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GUIDELINES ON DATA REQUIREMENTS FOR THE REGISTRATION OF CONVENTIONAL CHEMICAL PESTICIDES USED IN AGRICULTURE AND FORESTRY IN EAC PARTNER STATES

The present guidelines are an update of the Agriculture (Farm Input) Forms published by the East African Community in January 2005. These forms have been used by EAC Partner States as a basis for national data requirements for the registration of pesticides.

The main objective of the updated guidelines is to provide better information to applicants for the registration of a pesticide regarding the data and studies that they should submit to national pesticide registration authorities. Furthermore, these more detailed guidelines should facilitate that national authorities require the same, or very similar, data from applicants and thus harmonize the registration process across the EAC region.

The information to be provided by the applicant should be sufficient for the national registration authority to assess whether the pesticide is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment under the conditions of use in the country or region.

Data requirements are listed in two parts: Part I for data required on the active ingredient(s); and Part II for data required on the formulated product. If the product contains more than one active ingredient a separate dossier for part I should be submitted for each active ingredient.

Part III of the guidelines contains the application form for registration of a conventional chemical pesticide

The data requirements below are structured as follows:

Number: Data point number. Applicants should follow the numbering in these guidelines when constituting their dossier.

Data: Description of the data or study required

Use pattern: The pesticide uses patterns for which the data are required

- All: all uses
- Food uses: use of the pesticide on human food, or when food may be exposed to the pesticide (e.g. crops, stored products, livestock)
- Feed uses: use of the pesticide on animal feed, or when feed may be exposed to the pesticide (e.g. grazing land, fodder, feed crops)
- Outdoor uses: all outdoor uses of the pesticide (e.g. terrestrial fields, aquatic use (e.g. irrigated rice), forestry, gardens)
- Indoor uses: all indoor uses of the pesticide (e.g. glasshouse, store)

Conditions: R = always required; CR = conditionally required (conditions are specified in the remarks column)

Remarks: Details about the studies to be conducted, conditions under which these are required, etc.

Endpoint of study: The resulting value(s) or outcome(s) of a study. These are specified when relevant

Level of detail: The level of detail of the information or data to be provided is specified, when needed:

- endpoint = only the endpoint(s) of the study needs to be provided;
- summary = a summary of the study needs to be provided, describing – as a minimum – the title page, signed declaration page, materials and methods, main observations and outcomes of the study, the endpoint(s) of the study
- report = the full report of the study needs to be provided.

In **ALL CASES**, the source/reference of the data or study should be provided, as well as the method used to generate the data. Internationally accepted testing methods should be used, whenever possible (e.g. OECD, CIPAC, ASTM, EC)

List of abbreviations

ADI	Acceptable Daily Intake
a.i.	active ingredient
AOEL	Acceptable Operator Exposure Level
ARfD	Acute Reference Dose
bw	body weight
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
CIPAC	Collaborative International Pesticides Analytical Council
CR	Conditionally required
DT_{50}	Half-life (dissipation)
$DegT_{50}$	Half-life (degradation)
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
ISO	International Standards Organization
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	Octanol-water partition coefficient
K_{oc}	Adsoption coefficient (organic carbon)
K_{om}	Adsoption coefficient (organic matter)
LD_{50}	Median lethal dose
LC_{50}	Median lethal concentration
MRL	Maximum Residue Limit
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
Pa	Pascal
pK_a	Acid dissociation constant
R	Required

I. DATA TO BE PROVIDED ON THE **ACTIVE INGREDIENT**

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
1	**DESIGNATION / IDENTITY**					
1.1	Common name (ISO) of the active ingredient (a.i.)	All	R	According to the International Organization for Standardization (ISO) common name, or proposed ISO common name		
1.2	Applicant name and address	All	R	To be provided on the application form		
1.3	Name and address of manufacturer of the a.i.	All	R			
1.4	Name and address of toll manufacturer of the a.i. (i.e. secondary contract manufacturer) (if applicable)	All	R			
1.5	Name and address of manufacturing plant(s) of the a.i.	All	R			
1.6	Manufacturer or development code of the a.i.	All	R			
1.7	Methods of manufacture (synthesis pathway), including starting materials, pathways, by-products, impurities	All	R	To be treated as Confidential Business Information (CBI)		Summary
1.8	Purity of the active ingredient	All	R	Minimum content of pure active ingredient in the technical material used for production of the pesticide	In g/kg	
1.9	Identity, content, structural formula of isomers, impurities, and additives	All	R	If the active ingredient is a mixture of isomers, the ratio of the content of isomers should be specified Minimum and maximum content in g/kg of each impurity and additive To be treated as CBI; relevant impurities will not be considered as CBI	In g/kg	

