registration of pesticides (regulation, directives and guidelines).
2. To develop a proper pesticide registration system for Ethiopia and capacity building on dossier evaluation.
3. To develop a well-functioning post registration system (including monitoring, procurement guideline, inspection, storage of pesticides, capacity building and training).
4. To develop a formal consultation platform that will support PHRD with advice on (post)registration issues.
5. To execute an impact assessment of the new (post) registration system.

The PRRP project intends to serve as a pilot project for other African countries and regions.

The evaluation manual which is a document separate from this guideline, has been written as part of the Work Package B2.1 of the PRRP project. The goal of WP B2.1 of PRRP Ethiopia is to further develop the technical and scientific evaluation capacity to ensure sound pesticide management in Ethiopia at the pesticide registration stage, It focusses on plant protection products.

In a series of workshops with Ethiopian stakeholders (see www.prrp-ethiopia.org) the dossier evaluation system has been expanded, improved and priorities have been set. Procedures and guidelines to assess the efficacy have been developed. The existing SEARCH data requirements have been improved and the assessment of human health and environmental hazard and risks have been developed. This assessment, including the necessary data has been described in the evaluation manual. Finally, the entire human health and environmental risk assessment procedure has been implemented in a software tool, PRIMET, that will enable the PHRD to perform the risk evaluation in a reproducible, user-friendly and transparent way. This is described in a separate manual, which can be freely downloaded, together with the software, from www.pesticide.models.eu.

Guideline: Registration

The application form (Annex V) should be used for the application of a registration for a (chemical) Plant Protection Product.
A Plant Protection Product means a pesticide product intended for preventing, destroying or controlling any pest causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products. The term includes products intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.

A. Application for registration of agricultural remedy containing a new active ingredient requires the completion of forms and documents provided in Annex V:
   - Application form[1].
   - Dossier according to List I and List II, including the Table of Intended Uses.
   - Ethiopian Specific Requirements.

B. Application for registration of agricultural remedy where the sources or production method of the active ingredient (a) and/or the formulation (b) is not identical to that of a registered product requires the completion of:
   - Application form.
   - Letter from the manufacturer of the technical material stating that the applicant will be supplied with the technical material or formulated product containing the technical material. (a).
   - Full details on the equivalency on the identity and purity of the technical material and listing of the impurities present (a).
   - NB: Cognizance should be taken of FAO specifications where available. These are now available on internet.
   - Dossier according to List I and II, including the Table of Intended Uses.
   - Ethiopian Specific Requirements.

C. Registration transfer
   - Application form.
   - Written permission from the registration holder that the product concerned may be registered in favor of the applicant.
   - Proposed label.

D. Amendments to the existing registration
   - Application form.
   - Efficacy, and proposed label as per the requirement.

[1] This form is based upon the SEARCH format and has been updated in the framework of the PRRP project.

Guideline: Plant Protection Product Registration Application Form

APPLICANT

1. IDENTIFICATION

Name or corporate name
The applicant shall be the owner of the active ingredient (a.i.) having a representative or distributor duly specified in the country where the application is submitted. In cases where the applicant is not the owner of the a.i. a letter of consent is required from the original owner to use his data to obtain registration.

Address, telephone, fax
Self explanatory.

PRODUCT

2. DESIGNATION

Commercial name/ Trade mark/ Trade mark Owner- As relevant.

Function of the product

For instance- miticide
bactericide
fungicide
herbicide
insecticide
nematicide

Area of use

- Specify sector to be used in e.g. farming community, public health, industrial, home garden, use in home pest control operators only, others (please specify).

Formulation type and Global Crop Protection Federation (GCPF) code

- Indicate the wording of the formulation of the product, as well as the corresponding code of formulation.
- The main formulations are mentioned in the list hereafter.

CODE	FORMULATION TYPE	CODE	FORMULATION TYPE
AB	Grain bait	LA	Lacquer
AE	Aerosol generator	LS	Solution for seed treatment
AL	Other liquids to be applied undiluted	MG	Microgranule
BB	Block bait	OF	Oil miscible flowable concentrate (oil miscible suspension)
BR	Briquette	OL	Oil miscible liquid
CB	Bait concentrate	OP	Oil dispersible powder
CG	Encapsulated granule	PA	Paste
CS	Capsule suspension	PB	Plate bait
DC	Dispersible concentrate	PC	Gel or paste concentrate
DP	Dustable powder	PO	Pour-on
DS	Powder for seed treatment	PR	Plant rodlet
EC	Emulsifiable concentrate	PS	Seed coated with a pesticide
ED	Electrochargeable liquid	RB	Ready-to-use-bait
EO	Emulsion, water in oil	SA	Spot-on
ES	Emulsion, for seed treatment	SB	Scrap Bait
EW	Emulsion, oil in water	SC	Suspension concentrate

CODE	FORMULATION TYPE	CODE	FORMULATION TYPE
FD	Smoke tin	SG	Water soluble granules
FG	Fine granule	SL	Soluble concentrate
FK	Smoke candle	SO	Spreading concentrate
FP	Smoke cartridge	SP	Water soluble powder
FR	Smoke rodlet	SS	Water soluble powder for seed treatment
FS	Flowable concentrate for seed Treatment	SU	Ultra-low volume (ULV Suspension
FT	Smoke Tablet	TB	Tablet
FU	Smoke generator	TC	Technical material
FW	Smoke pellet	TK	Technical concentrate
GA	Gas	TP	Tracking powder
GB	Granular bait	UL	Ultra-low volume (ULV) liquid
GE	Gas generating product	VP	Vapour releasing product
GG	Macrogranule	WG	Water dispersible granules
GP	Flow-dust	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment Others
GS	Grease	XX	Existing registration number
HN	Hot fogging concentrate		
KN	Cold fogging concentrate		

Existing registration number

- In the cases of renewal of registration, of extended use, modification of composition or transfer of registration property, the previous registration number that was given in this country has to be specified.

Other registrations (country)

- List the names of the countries where certificates of registration already exist, and enclose in the dossier when that application is originally applied for. The order of the countries listed must be the same as that of the certificates in the dossier.
- The certificates of the countries where there are equivalent agro-ecological conditions (see map in Annex I) must be provided in first position. Where possible select countries where uses are identical to those recommended in the present application

3. ACTIVE INGREDIENT/S TECHNICAL

- The name and physical address of the a.i. manufacturer must be given as well as phone and fax number. If the a.i source is already registered a letter of consent must be provided. The rest is self-explanatory.

4. FORMULATION

Formulator

- The name and physical address of the formulator must be given as well as phone and fax number.

Composition

- Includes list of the active ingredient and the co-formulants (chemical name) and their percentage composition.
- As mentioned information can be separately provided in a sealed envelope.
- However, a basic description of the formulation should be reflected on the form as well as the acceptable range for the a.i. quantity within the formulation.

5. Formulated product

- Specific data requirements for physical chemical properties, toxicology, ecotoxicology, behaviour in the environment and residues in the plant: see List I and II of the application form.

6. Packaging

- Specify accordingly.

7. Declaration

- Specify accordingly and certify the accuracy in every respect of the information given in form and dossier.

LIST I GUIDELINE: ACTIVE INGREDIENT DOSSIER

The dossier accompanying the form should provide details of the information requested in the form i.e. details on the methods used (physical and chemical), full study reports (including summaries) of the methods and results used in toxicology and ecotoxicology studies, methods of analysis etc. Numbering used in the dossier must follow that used in the Application form.

ACTIVE INGREDIENT (TECHNICAL GRADE)

1. DESIGNATION

Requirements		REMARKS
a.	Common name (ISO)	Specify accordingly
b.	Manufacturer or development code	
c.	Chemical name (IUPAC)	
d.	Chemical group	
e.	Structural formula and molecular weight	
f.	Empirical formula	
g.	Patent status	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.
	Is the a.i. under patent	
	Who is patent holder	
	Expiry date	
h.	Method of manufacture	Method of manufacture, in terms of identity of starting materials, chemical pathways involved, and identity of by-products and impurities present in the final product, must be provided, for each manufacturing plant.
i.	Identity of isomers, impurities and additives	Maximum content of inactive isomers, impurities and additives, together with chemical names, and structural formula should be provided.
j.	Analytical profile of batches	Representative samples of the active substance must be analyzed for content of pure active substance, inactive isomers, impurities and additives, as appropriate, for all components of more than 1 g/kg and for at least 98% of the material analyzed. Five representative batches should be analyzed.
k.	Method of analysis for the determination of active substance purity and impurities	Methods, which must be described in full, must be provided for the determination of pure active substance in the active substance as manufactured as specified in the dossier submitted in support of approval. The applicability of existing CIPAC methods must be reported. CIPAC and AOAC methods can be used without validation. CIPAC methods can be obtained via http://www.cipac.org/

2. PHYSICAL AND CHEMICAL PROPERTIES
(active ingredient - technical grade)

Requirements:	REMARKS:
a. Physical state	Where relevant indicate method/test used and give value plus unit
b. Colour	
c. Odour	
d. Density at 20°C	
e. Vapour pressure at 20/25°C	
f. Henry's law constant	
g. Hydrolysis	Give the DT 50 (days) of the active ingredient, with mentioning 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 and effect of pH	Provide water solubility and effect on pH
j. Solubility organic solvents	Indicate value plus unit
k. n-octanol/water partition coefficient and effect of pH	Indicate value plus unit
l. Surface tension	Indicate value plus unit
m Dissociation constant (pKa)	Indicate value
n. Boiling point in °C	Indicate value plus unit
o. Melting point in °C	Indicate value plus unit
p. Decomposition temperature in °C	Indicate value plus unit
q. Spectra (UV/VIS, IR, NMR, MS)	Provide spectra including table of signal characteristics needed for interpretation.
r. GHS Classification and labelling	Indicate the GHS classification of the active substance with regard to physical chemical properties.