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
1.10	Batch analysis data	All	R	At least five analytical profiles of representative batches from current industrial scale production of the a.i. needs to be provided. They should include the content (in g/kg) of pure a.i., impurities, additives and other components, as appropriate. Representative batches shall, in principle, be within the last five years of manufacture. All components present in quantities of 1 g/kg or more should be analysed and the total of all components should account for at least 980 g/kg of the material analysed. To be treated as CBI	Analytical profiles. Contents in g/kg	Report
1.11	Chemical name (IUPAC)	All	R	According to the International Union of Pure and Applied Chemistry (IUPAC)		
1.12	Chemical group	All	R			
1.13	Structural formula	All	R			
1.14	Empirical formula	All	R			
1.15	Patent status	All	R	Name of patent holder; expiry date of patent		
1.16	Molecular mass	All	R			
1.17	CAS Number, CIPAC number	All	R	Chemical Abstracts Service (CAS) and Collaborative International Pesticides Analytical Council (CIPAC) numbers of the a.i., where they exist		
2	**PHYSICAL AND CHEMICAL PROPERTIES**					
2.1	Physical state	All	R	Solid, liquid etc.		Endpoint
2.2	Colour	All	R			Endpoint
2.3	Odour	All	R			Endpoint
2.4	Density	All	R	At 20 °C		Endpoint
2.5	Vapour pressure	All	R	At 20 or 25 °C.	In Pa	Endpoint

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
2.6	Volatility	All	R	If the a.i. is a solid or liquid, the volatility (Henry's law constant) of the purified a.i. needs to be determined or calculated.	In Pa × m^3 × mol^{-1}	Endpoint
2.7	Solubility in water	All	R	At 20 °C, in neutral pH range. If the pK_a (acid dissociation constant) is between 2 and 12, water solubility also needs to be determined in the acidic range (pH 4–5) and in the alkaline range (pH 9–10). If the solubility in water cannot be determined due to instability of the a.i., this should be justified.	g/L	Endpoint
2.8	Solubility in organic solvents	All	R	Provide for relevant solvents. Temperature should be specified.	g/L	Endpoint
2.9	N-octanol/water partition coefficient (K_{ow} or log P_{ow})	All	R	At 20 or 25 °C		Endpoint
2.10	Boiling point	All	R		In °C	Endpoint
2.11	Melting point	All	R		In °C	Endpoint
2.12	Decomposition temperature	All	R		In °C	Endpoint
2.13	Stability in water	All	R			Endpoint
2.14	Stability in organic solvents used in formulation	All	R			Endpoint
2.15	Thermal stability, identity of breakdown product	All	R			Endpoint
2.16	Flammability	All	R			Endpoint
2.17	Flash point	All	R	If the a.i. as manufactured has a melting point below 40 °C		Endpoint
2.18	Explosive properties	All	R			Endpoint
2.19	Oxidizing properties	All	R			Endpoint
2.20	Absorption spectra	All	R	Ultraviolet/visible (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR) and mass spectra (MS)		Endpoint
2.21	Reactivity towards container material	All	R			Endpoint