3. TOXICOLOGY
(Active Ingredient – technical grade)

Requirement		Remark
a. Reference values	ADI (mg/kg bw/d)	
	ARfD (mg/kg bw)	e.g. Guidance for the setting of an Acute Reference Dose (ARfD). [3]
	AOEL (mg/kg bw/d)	AOEL is used in the EU for risk assessments of pesticides. e.g. EU Guidance for the setting and application of Acceptable Operator Exposure Levels (AOELs). [4]
b. Acute oral toxicity (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 401, 423, 425.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LD50 (mg/kg bw)	Rat is the preferred species
c. Acute dermal toxicity (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 402.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LD50 (mg/kg bw)	Rat is the preferred species
d. Acute inhalation toxicity (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 403, 436
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LC50 (mg/kg bw)	As the exposure time in the study is usually 4 or 6h, the LC50 should be expressed as mg/kg bw/4h or mg/kg bw/6h.
e. Skin irritation (rabbit)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 404
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Classification skin irritation: yes/no	Indicate the GHS classification.
f. Eye irritation (rabbit)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 405
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.

	Classification eye irritation: yes/no	Indicate the GHS classification.
g. Skin sensitisation (guinea pig)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 406, 429, 442A/B.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Classification skin sensitisation: yes/no	Indicate the GHS classification.
h. Reproduction multi-generation study (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 415, 416, 443.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOAELparental (mg/kg bw/d) NOAELoffspring (mg/kg bw/d) NOAELrepro (mg/kg bw/d)	NOAEL for parents, offspring and reproduction effects should be mentioned.
	Reprotoxic: yes/no	Indicate GHS classification for reproduction toxicity.
i. Subchronic toxicity 90 day (rat or dog)	According to international guideline: yes/no. Indicate guideline[1]	At least one study (in rats) should be provided; preferably two studies (in rats and dogs) are submitted. Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 408, 409.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOAEL (mg/kg bw/d)	
j. Chronic toxicity (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 452, 453
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOAEL (mg/kg/day)	
k. Carcinogenicity (life time) (rat or mouse)	According to international guideline: yes/no Indicate guideline[1]	At least one study (in rats) should be provided; preferably two studies (in rats and mice) are submitted Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 451, 453.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOAEL (mg/kg/day) Carcinogenic: yes/no	Indicate NOAEL. Indicate GHS classification for carcinogenicity.
l. Neurotoxicity (specify species and duration)	According to international guideline: yes/no Indicate guideline[1]	Acute or short-term neurotoxicity studies may be required if there are indication for neurotoxicity in the other toxicity studies. Delayed neurotoxicity studies are required for insecticides with structures related to those known to cause delayed neurotoxicity, such as organophosphates. Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 418/419 (organophosphates), or 424.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOAEL (mg/kg bw/d)	
m. Teratogenicity (rat or rabbit)	According to international guideline: yes/no Indicate guideline[1]	At least one study should be provided; preferably two studies (in rats and rabbits) are submitted Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 414.
	GLP: yes/no[2]	Indicate whether study was performed. according to GLP.
	NOAELmaternal (mg/kg bw/d) NOAELoffspring (mg/kg bw/d) NOAELterato (mg/kg bw/d)	NOAEL for maternal, offspring and teratogenic/developmental effects should be mentioned.
	Teratogenic: yes/no	Indicate GHS classification for teratogenicity.
n. Mutagenicity / Genotoxicity	According to international guideline: yes/no	In vitro for gene mutation and chromosomal damage. If any in-vitro tests indicative positive results, in-vivo

	Indicate guideline[1]	genetic toxicity studies should also be carried out. Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 471-488
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Genotoxic: yes/no	Indicate GHS classification for mutagenicity and/or genotoxicity.
o. Metabolism (rat)	According to international guideline: yes/no Indicate guideline[1]	Provide the oral absorption value at the relevant dose level, i.e. around the lowest NO(A)EL used for setting of the AOEL. Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD 417.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Oral absorption (%)	Indicate % oral absorption.
p. Other studies		Provide further information relevant to the toxicity profile of the product.
q. GHS Classification and labelling		Indicate the GHS classification of the active substance with regard to mammalian toxicity.

1. The data should be based on internationally recognized testing guidelines and methods, such as those published by OECD or USEPA, among others.

2 Data should be generated following the principles of good laboratory practice (GLP), whenever applicable. Experiments performed after 25 July 1993 must have been performed in accordance with GLP.

3 WHO (Solecki et al., 2005):
http://www.google.nl/url?q=http://www.who.int/foodsafety/chem/jmpr/arfd_guidance.pdf&sa=U&ei=6hI3UZ26LYLdPdzXgfAG&ved=0CCMQFjAD&usg=AFQjCNEMy9nIINHOnAAdsxKo3vI5cM1a6g
JMPR report 2002: http://www.fao.org/ag/agp/agpp/pesticid/jmpr/Download/2002_rep/2002JMPRReport2.pdf

4 EU: http://ec.europa.eu/food/plant/protection/resources/7531_rev_10.pdf

4. ECOTOXICOLOGY

Requirement		Remark
a. Acute oral toxicity to birds (1 species, preferably Bobwhite quail).	According to international guideline: yes/no. Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline No 223: Avian acute oral toxicity study or US EPA OPPTS 850.2100: Avian oral toxicity test. The highest dose used in tests shall not exceed 2000 mg substance/kg body weight, however, depending on the expected exposure levels in the field following the intended use of the compound, higher doses may be required.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LD50 (mg as/kg bw) NOEL (mg as/kg bw)	
b. Chronic toxicity to birds (1 species, preferably Bobwhite quail).	According to international guideline: yes/no. Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 206: Avian Reproduction Test or US EPA OPPTS 850.2300: Avian Reproduction Test. The sub-chronic and reproductive toxicity of the active substance to birds shall be investigated, unless the applicant shows that exposure of adults, or exposure of nest sites during the breeding season is unlikely to occur. Such a justification shall be supported by information showing that no exposure or delayed effects will occur during the breeding season.

	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEL reproduction (mg as/kg bw/d)	
c. Acute toxicity to fish (one species; preferably rainbow trout).	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 203: Fish, Acute Toxicity Test.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LC_{50} (mg as/L)	
d. Chronic toxicity to fish (one species; preferably rainbow trout).	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 210: Fish, Early-Life Stage Toxicity Test. A long-term or chronic toxicity study on fish shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90% loss of the original substance over 24 hours via hydrolysis. A fish early life stage study shall be provided in these circumstances.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC reproduction (mg as/L)	
e. Bioconcentration in fish.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 305, Bioconcentration: Flow-through fish test. The bioconcentration of the substance, shall be assessed where: the log Pow is greater than three or there are other indications of bioconcentration; and the substance is considered stable, that is to say there is less than 90% loss of the original substance over 24 hours via hydrolysis.
	BCF value	Bioconcentration factors shall be expressed as a function of both total wet weight and of the lipid content of the fish.
f. Acute toxicity to Daphnia.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 202: Daphnia sp. Acute Immobilisation Test. A test shall be provided on the 24 and 48-hour acute toxicity of the active substance to *Daphnia magna*, expressed as the median effective concentration (EC_{50}) for immobilisation, and where possible, the highest concentration causing no immobilisation.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	EC_{50} (mg as/L)	
g. Acute toxicity to an additional aquatic invertebrate species (e.g. Chironomid larvae or Mysidopsis bahia).	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. US EPA OPPTS 850.1035 Mysid Acute Toxicity Test For active substances with an insecticidal mode of action or which show insecticidal activity a second species shall be tested, for example Chironomid larvae or Mysid shrimps (*Americamysis bahia*).
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	EC_{50} (mg/L)	
h. Chronic toxicity to Daphnia.	According to international guideline: yes/no	Indicate whether study was performed according to international guidelines and indicate which guideline.

	Indicate guideline[1]	E.g. OECD Test Guideline 211: Daphnia magna Reproduction Test. A long-term or chronic toxicity study on aquatic invertebrates shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90% loss of the original substance over 24 hours via hydrolysis.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/L)	
i. Chronic toxicity to an additional aquatic invertebrate species (e.g. Chironomid larvae).	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. US EPA OPPTS 850.1350 Mysid Chronic Toxicity Test or OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water. A chronic toxicity study shall be submitted on one aquatic invertebrate species. If acute tests have been conducted on two aquatic invertebrate species the acute endpoints shall be taken into account in order to determine the appropriate species to be tested in the chronic toxicity study. If the active substance is an insect growth regulator, an additional study on chronic toxicity shall be carried out using relevant non-crustacean species such as *Chironomus spp.*
	GLP: yes/no[2]	Indicate whether study was performed according to GLP
	NOEC (mg as/L)	
k. Effects on algae.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 201: Algae growth inhibition test. Testing shall be carried out on one green alga (such as *Pseudokirchneriellasubcapitata*, synonym *Selenastrumcapricornutum*). For active substances that exhibit herbicidal activity a test on a second species from a different taxonomic group shall be performed such as a diatom, for example *Naviculapelliculosa*.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	EC_{50} (mg as/L) NOEC (mg as/L)	
l. Effects on aquatic macrophytes.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 221: Lemna sp. Growth Inhibition Test. ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, *Myriophyllum sibiricum Komarov.* Development of a proposed test method for the rooted aquatic macrophyte Myriophyllum sp. In: L. Maltby, D. Arnold, G. Arts, J. Davies, F. Heimbach, C. Pickl and V. Poulsen (2010). Aquatic Macrophyte Risk Assessment for pesticides. SETAC Press & CRC Press, Taylor & - Francis Group, Boca Raton, London, New York., p. 46-56. Davies et al., 2003. Pest Management Science, Vol 59, Issue 2, 231-237. A laboratory test with *Lemna* species shall be

		performed for herbicides and plant growth regulators. Additional aquatic macrophyte species tests may be undertaken on a dicotyledonous species, such as *Myriophyllum spicatum, Myriophyllum aquaticum* or a monocotyledonous species, such as aquatic grass *Glyceria maxima,* as appropriate. The need to perform such studies shall be discussed with the national competent authorities.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	EC_{50} (mg as/L) NOEC (mg as/L)	
m. Acute toxicity to bees (acute oral as well as acute contact toxicity).	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. EPPO standard PP 1/170 (4): Side-effects on honeybees. OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test. OECD Test Guideline 214: Honeybees, Acute Contact Toxicity Test.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Oral LD_{50} (ug as/bee) Oral NOEC (ug as/bee) Contact LD_{50} (ug as/bee) Contact NOEC (ug as/bee)	
n. Bee brood study.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. Aupinel et al. (2007): A new larval in vitro rearing method to test effects of pesticides on honey bee brood. *Redia* XC: 87-90. Oomen, P., A. de Ruijter and J. van der Steen,1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616. A bee brood study shall be conducted to determine effects on honeybee development and brood activity. The bee brood study shall provide sufficient information to evaluate possible risks from the active substance on honeybee larvae. The test shall be carried out for active substances for which sub-lethal effects on growth or development cannot be excluded, unless the applicant shows that it is not possible that honeybee brood will be exposed to the active substance.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/kg food)	
o. Effects on non-target arthropods other than bees (*Aphidius rhopalosiphi* and *Typhlodromus pyri*).	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7. Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products With Non-Target Arthropods: From the Escort 2 Workshop (European Standard Characteristics of Non-Target Arthropod Regulatory Testing) ISBN 1-880611-52-x.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LR_{50} A. rhopalosiphi (g as/ha) NOER A. rhopalosiphi (g as/ha) LR_{50} T. pyri (g as/ha) NOEC T. pyri (g as/ha)	
p. Acute toxicity to	According to international	Indicate whether study was performed according to

earthworms.	guideline: yes/no Indicate guideline[1]	international guidelines and indicate which guideline. E.g. OECD Test Guideline207, Earthworm, acute toxicity test.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/kg soil)	
q. Chronic toxicity to earthworms.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 222: Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei).
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/kg soil)	
r. Effects on soil nitrogen transformation.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test. Soils used shall be freshly sampled agricultural soils. The sites from which soil is taken shall not have been treated during the previous two years with any substance that could substantially alter the diversity and levels of microbial populations present, other than in a transitory manner.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/kg soil)	
s. Effects of terrestrial non-target higher plants.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. Seedling emergence and seedling growth: OECD Test Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. Terrestrial plant vegetative vigour testing: OECD Test Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test. For active substances that exhibit herbicidal or plant growth regulator activity, vegetative vigour and seedling emergence concentration/response tests shall be provided for at least six species representing families for which herbicidal/plant growth regulatory action has been found. Where, from the mode of action, it can be clearly established that either seedling emergence or vegetative vigour is effected, only the relevant study shall be conducted.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	ER50 (g as/ha)	
t. GHS Classification and labelling.		Indicate the GHS classification of the active substance with regard to ecotoxicity.

1 The data should be based on internationally recognized testing guidelines and methods, such as those published by OECD or USEPA, among others.

2 Data should be generated following the principles of good laboratory practice (GLP), whenever applicable. Experiments performed after 25 July 1993 must have been performed in accordance with GLP.

5. BEHAVIOUR IN ENVIRONMENT
(active ingredient – technical grade)

Requirement		Remark
Behaviour, ways of degradation, degradation products in soil		Remark
a. Aerobic route and route of degradation active substance.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. Studies on the degradation pathway or pathways shall be reported for at least one representative soil. Oxygen levels shall be maintained at levels that do not restrict micro-organisms ability to metabolise aerobically. If there is reason to believe that the route of degradation is dependent on one or more properties of the soil, such as pH or clay content, the route of degradation shall be reported for at least one additional soil for which dependent properties are different. The duration of the study shall be at least 120 days, except where after a shorter period the levels of non-extractable residues and CO_2 are such that they can be extrapolated in a reliable way to 100 days. It shall be longer where this is necessary to establish the degradation pathway of the active substance and its metabolites, breakdown or reaction products. Studies on the rate of aerobic degradation of the active substance shall be reported for three representative soils in addition to the one required to investigate the route of degradation. Reliable DegT50 and 90 values shall be available for a minimum of four different representative soils.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Pathways of aerobic degradation. DegT50 and DegT90 of the active substance.	Describe the pathways.
b. Anaerobic route and rate of degradation active substance.	According to international guideline: yes/no. Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. An anaerobic degradation study shall be submitted unless the applicant shows that exposure of the plant protection products containing the active substance to anaerobic conditions is unlikely to occur for the intended uses.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Pathways of anaerobic degradation DegT50 and DegT90 of the active substance	Describe the pathways.
c. Soil photolysis.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. SETAC 1995 – Procedures for assessing the environmental fate and ecotoxicity of pesticides. A soil photolysis study shall be submitted unless the applicant shows that deposition of the active substance on the soil surface is unlikely to occur or that photolysis is not expected to contribute significantly to the degradation of the active substance in soil for example due to low light absorbance of the active substance.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Pathways of degradation by soil photolysis	Describe the pathways.
d. Aerobic degradation rate of	According to international	Indicate whether study was performed according to

major metabolites.	guideline: yes/no Indicate guideline[1]	international guidelines and indicate which guideline. E.g. OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. Aerobic degradation, DegT50 and 90 values from a minimum of three different soils shall be provided for metabolites, breakdown and reaction products which occur in soil if one of the following conditions is fulfilled: they account for more than 10% of the amount of active substance added at any time during the studies; they account for more than 5% of the amount of active substance added in at least two sequential measurements; the maximum of formation is not reached at the end of the study but accounts for at least 5% of the active substance at the final measurement. Studies shall not be required where three DegT50 and 90 values can be reliably determined from the results of the degradation studies where the active substance is applied as test substance.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	DegT50 and DegT90 major metabolites	
e. Adsorption and desorption of the active substance.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 106: Adsorption - Desorption Using a Batch Equilibrium Method. OECD Test Guideline 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC). Studies on the active substance shall be reported for at least four representative soils.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Koc or Kom	
f. Adsorption and desorption of major metabolites.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 106: Adsorption - Desorption Using a Batch Equilibrium Method. OECD Test Guideline 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC). Studies on metabolites, breakdown and reaction products shall be provided for at least three representative soils.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Koc or Kom	
Behaviour, ways of degradation, degradation products in water.		
g. Hydrolytic degradationof the active substance and major metabolites.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 111: Hydrolysis as a Function of pH. The hydrolysis rate of purified active substances shall be determined and reported at 20°C or 25°C. Studies on hydrolytic degradation shall also be performed for degradation and reaction products which account at any time for more than 10% of the amount of active substance added in the hydrolysis study, unless sufficient information on their degradation is available from the test performed with the active substance. No additional hydrolysis information on degradates shall be required if they are considered to be stable in water.