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
3	**ANALYTICAL METHODS**					
3.1	Methods for analysis of the active substance as manufactured	All	R	Provide methods for the determination of: – pure active substance in the a.i. as manufactured – significant and relevant impurities and additives (such as stabilisers) in the a.i. as manufactured. Refer to CIPAC methods, where applicable		Summary or Full method (to be determined by the national authority)
3.2	Analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Food uses	R	For all components of the residue definition		
		Non-food uses	CR	If dislodgeable residues need to be determined (e.g. for risk assessment of harvesting)		
3.3	Description of methods for analysis in the environment of the parent compound and metabolites of toxicological, ecotoxicological or environmental concern	All	CR	For environmental components (soil, water, organisms …), as relevant, depending on the proposed use pattern of the product		
4	**TOXICOLOGY**					
4.1	Toxicological reference values	All	R	– Acceptable Daily Intake (ADI) – Acute Reference Dose (ARfD) – Acceptable Operator Exposure Level (AOEL) Specify source.	mg a.i./kg body weight	Summary
4.2	Acute oral toxicity	All	R	Not required if test material is a gas or a highly volatile liquid. Study normally conducted in rat.	LD_{50} (mg a.i./kg bw)	Summary
4.3	Acute dermal toxicity	All	R	Not required if test material is a gas or a highly volatile liquid. Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Study normally conducted in rat, rabbit or guinea pig	LD_{50} (mg a.i./kg bw)	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
4.4	Inhalation toxicity	All	R	Required if the product consists of, or under conditions of use will result in, a respirable material (e.g. gas, vapour, aerosol or particulate). Study normally conducted in rat.	LC_{50} (mg a.i./L)	Summary
4.5	Skin irritation	All	R	Not required if test material is a gas or a highly volatile liquid. Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Study normally conducted in rabbit; alternatively, studies with skin disks of the rat or human skin models can be used	Categories for erythema/eschar formation, oedema formation, inflam-mation, reversibility of skin lesions	Summary
4.6	Eye irritation	All	R	Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Study normally conducted in rabbit; alternatively, corneas from cattle eyes, or chicken eyes can be used.	Categories for corneal opacity, iritis, conjuctival redness or oedema (chemosis), reversibility of eye lesions	Summary
4.7	Skin sensitization	All	R	Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Required if repeated dermal exposure is likely to occur under conditions of use. Conventional study normally conducted in guinea pig; local lymph node assay (LLNA) in mice	Conventional test: skin reaction (e.g. erythema) LLNA: proliferation of lymphocytes in the lymph nodes	Summary
4.8	Sub-chronic oral toxicity (90 day)	All	R	Study normally conducted in rat. Additional studies in a non-rodent species, or through dermal or inhalation exposure, may be required by the registration authority	NOAEL (mg a.i./kg bw/day)	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
4.9	Chronic oral toxicity	Food uses	R	Study normally conducted in rat. May be combined with the carcinogenicity study.	NOAEL (mg a.i./kg bw/day)	Summary
		Non-food uses	CR	Required if oral exposure could occur.		
4.10	Carcinogenicity	All	CR	Study normally conducted in two rodent species, rat and mouse. Required if: – the use of the pesticide is likely to result in significant human exposure over a considerable portion of the human lifespan which is significant in terms of either frequency, duration or magnitude of exposure; or – the use requires a maximum residue limit or an exemption from the requirement of a maximum residue limit; or – the active ingredient, metabolite, degradate, or impurity (a) is structurally related to a recognized carcinogen, or (b) causes mutagenic effects as demonstrated by in vitro or in vivo testing, or (c) produces a morphologic effect in any organ (e.g. hyperplasia, metaplasia) in sub-chronic studies that may lead to a neoplastic change.	NOAEL (mg a.i./kg bw/day)	Summary
4.11	Acute neurotoxicity	All	R	Study normally conducted in rat.	NOAEL (mg a.i./kg bw/day)	Summary
4.12	Sub-chronic neurotoxicity (90 days)	All	R	Study normally conducted in rat. May be adapted to be combined with the sub-chronic oral toxicity study	NOAEL (mg a.i./kg bw/day)	Summary
4.13	Delayed neurotoxicity following acute exposure	All	CR	Required if the pesticide is an organophosphorus substance or is structurally related to other substances that may cause the delayed neurotoxicity. Study normally conducted in hen.	Toxic response, including mortality	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
4.14	Teratogenicity	Food uses	R	Study normally conducted in two species: rat and rabbit.	NOAEL (mg a.i./kg bw/day)	Summary
		Non-food uses	CR	Required if use of the pesticide is likely to result in significant human exposure over a portion of the human lifespan in terms of frequency, magnitude or duration of exposure.		
4.15	Reproduction toxicity (two-generation study)	Food uses	R	Study normally conducted in rats	NOAEL (mg a.i./kg bw/day)	Summary
		Non-food uses	CR	Required if use of the pesticide is likely to result in significant human exposure over a portion of the human lifespan in terms of frequency, magnitude or duration of exposure.		
4.16	Mutagenicity / Genotoxicity	All	R	Both in vitro and in vivo cytogentics studies are required. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is needed.		Summary
4.17	Metabolism – Absorption, distribution, excretion and metabolism in mammals, with special reference to differences between laboratory animals and humans, kinetics, accumulation and half-lives	Food uses	R	Study normally conducted in rats		Summary
		Non-food uses	CR	Required when chronic or carcinogenicity studies are recommended. May be recommended if significant adverse effects are seen in available toxicology studies and these effects can be further elucidated by metabolism studies.		
4.18	Other studies	All	CR	As required by the registration authority		Summary
5	**ECOTOXICOLOGY**					
5.1	Birds – oral toxicity	Outdoor uses	R	Studies should be conducted on two relevant species: one passerine species and either one waterfowl species or one terrestrial bird species. Generally not required for pesticide products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.	LD_{50} (mg a.i./kg bw) NOAEL (mg a.i./kg bw/day)	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
		Indoor uses	CR	Required if exposure of birds may occur (e.g. open-sided greenhouses) Waterfowl or terrestrial bird species are preferred.		
5.2	Birds – reproduction toxicity	Outdoor uses	R	Studies should be conducted on two relevant species: waterfowl and terrestrial bird species are preferred. Generally not required for pesticide products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material. Not required for indoor uses.	NOAEL (mg a.i./kg bw/day)	Summary
5.3	Fish – acute toxicity	Outdoor uses	R	Studies should be conducted on two relevant fish species. If the pesticide is to be used in coastal areas, data on one marine/estuarine fish species should be provided.	LC_{50} (mg a.i./L)	Summary
		Indoor uses	CR	Required if exposure of waterways may occur (e.g. drainage of contaminated irrigation water from greenhouses) Studies should be conducted on one fish species.		
5.4	Fish – early-life stage	Outdoor uses	R	Studies should be conducted on one relevant fish species. If the pesticide is to be used in coastal areas, data on one additional marine/estuarine fish species should be provided. Not required for indoor uses.	NOEC (mg a.i./L)	Summary
5.5	Fish – life-cycle test	Outdoor uses	CR	Required if the pesticide is to be applied to water, and the results of the early-life stage test indicate that fish are sensitive to the pesticide. Not required for indoor uses.	NOEC (mg a.i./L)	Summary
5.6	Fish – bioconcentration	Outdoor uses	CR	Required if log K_{ow} > 3 and the pesticide is stable in water (i.e. < 90% loss by hydrolysis in 24 hours)	BCF	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
5.7	Daphnia – acute toxicity	Outdoor uses	R	If the pesticide is to be used in coastal areas, data on one additional marine/estuarine invertebrate species should be provided.	LC_{50} (mg a.i./L)	Summary
		Indoor uses	CR	Required if exposure of waterways may occur (e.g. drainage of contaminated irrigation water from greenhouses)		
5.8	Daphnia – life cycle study	Outdoor uses	R	If the pesticide is to be used in coastal areas, data on one additional marine/estuarine invertebrate species should be provided. Not required for indoor uses.	NOEC (mg a.i./L)	Summary
5.9	Algae	Outdoor uses	R	Studies should be conducted on one species of green algae. For phytotoxicants (e.g. herbicides), a second algal species, from a different taxonomic group, should be tested.	NOEC (mg a.i./L)	Summary
		Indoor uses	CR	Required if exposure of waterways may occur (e.g. drainage of contaminated irrigation water from greenhouses)		
5.10	Honey bees – acute oral and contact toxicity	Outdoor uses	R		LD_{50} (µg a.i./bee)	Summary
		Indoor uses	CR	Required if exposure of bees may occur (e.g. open-sided greenhouses, indoor pollination by bumblebees)		
5.11	Honey bee – toxicity of residues on foliage	Outdoor uses	CR	Required if acute contact LD_{50} is < 11 µg/bee	RT_{25} (hours)	Summary
5.12	Bee brood-feeding tests	Outdoor uses	CR	Required for pesticides that may have sublethal effects on growth or development	NOEC (mg a.i./kg food)	Summary
5.13	Non-target terrestrial arthropods	Outdoor uses and greenhouses	CR	Data on relevant predators, parasitoids and other beneficials are required if the pesticide is intended to be used in Integrated Pest Management (IPM).	Depends on test	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
5.14	Earthworms	Outdoor uses, except aquatic uses	R	Studies on other soil organisms may be required, in particular if the pesticide is intended to be used in semi-arid conditions	NOEC (mg a.i./kg soil)	Summary
5.15	Soil micro-organisms	Outdoor uses, except aquatic uses	R		NOEC (mg a.i./kg soil)	Summary
5.16	Terrestrial plants – screening data	Outdoor uses	R	Screening data can be used to show that the pesticide does not have herbicidal or plant growth regulatory activity. Screening should be done on at least 6 plant species from 6 different families		Summary
5.17	Terrestrial plants – toxicity tests	Outdoor uses	CR	Toxicity tests on terrestrial plants are required if the pesticide has herbicidal or plant growth regulatory activity. Studies on vegetative vigour and seedling emergence should be conducted	ER_{50} (g a.i./ha)	Summary
5.18	Other studies	All	CR	Other ecotoxicological studies (e.g., semi-field studies, micro-/mesocosms) may be required by the registration authority		
6	**BEHAVIOUR IN ENVIRONMENT**					
6.1	Behaviour, ways of degradation, degradation products in soil:					
6.1.1	Behaviour, ways of degradation, degradation products in soil – aerobic	Outdoor and greenhouse uses	R	Required, unless exposure of aerobic soils is unlikely to occur (e.g. indoor treatment of stored products)	Soil degradation pathways (schematic), major metabolites, $DegT_{50}$ (days)	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
6.1.2	Behaviour, ways of degradation, degradation products in soil – anaerobic	Outdoor uses	R	Required, unless it is unlikely that the pesticide will be exposed to anaerobic soil conditions	Soil degradation pathways (schematic), major metabolites, $DegT_{50}$ (days)	Summary
6.1.3	Mobility – adsorption/desorption studies of the a.i.	Outdoor and greenhouse uses	R	Required, unless exposure of soils is unlikely to occur (e.g. indoor treatment of stored products)	K_{oc} , K_{om}	Summary
6.1.4	Mobility – adsorption/desorption studies of the metabolites	Outdoor and greenhouse uses	R	Required if metabolites account for more than 5% of the active ingredient in the soil degradation studies	K_{oc}, K_{om}	Summary
6.2	Behaviour, ways of degradation, degradation products in water:					
6.2.1	Hydrolysis	Outdoor and greenhouse uses	R		Major metabolites, $DegT_{50}$ (days)	Summary
6.2.2	Photolysis	Outdoor uses	R		Major metabolites, $DegT_{50}$ (days)	Summary
6.2.3	Water-sediment studies	Outdoor uses	R		Major metabolites, $DegT_{50}$ (days), DT_{50} (days)	Summary
6.3	Behaviour, ways of degradation, degradation products in air	All	CR	Required for fumigants and other volatile products		
7	**MODE OF ACTION**					
7.1	Function (e.g. herbicide, insecticide)	All	R			Endpoint
7.2	Mode of action of the active ingredient	All	R			Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
8	**RESIDUES**					
8.1	Storage stability of residues	Food uses	R			Summary
8.2	Metabolism and behaviour of residues					
8.2.1	Nature and chemical identity of the residue in plants, including major metabolites	Food uses (crops, stored products)	R	Also required for green tobacco. Depending on the level of residues found on the green tobacco, additional data may be required on cured or dried tobacco and pyrolysis products.	Include schematic diagramme of the metabolic pathways in plants	Summary
8.2.2	Nature and chemical identity of the residue in animal products, including major metabolites	Food use (animals)	CR	Required if the pesticide use is directly applied to livestock. Required if pesticide residues are present in or on livestock feed items or intentionally added to drinking-water, unless livestock metabolism studies indicate negligible transfer of the pesticide residues of concern to tissues, milk and eggs from animals exposed at the maximum expected level.	Include schematic diagramme of the metabolic pathways in animals	Summary
8.2.3	Nature and chemical identity of the residue in fish, including major metabolites	Aquatic food use	R	Required if the pesticide is applied directly to water inhabited, or to be inhabited, by fish that may be caught or harvested for human consumption.	Include schematic diagramme of the metabolic pathways in animals	Summary
8.3	Residue trials	Residue trials in EAC partner states are required, unless: - A Codex MRL has been established, and the proposed GAP of the pesticide to be registered is similar to the Codex GAP (i.e. ±25% of the reference GAP), and no specific dietary concerns exist; or - An MRL has been established by the EU, the USA, Australia, New Zealand, Japan, Canada or Brazil, and the proposed GAP of the pesticide to be registered is similar to the reference GAP, and no specific dietary concerns exist. or - If residue data extrapolation is possible base on Codex crop grouping.				