	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Degradation pathways DT50 active substance and major metabolites	Describe the pathways
h. Photochemical degradation of the active substance and major metabolites.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 316: Phototransformation of Chemicals in Water - Direct Photolysis. For compounds with a molar (decadic) absorption coefficient (ε) > 10 L mol^{-1} cm^{-1} at a wavelength (λ) $\geq$ 295 nm direct phototransformation of purified active substances shall be determined and reported unless the applicant shows that contamination of surface water will not occur. Studies on direct photochemical degradation shall also be performed for metabolites, breakdown and reaction products which account at any time for more than 10% of the amount of active substance added in the photolysis study, unless sufficient information on their degradation is available from the test performed with the active substance. No additional photolysis information on degradates shall be required if they are considered to be stable under photolytic conditions.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Degradation pathways DT50 active substance and major metabolites	Describe the pathways.
i. Water/sediment study.	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. E.g. OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH. The duration of the study shall be at least 100 days. It shall be longer where this is necessary to establish the degradation pathway and water/sediment distribution pattern of the active substance and its metabolites, breakdown and reaction products. If more than 90% of the active substance is degraded before the period of 100 days expires, the test duration may be shorter. The degradation pattern of potentially relevant metabolites occurring within the water sediment study shall be established either by extension of the study for the active substance, or by conducting a separate study for potentially relevant metabolites.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	Degradation pathways DT50 active substance and major metabolites	Describe the pathways.

1 The data should be based on internationally recognized testing guidelines and methods, such as those published by OECD or USEPA, among others.

2 Data should be generated following the principles of good laboratory practice (GLP), whenever applicable. Experiments performed after 25 July 1993 must have been performed in accordance with GLP.

6. MODE OF ACTION

Requirement	Remark
Summary	Please provide a summary of the mode of action. A more detailed mode of action should be included in the efficacy dossier.

7. RESIDUES IN THE PLANT

Requirement		Remark
a. Metabolism	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline. e.g.: OECD Test No. 501: Metabolism in Crops Lundehn Appendix A (SANCO 7028/VI/95 rev 3) OPPTS Guideline 860.1300
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
b. Major metabolites/residue definition		Argumentation for the residue definition for (1) MRL setting and monitoring and (2) risk assessment. If (2) is more extended than is (1) give conversion factor.
c. Magnitude of residues	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline e.g.: OECD Test No. 509: Crop Field Trial Lundehn appendix B (SANCO 7029/VI/95 rev 5) Lundehn appendix D (SANCO 7525/VI/95 rev 9) OPPTS Guideline 860.1500 Indicate the action and the persistence of the metabolites in the plant. The residue level at the proposed critical GAP (dose, number of applications, interval, PHI) should be derived from the residue trials with the crop of interest (or a closely related crop for extrapolation). The objectives of magnitude of residue trials in plants shall be the following: to quantify the highest likely residue levels of all components of the different residue definitions in treated crops, at harvest or outloading from store, in accordance with the proposed GAP; and for guidance on the number of trials, the number of different geographical zones and the number of seasons in which the trials should be performed as well as extrapolation rules, see Evaluation Manual.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
d. storage stability	According to international guideline: yes/no Indicate guideline[1]	In case samples from studies in plants are not analysed within 30 days after sampling (stored frozen), trials to assess the stability of the active compounds and relevant residues needs to be submitted. To verify the stability of residues in sampled commodities during (frozen) storage. The duration and conditions of the studied storage must correspond with the maximum duration and storage conditions in the supervised residue trials and the metabolism studies. Indicate whether study was performed according to international guidelines and indicate which guideline e.g.: OECD Test No. 506: Stability of pesticide residues in stored commodities `

		Lundehn Appendix H (SANCO 7032/VI/95 rev 5) OPPTS 860.1380 Storage Stability Data Furthermore, indicate the matrix tested.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP
e. MRL codex and/or other country together with their critical GAPs		Give the MRLs set for the crops of interest together with their respective GAPs. If the uses applied for have been covered by these GAPs these MRLs might be adopted. Codex Pesticides Residues in Food Online Database EU pesticides database USDA MRL database
f. Method of residue analysis	According to international guideline: yes/no[1]	A full description shall be submitted for methods of residues in food and drinking water in accordance with e.g. guidance document SANCO/825/00. or OPPTS Guideline 860.1340 (a) the determination of all components included in the monitoring residue definition in order to enable to determine compliance with established maximum residue levels (MRLs); they shall cover residues in or on food of plant origin; (b) the determination of all components included for monitoring purposes in the residue definitions for water. As far as practicable these methods shall employ the simplest approach, involve the minimum cost, and require commonly available equipment. The specificity of the methods shall be determined and reported. It shall enable all components included in the monitoring residue definition to be determined. Validated confirmatory methods shall be submitted if appropriate. The linearity, recovery and precision (repeatability) of methods shall be determined and reported. Data shall be generated at the LOQ and either the likely residue levels or ten times the LOQ. The LOQ shall be determined and reported for each component included in the monitoring residue definition.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
g. Additional information for refinement of intake	According to international guideline: yes/no Indicate guideline[1]	Additional information can be provided when the first tier risk assessment results in an exceeded ADI and/or ARfD (NEDI>100% ADI, IESTI>100%ARfD. For refinement of intake assessment, processing data are generally the most appropriate. e.g. OECD Test No. 507 and No 508 Lundehn Appendix E (7035/VI/95 rev. 5) OPPTS 860.150
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.

LIST II GUIDELINE: FORMULATED PRODUCT DOSSIER

The dossier accompanying the form should provide details of the information requested in the form i.e. details on the methods used (physical and chemical), full study reports (including summaries) of the methods and results used in toxicology and ecotoxicology studies, methods of analysis etc. Numbering used in the dossier must follow that used in the Application form.

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	Where relevant indicate method/test used and give value plus unit.
b.	Colour	
c.	Odour	
d.	Storage stability - accelerated (CIPAC MT46.3) - at low temperature (CIPAC MT39.3).	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 (liquids).	Indicate the density of liquids (value plus unit).
g.	Bulk density (solids).	Indicate the density of solids after compression (value plus unit).
h.	Compatibility with other pesticides.	Full Summary report.
i.	pH of aqueous formulations.	Value (if liquid).
j.	pH of 1% aqueous dilution.	Relevant to products to be diluted in water. Value.
k.	Acidity / alkalinity if pH <4 or >10.	Indication of buffer capacity, expressed in %H2SO4 (acidity) or NaOH (alkalinity).
l.	Viscosity.	For formulations to be used at very low volume, it is necessary to know the viscosity.
m.	Surface tension of the undiluted product at 25 °C.	Data to indicate flow behaviour and droplet size.
n.	Technical properties according to GCPF code and FAO pesticide specification manual.	Application related properties to ensure no problems need to be expected related to flow behaviour, foam, inhalatory risks (particle size and dust), nozzle and filter blocking, and/or homogeneity of the spray fluid, depending on the formulation type.
o.	Particle size distribution of granules.	Particle size for powders and/or granules.
p.	Dust content of granules.	Particle size for powders. Dust content, friability and attrition for granules.
q.	Other properties (where applicable).	e.g. dry/wet sieve test.
r.	Classification and labeling related data	
s.	Method of analysis.	Full Study report.
t.	Method of analysis of soil for parent compound and metabolites of toxicological, ecotoxicological or environmental concern.	Full study report.
u.	Method of analysis of water for parent compound and metabolites of toxicological, ecotoxicological and environmental concern.	Full study report.
w.	Method of manufacture.	Method of manufacture, in terms of identity of starting materials, chemical pathways involved, and identity of by-products and impurities present in the final product, must be provided, for each manufacturing plant.