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
		Residue trials conducted in other EAC partner states may be submitted, if conducted under comparable agronomic practices for crop/pesticide combinations and following a similar GAP. Such studies should follow the *Guidelines for the Conduct of Supervised Residue Field Trials on Crops in the East African Community*, and be conducted by institutions certified by the designated national regulatory authority. Residue trials conducted in other countries may be submitted, if conducted under comparable agronomic practices for crop/pesticide combinations and following a similar GAP. Such studies should be conducted by GLP certified institutions and follow internationally accepted guidelines. For further details on the number and design of residue trials, the applicant should refer to the *Guidelines for the Conduct of Supervised Residue Field Trials on Crops in the East African Community.*				
8.3.1	Residue trials for crops or plant product used as food or feed on which use is proposed or from which residues from soil can be taken up (crop field trials)	Food use (crops)	R	Also required if indoor use could result in pesticide residues in or on food or feed.		Summary Full reports for trials conducted in the EAC
8.3.2	Livestock feeding studies on the nature of the residue in livestock	Feed use	CR	Required if a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking-water, or to crops used for livestock feed. If the results of the plant metabolism study show differing metabolites in plants and animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be needed.		Summary Full reports for trials conducted in the EAC
8.3.3	Effects of industrial processing and/or household preparation on the nature of the residue, distribution of the residue, and residue levels	Food and feed use.	CR	Required if residues could potentially concentrate during processing thus requiring the establishment of a separate MRL higher than that of the raw agricultural commodity.		Summary Full reports for trials conducted in the EAC

	Data	Use pattern	Conditions	Remarks	Endpoint of study	Level of detail
8.3.4	Residues in succeeding crop (rotational crops)	Food and feed use.	CR	Required if it is reasonably foreseeable that a food or feed crop could subsequently be planted on the site of pesticide application after harvest or failure of the treated crop. Not required for pesticide uses in permanent food crops (e.g. various tree crops, vines) or semi-permanent crops (e.g. asparagus, pineapples) or for greenhouse crops if the substrate is replaced.		Summary Full reports for traials conducted in the EAC
8.4	National or regional residue definition and MRL (if established), or proposed national residue definition and MRL. (incl. associated GAP)	Food and feed use	R	Required if use could result in pesticide residues in or on food or feed.		Summary
8.5	Residue definition and MRL by the Codex Alimentarius (if established) and by other relevant authorities (e.g. European Union, US-EPA, countries to which treated commodities are likely to be exported). (incl. associated GAP)	Food and feed use	R	Required if use could result in pesticide residues in or on food or feed.		Summary
8.6	Proposed pre-harvest intervals, withholding periods in case of post-harvest use.	Food and feed use	R	Required if use could result in pesticide residues in or on food or feed.		Summary

II. DATA TO BE PROVIDED ON THE **FORMULATED PRODUCT**

For terminology and the list of abbreviations, see the Part I – Active Ingredient

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
1	**IDENTITY**					
1.1	Trade or commercial or brand name	All	R	Trade name of the pesticide product should be unique in the EAC Partner States; identical trade names for the different products are not allowed.		
1.2	Type and code of formulation	All	R	According to the latest *Catalogue of pesticide formulation types and international coding system* of CropLife International		
1.3	Detailed quantitative and qualitative information on the composition of the formulation, including: – content of technical active substance and formulants – certified limits of each compound – salt, ester, anion or cation present for each active substance – for each formulant, or component of formulants: chemical name, structure or structural formula, CAS or CIPAC numbers, trade name, specification of formulation, function of each formulant – description of formulation process and discussion of the formation of impurities of toxicological concern	All	R	To be treated as Confidential Business Information (CBI)		Complete recipe
1.4	Certificate of analysis	All	R	Certificate should be from a GLP laboratory Contact details of the laboratory should be provided		

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
2	**PHYSICAL AND CHEMICAL PROPERTIES**					
2.1	Physical state/formulation type	All	R	Solid, liquid etc.		Endpoint
2.2	Colour	All	R			Endpoint
2.3	Odour	All	R			Endpoint
2.4	Storage stability	All	R	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.		Endpoint(s)
2.5	Shelf-life	All	R	The shelf-life of the product at room temperatures (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.		Endpoint
2.6	Relative density	All	CR	Required for liquids		Endpoint
2.7	Bulk density	All	CR	Required for solids, after compression		Endpoint
2.8	Flammability	All	R			Endpoint
2.9	Flash point	All	R			Endpoint
2.10	Compatibility/in-compatibility with other pesticides	All	R	Indicate types of pesticides that the product is incompatible with. Explain the hazards or adverse effects		Summary
2.11	pH range	All	R	State the effect of pH on stability and effectiveness.		Summary
2.12	pH of 1% aqueous dilution	All	R	Required for products to be diluted in water		Endpoint
2.13	Oxidizing properties	All	R	Indicate materials that can be damaged by oxidizing properties of the formulation.		Endpoint
2.14	Corrosiveness	All	R	Specify effect on containers, equipment, skin etc.		Endpoint
2.15	Water content	All	R	Indicate the maximum water content when it has an influence on the quality of the product		Endpoint
2.16	Degree of dissolution and/or solution stability	All	CR	Required for water soluble formulations.		Endpoint