2. (ECO)TOXICOLOGY

The dossier must contain a detailed **Material Safety Data Sheet** for the active substance, each co-formulant, and the formulation

Requirement		Remark
a. Acute oral toxicity (rat)	According to international guideline: yes/no. Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LD50 (mg/kg bw)	Rat is the preferred species.
b. Acute dermal toxicity (rat)	According to international guideline: yes/no. Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LD50 (mg/kg bw)	Rat is the preferred species.
c. Acute inhalation toxicity (rat)	According to international guideline: yes/no. Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	LC50 (mg/kg bw).	As the exposure time in the study is usually 4 or 6h, the LC50 should be expressed as mg/kg bw/4h or mg/kg bw/6h.
d. Skin irritation (rabbit)	According to international guideline: yes/no Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline. The skin irritancy of the active substance must be determined except where it is likely, as indicated in the test guideline, that severe skin effects may be produced or that effects can be excluded.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	Classification skin irritation: yes/no.	Indicate the classification.
e. Eye irritation (rabbit)	According to international guideline: yes/no. Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline. Eye irritation tests must be conducted except where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	Classification eye irritation: yes/no.	Indicate the classification.
f. Skin sensitisation (guinea pig)	According to international guideline: yes/no Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline. The test must always be carried out except where the substance is a known sensitizer.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	Classification skin. sensitisation: yes/no.	Indicate the classification.
g. WHO classification		WHO classification is revised in 2009 (see WHO, 2010).
h. Other toxicological studies		Provide further information relevant to the mammalian toxicity profile of the product.
h1.Dermal absorption study	According to international guideline: yes/no Indicate guideline[1.]	Indicate whether study was performed according to international guidelines and indicate which guideline. The test may be performed, or default values to be used. The representative product should be tested.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	Value for concentrate Value for spray dilution.	Values for dermal absorption for the concentrated product and for the spray dilution should be provided: either by using the default value of 10% or value based on the study data.

i. Acute oral toxicity to birds	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding question for the active substance. The acute oral toxicity of the plant protection product shall be investigated if toxicity cannot be predicted on the basis of the data for the active substance, or where results from mammalian testing give evidence of higher toxicity of the plant protection product compared to the active substance, unless the applicant shows that it is not likely that birds are exposed to the plant protection product itself. Other remarks: see corresponding question for the active substance.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	LD50 (mg/kg bw).	
j. Effects on aquatic organisms	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding questions for the active substance. Possible effects on aquatic species (fish, aquatic invertebrates, algae and in the case of herbicides and plant growth regulators also aquatic macrophytes) shall be investigated except where the possibility that aquatic species will be exposed can be ruled out. Testing shall be performed where: the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance; or the intended use includes direct application on water; extrapolation on the basis of available data for a similar plant protection product is not possible. However, where the available information permits to conclude that one of these groups is clearly more sensitive, tests on only the relevant group shall be performed. If the plant protection product contains two or more active substances, and the most sensitive taxonomic groups for the individual active substances are not the same, testing on all three/four aquatic groups, that is to say fish, aquatic invertebrates, algae and, where relevant, macrophytes, shall be required. Other remarks: see corresponding questions for the active substance.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	L(E)C50 (mg/L)	
k. Effects on bees	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding questions for the active substance. Testing shall be required if: the plant protection product contains more than one active substance; the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the active substance. Other remarks: see corresponding questions for the active substance.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	Oral LD_{50} (ug as/bee) Oral NOEC (ug as/bee) Contact LD_{50} (ug as/bee) Contact NOEC (ug as/bee) NOEC (mg/kg or g as/ha)	Oral and contact LD50 and NOEC values are endpoints from acute oral and contact toxicity studies with bees. NOEC values could be from bee brood test or cage, tunnel and field tests with bees.
l. Effects on non-target arthropods other than bees (*Aphidius rhopalosiphi* and *Typhlodromus pyri*)	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding questions for the active substance. Testing shall be required if: the plant protection product contains more than one active substance; the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than

		the active substance. Other remarks: see corresponding questions for the active substance.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	LR_{50} A. rhopalosiphi (g as/ha) NOER A. rhopalosiphi (g as/ha) LR_{50} T. pyri (g as/ha) NOEC T. pyri (g as/ha)	LR50 and NOER values for the two standard organisms are endpoints from (extended) lab studies. If there is a risk (semi-)field studies may be necessary.
m. Acute toxicity to earthworms	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding question for the active substance. Testing shall be required if: the plant protection product contains more than one active substance; the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the active substance. Other remarks: see corresponding question for the active substance.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	LC50 (mg as/kg soil)	
n. Chronic toxicity to earthworms	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding question for the active substance. Testing shall be required if: the plant protection product contains more than one active substance; the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the active substance. Other remarks: see corresponding question for the active substance.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/kg soil)	
o. Effects on soil nitrogen transformation	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding question for the active substance. The effects of plant protection products on soil microbial function shall be investigated if the toxicity of the plant protection product cannot be predicted on the basis of data for the active substance.
	GLP: yes/no[2]	Indicate whether study was performed according to GLP.
	NOEC (mg as/kg soil)	
p. Effects of terrestrial non-target higher plants	According to international guideline: yes/no Indicate guideline[1.]	Testing Guidelines: see corresponding question for the active substance. Studies of effects on non-target plants shall be required for herbicide and plant growth regulator plant protection products, when the risk cannot be reliably predicted on the basis of the active substance data. Other remarks: see corresponding question for the active substance.
	GLP: yes/no[2.]	Indicate whether study was performed according to GLP.
	ER50 (g as/ha)	

1 The data should be based on internationally recognized testing guidelines and methods, such as those published by OECD or USEPA, among others.

2 Data should be generated following the principles of good laboratory practice (GLP), whenever applicable. Experiments performed after 25 July 1993 must have been performed in accordance with GLP.

The FAO/WHO class must be given as per the table hereunder (revised criteria for classification, see the WHO recommended classification of pesticides by hazard and guidelines to classification: 2009 (WHO, 2010)). WHO now uses the Acute Toxicity Hazard Categories from the GHS as the starting point for classification.

WHO-Classification Scheme

WHO class		LD50 for the rat (mg/kg body weight)	
		Oral	Dermal
Ia	Extremely hazardous	< 5	< 5
Ib	Highly hazardous	5-50	5-200
II	Moderately hazardous	50-2000	200-2000
III	Slightly hazardous	Over 2000	Over 2000
U	Unlikely to present acute hazard	5000 or higher	

3. EMERGENCY MEASURES IN CASES OF ACCIDENTAL EXPOSURE OR POISONING

Self explanatory, list relevant information on the form and refer to relevant section in MSDS in Section 3 of dossier.

4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE

Self explanatory, list relevant information on form and refer to relevant section in MSDS in Section 2 of dossier.

5. USES

An example format of the Table of Intended Uses is given in Annex 2.

Requirements	REMARKS
a. Crop/area of use	The common name of the crop at which the product is aimed must be clearly specified. When the product is not aimed at a crop, indicate the area of use, e.g. Premises and equipment of transportation, Premises of storage.
b. Mode of action	Specify the mode of action of the product on its target, and indicate if the active ingredient is translocated inside the plants.
c. Target organism	Target organisms must be identified by common and Latin name.
d. Application rate, including number and interval of applications if relevant	The application rate of the product must be indicated on the basis of area treated or volume used e.g. L/ha, g/ha, etc.
e. Growth stage of treatment	Specify the growth stage of the crop or target organism at which application must be made and/or the minimum interval between the last application and harvest.
f. Directions for use	Indicate the recommended directions for use in a proposed label text in both Amharic and English (correctly translated).
g. Residue data and pre-harvest interval	Indicate restrictions. Study report.
h. Phytotoxicity	Indicate restrictions.
i. Contraindications	Indicate restrictions i.e. follow up crops, adjacent crops etc. and particularity specifications, as well as possible incompatibilities of the formulation with other products.
j. Resistance risk analysis	Provide the resistance code resulting from a risk analysis according to EPPO 1/213(3).

6. MINIMUM LABEL REQUIREMENTS

Specify the warnings, use restrictions and safety precautions which must be present on the label in all countries.
The proposed label must be included in the dossier, contain the specified warnings, use restrictions and safety precautions as well as the country specific information required, recommendations etc. Inclusion of the pictograms and color code is recommended for the label, indicate these on the form even for countries where these are not allowed on the label.

7. ETHIOPIAN SPECIFIC REQUIREMENTS

Any registrant should fill **'APPLICATION FOR THE REGISTRATION OF A PLANT PROTECTION PRODUCT' form** and submit the following to the registration office:

a. A. Two copies of the Plant Protection Product dossier included under List I and List II (active ingredient dossier index and formulated product dossier index), including a Table of Intended Uses, with signed and sealed application form. Every part of this dossier (application form, List I and List II, Table of Intended Uses) needs to be filled duly with the appropriate data.

b. Local efficacy report from research organization
   - Efficacy data generated from research institutions or universities in accordance with the national local efficacy test procedure (see Annex I for similarities in agro-ecological zones of eastern Africa).

c. Sample of the technical grade and the formulated product
   - 2 lots of 500 g or ml formulated product and 1 lot of 1 g or ml of the technical grade.

d. Agency agreement between the local agent and the registration holder.

e. Third party batch certificate of analysis from accredited laboratory (authenticated by chamber of commerce or any relevant government office).
   - If the analysis is done by the organization itself, it requires a GLP Certificate.

f. Manufacturing license - A letter of recognition that the pesticide is registered and is permitted to be produced in the country of origin. This should be authenticated by the government body (chamber of commerce) and should be original.

g. Label in English and Amharic for the intended pest and crop and according to pack size (Annex III and IV).

h. Table with the intended uses (Annex II).