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
2.17	Wettability	All	CR	Required for solid formulations to be dispersed or dissolved in water.		Endpoint
2.18	Persistent foaming	All	CR	Required for formulations intended for dilution with water before use.		Endpoint
2.19	Particle size	All	CR	Required for formulations containing particles		Endpoint
2.20	Nominal size range	All	CR	Required for granular formulations		Endpoint
2.21	Dustiness	All	CR	Required for granular formulations		Endpoint
2.22	Attrition resistance & tablet integrity	All	CR	Required for granular and tablet formulations		Endpoint
2.23	Suspensibility	All	CR	Required for wettable powders (WP), suspension concentrates (SC), flowable concentrate for seed treatment (FS) which are diluted for use, capsule suspensions (CS), water dispersible granules (WG) and water dispersible tablets (WT)		Endpoint
2.24	Dispersibility and spontaneity of dispersion	All	CR	Required for suspension concentrates (SC), aqueous capsule suspensions (CS) and water dispersible granules (WG)		Endpoint
2.25	Wet sieve test	All	CR	Required for wettable powders (WP); suspension concentrates including those for seed treatment and oil-based (SC, FS and OD); water dispersible granules (WG) and water dispersible powder for slurry seed treatment (WS); aqueous capsule suspensions (CS); dispersible concentrates (DC); suspo-emulsions (SE); water-soluble and dispersible tablets (ST and WT); and emulsifiable granules and powders (EG and EP)		Endpoint
2.26	Dry sieve test	All	CR	Required for powders and granules intended for direct application and seed treatment		Endpoint
2.27	Emulsion stability	All	CR	Required for emulsifiable concentrates (EC), emulsions, oil in water (EW) and microemulsions (ME)		Endpoint
2.28	Flowability	All	CR	Required for water dispersible granules (WG), water soluble granules (SG), granules (GR) and emulsifiable granules (EG)		Endpoint

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
2.29	Pourability	All	CR	Required for suspension concentrates (SC, FS and OD), aqueous capsule suspensions (CS), suspo-emulsions (SE) oil-in-water emulsions (EW) and similarly viscous formulations, but may also be applied to formulations in solution, such as soluble concentrates (SL) and emulsifiable concentrates (EC)		Endpoint
2.30	Dispersion stability	All	CR	Required for suspo-emulsions (SE), emulsifiable granules (EG), emulsifiable powders (EP), dispersible concentrates (DC) and oil-based suspension concentrates (OD)		Endpoint
2.31	Miscibility with hydrocarbon oil	All	CR	Required for any formulation intended to be diluted with oil before use (e.g. OL)		Endpoint
2.32	Volatility	All	CR	Required for ultra-low volume liquids (UL)		Endpoint
2.33	Viscosity	All	CR	Required for formulations to be used at very low volume		Endpoint
2.34	Adhesion to seeds	All	CR	Required for seed treatment formulations		Endpoint
2.35	Dissolution of water-soluble bags	All	CR	Required for formulations packaged in water soluble bags		Endpoint
3	**METHODS OF ANALYSIS**					
3.1	Methods of analysis	All	R	Analytical methods for the determination of the active ingredient, impurities of toxicological concern and formulants in the formulated product. Refer to CIPAC methods, where applicable		Summary or Full method (depending on the presence of a pesticide analytical laboratory in the country)
4	**TOXICOLOGY**					
4.1	Acute oral toxicity	All	R	Not required if the product is a gas or a highly volatile liquid.	LD_{50} (mg a.i./kg bw)	Summary
4.2	Acute dermal toxicity	All	R	Not required if the product is a gas or a highly volatile liquid. Not recommended if the test material is corrosive to skin or has a pH of < 2 or > 11.5.	LD_{50} (mg a.i./kg bw)	Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
4.3	Inhalation toxicity	All	R	Required if the product consists of, or under conditions of use will result in, a respirable material (e.g. gas, vapour, aerosol or particulate).	LC_{50} (mg a.i./L)	Summary
4.4	Skin irritation	All	R	Not required if the product is corrosive to skin or has a pH of < 2 or > 11.5.	Categories for erythema/eschar formation, oedema formation, inflam-mation, reversibility of skin lesions	Summary
4.5	Eye irritation	All	R	Not required if the product is a gas or a highly volatile liquid. Not required if the product is corrosive to skin or has a pH of < 2 or > 11.5.	Categories for corneal opacity, iritis, conjunctival redness or oedema (chemosis), reversibility of eye lesions	Summary
4.6	Skin sensitization	All	R	Not required if the product is corrosive to skin or has a pH of < 2 or > 11.5. Required if repeated dermal exposure is likely under conditions of use.	Conventional test: skin reaction (e.g. erythema) LLNA: proliferation of lymphocytes in the lymph nodes	Summary
4.7	Dermal absorption.	All	CR	Dermal absorption data of the formulation may be provided when dermal exposure is a significant exposure route, and default absorption values result in no acceptable risk.		Summary
4.8	Other toxicity studies	All	CR	Additional toxicological studies with the formulated product may be required by the registration authority.		Summary