Note: The dossier should be well filed with the relevant documents only, it should have table of contents and need to be indexed.

8. Content of a Label

8.1 One panel label (Annex III)

A. Content of the label on the container should include:
   a. Product name: Trade name
   b. Concentration of active ingredient and formulation type
   c. 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
   d. Product group code according to mode of action. Fungicide Resistance Action Committee (FRAC), Insecticide Resistance Action Committee (IRAC)

e. Warning phrase: 'Read the label & attached leaflet before use' and 'Keep locked out of the reach of children'
f. The name of manufacturer
g. The name of distributor, agent or registrant
h. The pesticide registration number
i. Date of manufacture
j. Shelf life
k. Batch number
l. The net content of the package
m. Pictogram
n. Color band:- Red to WHO class I, Yellow to WHO class II and Blue to WHO class III, Green to WHO class U
o. Hazard symbol
p. Hazard statement

B. Leaflet prepared in Amharic and English should be attached and it should include:

a. Safety precautions: Disposal methods and storage conditions
b. Symptoms of poisoning
c. First aid
d. Advice to doctor
e. Direction for use: Mixing instructions, Application rate, Number of applications, Application interval, Compatibility, Ground application and Arial application (when applicable) phytotoxicity warning
f. Resistance warning
g. Waiting period for follow-up crops (when applicable)
h. Environmental hazards
i. Crop tolerance
j. Mode of action
k. Re-entry period (when applicable)
l. Pre-harvest interval (PHI)
m. Legal responsibilities

8.2 Three panel label

All information indicated above (A and B of 8.1) should be included on the label in English and Amharic (Annex IV).

Annex I Similar agro-ecological zones of eastern Africa

Annex II Example format for a Table of Intended Uses

Use Pattern													
1	2	3	4	5	6			7			8	9	
Crop and / or situation	F G Or I	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks	
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hectoliter	water l/ha	kg a.i./ha			
(a)	(b)	(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)	

Remarks:

a. In case of group of crops the Codex classification should be used.
b. Outdoor or field use (F), glasshouse application (G) or indoor application (I).
c. e.g. biting and sucking insects, soil born insects, foliar fungi.
d. e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR).
e. Use CIPAC/FAO Codes where appropriate.
f. All abbreviations used must be explained.
g. Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
h. Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants.
i. g/kg or g/l.
j. Growth stage at last treatment.
k. PHI = Pre-harvest interval.
l. Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications; for seed treatments specify the dose in kg a.i. per kg seed and number of seeds per kg seed.

Annex III Ethiopian Label Requirement for one panel label

English version	Amharic version
Before using this product READ the LABEL& enclosed LEAFLET 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:	
Distributor, agent:	
Manufacturing date:	
Expiry date/Shelf life:	
Batch number:	
Net content: Trade mark acknowledgement (s)	
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

Annex IV Ethiopian Minimum Label Requirement for three-panel label (English and Amharic version). Based on the FAO and SEARCH three panel label

LEFT PANEL:	CENTRE OR SALES PANEL:	RIGHT PANEL:
Before using this product READ the LABEL CAREFULLY!		
SAFETY & PRECAUTIONS: Disposal methods Storage conditions 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: Distributor, agent: Manufacturing date: Expiry date/Shelf life: Batch number: Net content: Trade mark acknowledgement(s)	DIRECTION FOR USE: Mixing instructions: Application Rate: Number of applications: Application interval: Compatibility: Ground Application: Aerial application (when applicable): RE-ENTRY PERIOD: (when applicable) PRE-HARVEST INTERVAL: LEGAL RESPONSIBILITY/WARRANTY:
Pictograms	Hazard symbol according to WHO hazard classification Hazard statement (WHO Hazard classification color band; should be not less than 15% of label area)	Pictograms

Annex V Registration form to be submitted upon application of registration

This Annex contains the application form which should be used for the application of a registration for a (chemical) Plant Protection Product.

A Plant Protection Product means a pesticide product intended for preventing, destroying or controlling any pest causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products. The term includes products intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.

a. Application for registration of agricultural remedy containing a new active ingredient requires the completion of forms and documents provided in Annex V:
   - Application form[2].
   - Dossier according to List I and List II, including the Table of Intended Uses.
   - Ethiopian Specific Requirements.

b. Application for registration of agricultural remedy where the sources or production method of the active ingredient (a) and/or the formulation (b) is not identical to that of a registered product requires the completion of:
   - Application form.
   - Letter from the manufacturer of the technical material stating that the applicant will be supplied with the technical material or formulated product containing the technical material. (a)
   - Full details on the equivalency on the identity and purity of the technical material and listing of the impurities present (a)
   - NB: Cognizance should be taken of FAO specifications where available. These are now available on internet.
   - Dossier according to List I and II, including the Table of Intended Uses.
   - Ethiopian Specific Requirements.

c. Registration transfer
   - Application form.
   - Written permission from the registration holder that the product concerned may be registered in favor of the applicant.
   - Proposed label.

d. Amendments to the existing registration
   - Application form.
   - Efficacy, and proposed label as per the requirement.

[2] This form is based upon the SEARCH format and has been updated in the framework of the PRRP-project.

APPLICATION FOR THE REGISTRATION OF A PLANT PROTECTION PRODUCT IN ETHIOPIA

(Ethiopian November 2013 version of the SEARCH form, see the Registration Guideline for completing this form)

This application form should be used for the application of a registration for a (chemical) Plant Protection Product.

A Plant Protection Product means a pesticide product intended for preventing, destroying or controlling any pest causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products. The term includes products intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.

Indicate where appropriate:

A.	**Plant protection product containing a new active ingredient:**	**Yes/no**
B.	**Plant protection product where source of active and/or formulation is not identical to that of a registered product:**	**Yes/no**
C.	Registration transfer:	Yes/no
D.	**Amendments to existing registration:**	**Yes/no**
E.	**Other (please specify):**	**Yes/no**

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:	e.g. Herbicide/insecticide/fungicide			
2.3	Intended use: (mention agricultural crops)	Please refer to the Table of Intended Uses on page 39			
2.4	Target pest(s) and host(s):				
2.5	Method, dosage rates, frequency and interval 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 Is the product registered in country of manufacture and formulation:	If not, why not?		If yes, 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. SPECIFIC DATA REQUIREMENTS FOR PHYSICAL CHEMICAL PROPERTIES, TOXICOLOGY, ECOTOXICOLOGY, BEHAVIOUR IN THE ENVIRONMENT AND RESIDUES IN THE PLANT: SEE LIST I AND II OF THIS FORM

6. PACKAGING

6.1 Packaging material / container:	
6.2 Pack size(s):	
6.3 Closures / size of opening	
6.4 Disposal of empty container(s):	

7. DECLARATION

For and on behalf of …….…….. 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:

Table of Intended Uses

Use Pattern

1	2	3	4	5	6			7			8	9
Crop and / or situation	**F G or I**	**Pest or group of pests controlled**	**Formulation**		**Application**			**Application rate per treatment**			**PHI (days)**	**Remarks**
			Type	**Conc. of a.i.**	**method, kind**	**growth stage**	**number (range)**	**kg a.i./hectoliter**	**water l/ha**	**kg a.i./ha**		
(a)	**(b)**	**(c)**	**(d - f)**	**(i)**	**(f - h)**	**(j)**					**(k)**	**(l)**

Remarks:

a. In case of group of crops the Codex classification should be used.
b. Outdoor or field use (F), glasshouse application (G) or indoor application (I).
c. e.g. biting and sucking insects, soil born insects, foliar fungi.
d. e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR).
e. Use CIPAC/FAO Codes where appropriate.
f. All abbreviations used must be explained.
g. Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
h. Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants.
i. g/kg or g/l.
j. Growth stage at last treatment.
k. PHI = Pre-harvest interval.
l. Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications; for seed treatments specify the dose in kg a.i. per kg seed and number of seeds per kg seed.

List I ACTIVE INGREDIENT: DOSSIER INDEX

(If the product contains more than one active ingredient, compile a separate dossier for each active ingredient).

The dossier accompanying List I should provide details of the information requested in List I, i.e. details on the methods used (physical & chemical), full study reports (including summaries) of the methods and results used in toxicology and ecotoxicology studies, methods of analysis etc. Numbering used in the dossier must follow the ones used here below.