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
5	**EFFICACY**					
5.1	Efficacy data, demonstrating efficacy for the crops/pests for which a registration has been requested	All	R	(a) Where an applicant submits an application to one Partner State for registration of a product not registered in the region according to this guideline, the product shall be subjected to two (2) successful cropping seasons trials at two sites in different agro-ecological zones. Where a commercial crop is only grown in one agro-ecological zone, data from that one zone will suffice. (b) Where an applicant submits an application for registration of a product on the same crop/pest combination, simultaneously to more than one Partner State, two (2) cropping seasons on one site will be required in each of the respective Partner States and all data from the region will be submitted for assessment. Partner States conducting the trials should be required to avail raw data to the other participating Partner State(s) for decision making when necessary. For the purpose of these guidelines, simultaneous submission means submissions made within 3 months to different Partner States. A Partner State can make a decision on product approval on the basis of 4 data sets (of which 2 from local trials) from a simultaneous submission. (c) Where a trial on product has already been conducted for two cropping seasons at one site within a Partner State in accordance with this guideline, only one season of trials at two sites in different agro-ecological zones would be required in the next Partner State.		Full report

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
				(d) Where applications for label extensions (new uses) are submitted in a Partner State, the product will undergo one cropping season of efficacy trials at two sites in different agro-ecological zones in the Partner State. (e) If an applicant submits an application to more than one partner state for a label extension, one cropping season's trial shall be conducted at a representative site in each Partner State and all data from the region shall be submitted to the respective Partner States for decision-making. (f) Where an application for a label extension has been approved in one Partner State in accordance with these guidelines, one cropping season's trial shall be conducted at a representative site in each next Partner State and all data shall be submitted to the respective partner states for decision-making. (g) The above conditions for label extension apply to specific crop and pest combinations but may be adopted in the context of crop grouping and data extrapolation where a Partner State may have adopted this concept. (h) Efficacy trials should be conducted according to the *EAC Guidelines for Evaluating and Reporting the Efficacy of Pest Control Products for Plants.*		
5.2	Adverse effects (e.g. phytotoxicity, effects on succeeding or adjacent crops, development of resistance)	All	R	Observations to be included in the efficacy trials under 5.1, whenever possible. Specify any contraindications with respect to follow-up crops, adjacent crops etc		Full report
5.3	Good Agricultural Practices (GAP) table for all uses/crops/pests for which a registration has been requested, including:	All	R	Use OECD format for GAP table, or similar.		Table

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
5.3.1	Crop/area of use			The common name of the crop on which the product is aimed at should be clearly specified. When the product is not aimed at a crop, indicate the areas of use, e.g. livestock, public health, post-harvest		
5.3.2	Target organism			The target organisms should be identified by common and scientific name.		
5.3.3	Nature of effects on the target organisms			Nature of effects of the pesticide should be specified; e.g. contact action, whether the active ingredient is trans-located inside the organism, etc.)		
5.3.4	Application rate			The rate of application must be indicated on the basis area treated or volume used e.g. l/ha, g/ha, l/m^3 etc.		
5.3.5	Application frequency			Specify the minimum and maximum number of treatments per year or per growing season		
5.3.6	Method of application			Specify the methods(s) of application of the product that are recommended to be used		
5.3.7	Stage of treatment			Specify the stage of the crop or target organism at which application must be made		
5.3.8	Pre-harvest interval or waiting period			Minimum time needed between the last treatment and harvest, re-entry of livestock, entry of workers, etc.		
5.4	Data on efficacy, as well as on effects on beneficial organisms, of the use of the pesticide within IPM/IVM	All	CR	Required in case a claim of compatibility within IPM/IVM is made		Full report
6	**OTHER INFORMATION**					
6.1	Material Safety Data Sheet (MSDS)	All	R			
6.2	Hazard classification (WHO)	All	R	Provide the hazard classification of the formulated product according to the *WHO classification of pesticides by hazard*		

	Data	Use pattern	Conditions	Remarks	Endpoint of Study	Level of detail
6.3	Hazard classification (GHS)	All	R	Provide the complete hazard classification of the formulated product according to the *Globally Harmonized System of classification and labelling of chemicals (GHS).* This includes physical hazards, health hazards and environmental hazards, as far they product triggers a hazard classification		
6.4	Emergency measures in case of exposure or poisoning	All	R	Include information on treatment of poisoning and antidotes (if relevant)		
6.5	Emergency measures in case of spillage or fire	All	R	Include decontamination procedures and neutralizing chemicals (if relevant), and information of combustion products likely to be generated in case of fire		
6.6	Type of packaging, pack size(s) and (in-) compatibility with the formulation	All	R			
6.7	Procedures for cleaning application equipment	All	R			
6.8	Risk statements and precautionary statements	All	R	Statement of risks arising from the recommended methods, and precautions and handling procedures to minimize those risks, including: storage; transport; protective clothing; procedures to minimize generation of waste		
6.9	Pyrolytic behaviour	All	R	Pyrolytic behaviour of the active substance under controlled conditions at 800 °C, and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis		
6.10	Disposal procedures for the pesticide	All	R	Provide realistic safe disposal method of the product		
6.11	Proposed label	All	R	Provide a realistic mock-up of the proposed label, as required by respective member state pesticide laws.		
6.12	Registration of the product in other countries	All	R	Provide a complete list of registrations of the formulated product in other countries. Specify for which uses the product has been registered, as well as national or regional registration numbers and expiry dates. Indicate whether the product is registered in the country of formulation and/or manufacture; if the product is not registered, indicate why this is the case.		