ACTIVE INGREDIENT (Technical grade)		Result		Annex. No. in dossier if study included	Official use only
1. DESIGNATION					
a	Common name (ISO)				
b.	Manufacturer or development code				
c.	Chemical name (IUPAC)				
d.	Chemical group				
e.	Structural formula and molecular weight				
f.	Empirical formula				
g.	Patent status				
	Is the a.i. under patent				
	Who is patent holder				
	Expiry date				
h.	Method of manufacture				
i.	Identity of isomers, impurities and additives				
j.	Analytical profile of batches				
k.	Method of analysis for the determination of active substance purity and impurities				
2. PHYSICAL AND CHEMICAL PROPERTIES					
a.	Physical state				
b.	Colour				
c.	Odour				
d.	Density at 20 °C	According to international guideline (e.g. OECD 109, EC A.3): yes/no Indicate guideline1			
e.	Vapour pressure at 20/25 °C	According to international guideline (e.g. OECD 104, EC A.4): yes/no Indicate guideline1			
		GLP: yes/no2			
f.	Henry's law constant				
g.	Hydrolysis	According to international guideline (e.g. OECD 111, EC C.7): yes/no Indicate guideline1			
		GLP: yes/no2			
h.	Photolysis	According to international guideline (e.g. OECD 316): yes/no Indicate guideline1			
		GLP: yes/no2			

ACTIVE INGREDIENT (Technical grade)	Result		Annex. No. in dossier if study included	Official use only
i. Solubility in water and effect of pH	According to international guideline (e.g OECD 105, EC A.6): yes/no Indicate guideline1			
	GLP: yes/no2			
j. Solubility organic solvents	According to international guideline (e.g. CIPAC MT181): yes/no Indicate guideline1			
	GLP: yes/no2			
k. n-octanol/water partition coefficient and effect of pH	According to international guideline (e.g. OECD 117, EC A.8): yes/no Indicate guideline1			
	GLP: yes/no2			
l. Surface tension	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
m. Dissociation constant pKa	According to international guideline (e.g. OECD 115, EC A.5): yes/no Indicate guideline1			
	GLP: yes/no2			
n. Boiling point in °C	According to international guideline (e.g. OECD 102, EC A.1): yes/no Indicate guideline1			
o. Melting point in °C	According to international guideline (e.g. OECD 103, EC A.2): yes/no Indicate guideline1			
p. Decomposition temperature in °C	According to international guideline (e.g. OECD 113): yes/no Indicate guideline1			
q. Spectra (UV/VIS, IR, NMR, MS)	According to international guideline (e.g. OECD 101 for UV/VIS): yes/no Indicate guideline1			
	UV/VIS GLP: yes/no			
r. GHS Classification and labelling				
3. TOXICOLOGY				
a. Reference values	ADI (mg/kg bw/d)			
	ARfD (mg/kg bw)			
	AOEL (mg/kg bw/d)			
b. Acute oral toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LD50 (mg/kg bw)			
c. Acute dermal toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LD50 (mg/kg bw)			
d. Acute inhalation toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LC50 (mg/kg bw)			
e. Skin irritation (rabbit)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Classification skin irritation: yes/no			

ACTIVE INGREDIENT (Technical grade)	Result		Annex. No. in dossier if study included	Official use only
f. Eye irritation (rabbit)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Classification eye irritation: yes/no			
g. Skin sensitisation (guinea pig)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Classification skin sensitisation: yes/no			
h. Reproduction multi-generation study (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAELpar (mg/kg bw/d) NOAELoffspring (mg/kg bw/d) NOAELrepro (mg/kg bw/d)			
i. Subchronic toxicity 90 day (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAEL (mg/kg bw/d)			
Subchronic toxicity 90 day (dog)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAEL (mg/kg bw/d)			
j. Chronic toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAEL (mg/kg/day)			
k. Carcinogenicity (life time) (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAEL (mg/kg/day) Carcinogenic: yes/no			
Carcinogenicity (mouse)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAEL (mg/kg/day) Carcinogenic: yes/no			
l. Neurotoxicity (specify species and duration)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAEL (mg/kg bw/d)			
m. Teratogenicity (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAELmat (mg/kg bw/d) NOAELoffspring (mg/kg bw/d) NOAELterato (mg/kg bw/d)			
Teratogenicity (rabbit)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOAELmat (mg/kg bw/d) NOAELoffspring (mg/kg bw/d) NOAELterato (mg/kg bw/d)			
n. Mutagenicity / Genotoxicity	According to international			

ACTIVE INGREDIENT (Technical grade)	Result		Annex. No. in dossier if study included	Official use only
	guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Genotoxic: yes/no			
o. Metabolism (rat)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Oral absorption (%)			
p. Other studies				
q. GHS Classification and labelling				
4. **ECOTOXICOLOGY**				
a. Acute oral toxicity to birds (1 species, preferably Bobwhite quail)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LD50 (mg as/kg bw) NOEL (mg as/kg bw)			
b. Chronic toxicity to birds (1 species, preferably Bobwhite quail)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEL reproduction (mg as/kg bw/d)			
c. Acute toxicity to fish (1 species; preferably rainbow trout)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LC50 (mg as/L)			
d. Chronic toxicity to fish (1 species; preferably rainbow trout)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC reproduction (mg as/L)			
e. Bioconcentration in fish	According to international guideline: yes/no Indicate guideline1			
	BCF value			
f. Acute toxicity to Daphnia	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	EC50 (mg as/L)			
g. Acute toxicity to an additional aquatic invertebrate species (e.g. Chironomid larvae or Mysidopsis bahia)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	EC50 (mg/L):			
h. Chronic toxicity to Daphnia	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/L)			
i. Chronic toxicity to an additional aquatic invertebrate species (e.g. Chironomid larvae)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/L)			
k. Effects on algae	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	EC50 (mg as/L) NOEC (mg as/L)			
l. Effects on aquatic macrophytes	According to international guideline: yes/no			

ACTIVE INGREDIENT (Technical grade)	Result		Annex. No. in dossier if study included	Official use only
	Indicate guideline1			
	GLP: yes/no2			
	EC50 (mg as/L) NOEC (mg as/L)			
m. Acute toxicity to bees (acute oral as well as acute contact toxicity)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Oral LD50 (ug as/bee) Oral NOEC (ug as/bee) Contact LD50 (ug as/bee) Contact NOEC (ug as/bee)			
n. Bee brood study	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/kg food)			
o. Effects on non-target arthropods other than bees (Aphidius rhopalosiphi and Typhlodromus pyri)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LR50 A. rhopalosiphi (g as/ha) NOER A. rhopalosiphi (g as/ha) LR50 T. pyri (g as/ha) NOEC T. pyri (g as/ha)			
p. Acute toxicity to earthworms	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LC50 (mg/kg soil)			
q. Chronic toxicity to earthworms	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/kg soil)			
r. Effects on soil nitrogen transformation	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/kg soil)			
s. Effects of terrestrial non-target higher plants	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	ER50 (g as/ha)			
t. GHS Classification and labelling				
5.BEHAVIOUR IN ENVIRONMENT Behaviour, ways of degradation, degradation products in soil				
a. Aerobic route and rate of degradation active substance	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Pathways of aerobic degradation DegT50 and DegT90 of the active substance			
b. Anaerobic route and rate of degradation active substance	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Pathways of anaerobic degradation			

ACTIVE INGREDIENT (Technical grade)	Result		Annex. No. in dossier if study included	Official use only
	DegT50 and DegT90 of the active substance			
c. Soil photolysis	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Pathways of degradation by soil photolysis			
d. Aerobic degradation rate of major metabolites	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	DegT50 and DegT90 major metabolites			
e. Adsorption and desorption of the active substance	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Koc or Kom			
f. Adsorption and desorption of major metabolites	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Koc or Kom			
Behaviour, ways of degradation, degradation products in water.				
g. Hydrolytic degradation of the active substance and major metabolites	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Degradation pathways DT50 active substance and major metabolites			
h. Photochemical degradation of the active substance and major metabolites	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Degradation pathways DT50 active substance and major metabolites			
i. Water/sediment study	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Degradation pathways DT50 active substance and major metabolites			
6. MODE OF ACTION				
7. RESIDUES IN THE PLANT				
a1. Metabolism (crop group 1)	Crop:			
	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
a2, a3, etc. Metabolism (other relevant crop groups)	Crop:			
	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
b. Major metabolites/residue definition	residue definition for monitoring and risk assessment			
c1. Magnitude of residues (crop 1)	Crop:			
	Proposed GAP:			
	Residue trials according to international guideline: yes/no			

ACTIVE INGREDIENT (Technical grade)	Result		Annex. No. in dossier if study included	Official use only
	Indicate guideline1			
	GLP: yes/no2			
	According to GAP (± 25%)?			
	Residue levels found according to residue definition:			
c2, c3, etc.Magnitude of residues (other relevant crops)	Crop:			
	Proposed GAP:			
	Residue trials according to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	According to GAP (± 25%)?			
	Residue levels found according to residue definition:			
d1. storage stability (matrix 1)	Matrix:			
	GLP: yes/no2			
	According to international guideline: yes/no Indicate guideline1			
	Period stability proven:			
	Conditions (temperature °C)			
d2, d3, etc. storage stability (other relevant matrices)	Matrix:			
	GLP: yes/no2			
	According to international guideline: yes/no Indicate guideline1			
	Period stability proven:			
	Conditions (temperature °C)			
e. MRL codex and/or country + critical GAP and evaluation	If existing evaluations cover the the MRL proposal might be adopted if the GAP is similar to the Ethiopian GAP and trials were performed in a similar agro-ecological zone			
f. Method of residue analysis	Analytical method for analysis of residues for post-registration monitoring			
	GLP: yes/no2			
	According to international guideline: yes/no Indicate guideline1			
g. Additional information for refinement of intake				
	GLP: yes/no2			
	According to international guideline: yes/no Indicate guideline1			

1 The data should be based on internationally recognized testing guidelines and methods, such as those published by OECD or USEPA, among others.