East African Community

One People, One Destiny

National logo/crown

APPLICATION FORM FOR THE REGISTRATION OF A PEST CONTROL PRODUCT IN PARTNER STATES OF THE EAST AFRICAN COMMUNITY (EAC)

Form A1

Information for applicants

1. The applicant is the natural or legal person that manufactures the pest control product and/or places it on the market. After approval of the registration, the applicant will become the registration holder of the product.

2. The applicant shall be a legal entity in – *name of EAC country* –, or be represented by a local agent who is a permanent resident in – *name of EAC country* – and duly recognized by the national pesticide registration authority.

3. The application form shall be completed by a person duly authorized by the applicant.

4. The application shall be submitted in triplicate to:

   – name and address of the national pesticide registration authority –

5. Every application must be accompanied by:

   a) proof of payment of the application fee as prescribed by the national pesticide registration authority;

   b) three (3) copies of the draft label

   c) three (3) copies of the technical dossier as per the data requirements detailed in List I (active ingredient) and List II (formulated product).

6. The applicant may be required to submit:

   a) Registration authorization letter: In case the applicant is not the owner of the TGAI/product, provide a letter in which the owner of the TGAI/product authorizes the applicant to apply for registration;

   b) sample of the pest control product, for bio efficacy trial purposes;

   c) a sample of the pest control product for residue trial purposes;

   d) a sample of the technical grade of its active ingredient(s);

   e) a sample of the analytical standard of its active ingredient(s);

   f) any other sample as may be required by the pesticide registration authority

1	**PRODUCT**	
1.1	Product name (brand name)	
1.2	Type of formulation (CropLife code[1])	
1.3	Active ingredient(s) (common name)	
1.4	Active ingredient concentration(s)	
1.5	Patent status and expiry date (if applicable)	
1.6	Quick Response (QR) code (if available)	
2	**APPLICANT**	
2.1	Applicant name (corporate name of company)	
2.2	Status	☐ manufacturer ☐ formulator ☐ other: ….
2.3	Business registration number	
2.4	Physical address	
2.5	Postal address	
2.6	Telephone number	
2.7	E-mail address	
2.8	Web site	
2.9	Contact person at applicant company	
2.10	Contact person telephone number	
3	**LOCAL AGENT**	
3.1	Local agent name (corporate name of company) (if different from applicant)	
3.2	Status	☐ formulator ☐ importer ☐ distributor ☐ other: ….
3.3	Business registration number	
3.4	Physical address	
3.5	Postal address	
3.6	Telephone number	
3.7	E-mail address	
3.8	Contact person at local agent	
3.9	Contact person telephone number	

[1] The CropLife code is the two-letter code for the type of formulation according to the Crop Life International Catalogue of pesticide formulation types and international coding system. It can be found at: https://croplife-r9qnrxt3qxgjra4.netdna-ssl.com/wp-content/uploads/2017/04/Technical-Monograph-2-7th-Edition-Revised-March-2017.pdf

4	**PURPOSE OF APPLICATION**			
a	☐ New pest control product containing a new active ingredient (a.i.)			
b	☐ New pest control product containing an a.i. already registered in the country			
c	☐ New source of active ingredient and/or formulation of an existing registration			
d	☐ Amendment or extension to an existing registration			
e	☐ Registration transfer (between registrants)			
f	☐ Other (specify):	…		
5	**INTENDED USE**			
5.1	Function/category of product (more functions/categories possible)	☐ Insecticide	☐ Fungicide	☐ Herbicide
		☐ Acaricide	☐ Rodenticide	☐ Molluscicide
		☐ Bactericide	☐ Defoliant	☐ Plant growth regulator
		☐ Other (specify):	…	
5.2	Type of use (more types possible)	☐ Agriculture	☐ Veterinary	☐ Public health
		☐ Household	☐ Forestry	☐ Industrial
		☐ Other (specify):	…	
5.3	Target pest(s)/disease(s) and crop(s)/use(s)	1	…	
		2	…	
		3	…	
		4	…	
6	**HAZARD CLASSIFICATION**			
6.1	WHO Hazard Class of the formulated product	☐ Class Ia	☐ Class Ib	☐ Class II
		☐ Class III	☐ Class U	
6.2	GHS classification of the formulated product (list all classifiable hazards)			
	Physical hazards	…		
	Health hazards	…		
	Environmental hazards	…		

7	**DECLARATION**	
	For and on behalf of ……. I hereby certify that the above-mentioned information, as well as the data provided in the technical dossier, in support of this application are true, correct and complete.	
	…… Name in full (print)	…… Signature
	…… Official title	…… Date
	Official stamp of applicant/company	
8	**FOR OFFICIAL USE**	
	Application No: …	Remarks: ….
	Reception date: …	
	Fees received: ☐ Yes ☐ No	
	Amount paid:	
	Status of application:	☐ Approved ☐ Rejected ☐ Pending