2 Data should be generated following the principles of good laboratory practice (GLP), whenever applicable. Experiments performed after 25 July 1993 must have been performed in accordance with GLP.

List II FORMULATED PRODUCT: DOSSIER INDEX

The dossier accompanying List II should provide details of the information requested in List II, i.e. details on the methods used (physical & chemical), full study reports (including summaries) of the methods and results used in toxicology and ecotoxicology studies, methods of analysis etc. Numbering used in the dossier must follow the ones used here below.

FORMULATED PRODUCT 1. PHYSICAL AND CHEMICAL PROPERTIES		Result	Annex. No. in dossier if study included	Official use only
a. Physical state/formulation type				
b. Colour				
c. Odour				
d. Storage stability - accelerated (CIPAC MT46.3) - at low temperature (CIPAC MT39.3)	According to international guideline: yes/no Indicate guideline[1]			
e. Shelf life	According to international guideline (e.g. Croplife Int. Monograph No. 17): yes/no Indicate guideline[1]			
	GLP (only required in case of > 5% active substance degradation): yes/no[2]			
f. Density (liquids)	According to international guideline (e.g. OECD 109, EC A.3): yes/no Indicate guideline[1]			
g. Bulk density (solids)	According to international guideline (CIPAC MT186): yes/no Indicate guideline[1]			
h. Compatibility with other pesticides	According to international guideline (e.g. ASTM1518): yes/no Indicate guideline[1]			
i. pH of aqueous formulations	According to international guideline (CIPAC MT75.3) : yes/no Indicate guideline[1]			
	GLP: yes/no[2]			
j. pH of 1% aqueous dilution	According to international guideline (CIPAC MT75.3): yes/no Indicate guideline[1]			
	GLP: yes/no[2]			
k. Acidity / alkalinity if pH <4 or >10	According to international guideline (CIPAC MT191): yes/no Indicate guideline[1]			
	GLP: yes/no[2]			
m. Viscosity	According to international guideline: yes/no Indicate guideline[1]			
m. Surface tension of the undiluted product at 25 °C	According to international guideline: yes/no Indicate guideline[1]			
n. Technical properties according	According to international			

FORMULATED PRODUCT			Result	Annex. No. in dossier if study included	Official use only
	to GCPF code and FAO pesticide specification manual	guideline (e.g. CIPAC): yes/no Indicate guideline[1]			
o.	Particle size distribution of granules	According to international guideline (CIPAC MT170): yes/no Indicate guideline[1]			
		GLP: yes/no[2]			
p.	Dust content of granules	According to international guideline (CIPAC MT171): yes/no Indicate guideline[1]			
		GLP: yes/no[2]			
q.	Other properties (where applicable)				
r.	Classification and labelling related data				
s.	Method of analysis for determination of the active substance content in the formulation				
t.	Description of methods for analysis of soil for parent compound and metabolites of toxicological, ecotoxicological or environmental concern				
u.	Description of methods for analysis of water for parent compound and metabolites of toxicological, ecotoxicological and environmental concern				
w.	Method of manufacture				
2.	**(ECO)TOXICOLOGY**				
a.	Acute oral toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
		GLP: yes/no2			
		LD50 (mg/kg bw)			
b.	Acute dermal toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
		GLP: yes/no2			
		LD50 (mg/kg bw)			
c.	Acute inhalation toxicity (rat)	According to international guideline: yes/no Indicate guideline1			
		GLP: yes/no2			
		LC50 (mg/kg bw)			
d.	Skin irritation (rabbit)	According to international guideline: yes/no Indicate guideline1			
		GLP: yes/no2			
		Classification skin irritation: yes/no			
e.	Eye irritation (rabbit)	According to international guideline: yes/no Indicate guideline1			
		GLP: yes/no2			
		Classification eye irritation: yes/no			
f.	Skin sensitisation (guinea pig)	According to international guideline: yes/no Indicate guideline1			
		GLP: yes/no2			
		Classification skin sensitisation: yes/no			
g.	WHO classification				
h.	Other toxicological studies				
h1.	Dermal absorption study	According to international guideline: yes/no			

FORMULATED PRODUCT		Result	Annex. No. in dossier if study included	Official use only
	Indicate guideline1			
	GLP: yes/no2			
	Value for concentrate Value for spray dilution			
i. Acute oral toxicity to birds	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LD50 (mg/kg bw)			
j. Effects on aquatic organisms	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	L(E)C50 (mg/kg bw/d)			
k. Effects on bees	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	Oral LD50 (ug as/bee) Oral NOEC (ug as/bee) Contact LD50 (ug as/bee) Contact NOEC (ug as/bee NOEC (mg/kg or g as/ha)			
l. Effects on non-target arthropods other than bees (Aphidius rhopalosiphi and Typhlodromus pyri)	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LR50 A. rhopalosiphi (g as/ha) NOER A. rhopalosiphi (g as/ha) LR50 T. pyri (g as/ha) NOEC T. pyri (g as/ha)			
m. Acute toxicity to earthworms	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	LC50 (mg as/kg soil)			
n. Chronic toxicity to earthworms	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/kg soil)			
o. Effects on soil nitrogen transformation	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	NOEC (mg as/kg soil)			
p. Effects of terrestrial non-target higher plants	According to international guideline: yes/no Indicate guideline1			
	GLP: yes/no2			
	ER50 (g as/ha)			
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE ORPOISONING				
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				
4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE				

FORMULATED PRODUCT		Result	Annex. No. in dossier if study included	Official use only
a. Fire fighting measures				
b. Procedures in case of spillage				
5. USES (New label claims this application)	**New uses should be listed in a Table of Intended Uses similar to the format given on Page 4**			
a. Crop/area of use				
b. Mode of action				
c. Target organism				
d. Application rate, including number and interval of applications if relevant				
e. Growth stage of treatment				
f. Directions for use				
g. Residue data and pre-harvest interval (PHI)				
h. Phytotoxicity	Include on product leaflet			
i. Contraindications				
j. Resistance risk analysis	According to EPPO 1/213(3)			
6. MINIMUM LABEL REQUIREMENTS				
a. Product identification				
b. Warnings and use restrictions				
c. Safety precautions				
d. First aid/note to physician (as applicable)				
e. Pictograms (if applicable)				
f. FAO colour code (if applicable) group				
g. Directions for use				

1 The data should be based on internationally recognized testing guidelines and methods, such as those published by OECD or USEPA, among others.

2 Data should be generated following the principles of good laboratory practice (GLP), whenever applicable. Experiments performed after 25 July 1993 must have been performed in accordance with GLP.

ADDITIONAL REQUIREMENTS

No	Requirement	Submitted (check box)
A.	Two copies of the Plant Protection Product dossier included under List I and List II (active ingredient dossier index and formulated product dossier index) including a Table of Intended Uses, with signed and sealed application form. Every part of this dossier (application form, List I and List II, Table of Intended Uses) needs to be filled duly with the appropriate data.	yes☐ no ☐
B.	Local efficacy report from research organization • Efficacy data generated from research institutions or universities in accordance with the national local efficacy test procedure.	yes☐ no ☐
C.	Samples of the technical grade and the formulated product • 2 lots of 500 g or ml formulated product • 1 lot of 1 g or ml of the technical grade.	yes☐ no ☐ yes☐ no ☐
D.	Agency agreement between the agent and the manufacturer/formulator.	yes☐ no ☐
E.	Third party batch certificate of analysis from accredited laboratory (authenticated by chamber of commerce or any relevant government office). If the analysis is done by the organization itself, it requires a GLP Certificate.	yes☐ no ☐
F.	Manufacturing license - A letter of recognition that the pesticide is registered and is permitted to be produced in the country of origin. This should be authenticated by the government body (chamber of commerce) and should be original.	yes☐ no ☐
G.	Label for the intended pest and crop and according to pack size in: • English • Amharic	yes☐ no ☐ yes☐ no ☐
H.	Table with the intended uses.	yes ☐ no ☐