Annex I

THIS STANDARD COVER LETTER IS TO BE TYPED ON APPLICANT'S COMPANY LETTERHEAD

Date :

Secretary
Pesticides Board
Pesticides Control and Fertilizers Division
Department of Agriculture
4th – 6th Floor, Wisma Tani
Jalan Sultan Salahuddin
50632 Kuala Lumpur

Dear Sir,

APPLICATION TO REGISTER/RE-REGISTER PESTICIDE

Herewith is an application to register/re-register *

_____

(*State trade name*)

(*Please tick whichever is applicable*)

[___]	Commodity Pesticide		
[___]	Proprietary Pesticide		
[___]	**New Registration**	[___]	**Re-registration**
			LRMP/R1 No. : ..... File No. : JP KRP 207/12/171/.....
[___]	5 sets of application (Form A**)	[___]	1 set of application (Form A**)
[___]	5 sets (1 original + 4 copy) of data requirements (Part E- Form A**)	[___]	1 copy of endorsed printed label
[___]	4 copy of proposed label in each set and each packsize	[___]	4 copies of amended draft labels
[___]	Summary of Data Requirements for Pesticides Registration	[___]	Copy of current Registration Certificate
As per circular JP/KRP/207/12/656/2/Jld.VI(74) dated 22 January 2019		As per circular JP/KRP/207/12/656/2/Jld.VI(65) dated 13 January 2017	

APPLICABLE TO REGISTRATION & RE-REGISTRATION

[___] Sample suitably packed and labeled. (With copy of Import Permit, if applicable)

[___] Sample of analytical standard suitably packed and labeled. (With copy of Import Permit, if applicable)

[___] Letter of Certification from source of the pesticide (LOS) (For TGAI and formulated product)

[___] Letter of Authorization on the use of data (LOA)

[___] Certified Letter of Country of Origin (COO) (e.g. Registration Certification of Product/Manufacturing Licence)

[___] Copy of Company Registration (ROC/ROB)

THE SOURCE OF THE PESTICIDE WILL BE OBTAINED FROM THE FOLLOWING MANUFACTURER(S):

a) Source of Technical Material (TGAI)

i. ……

b) Manufacturer of Product (Formulated Product)

i. ……....

c) Invoicing, Shipping, Exporter (if applicable)

i. ……

Thank you.

Yours faithfully,

_____
(Name and Signature of
Applicant & Company Stamp)

[**KEY** : FORM A** - Application Form, Form A [Subrule 2(1)] (Application For Registration/Re-registration Of A Pesticide)]

Annex II

SUMMARY OF DATA REQUIREMENTS FOR COMMODITY AND PROPRIETARY PESTICIDES ACCORDING TO GENERAL USE PATTERN (REFER APPLICATION FORM, FORM A [SUBRULE 2(1)] (APPLICATION FOR REGISTRATION/RE-REGISTRATION OF A PESTICIDE); PART E: PARTICULARS ON DATA REQUIREMENTS)

Chapter	General Use Pattern							Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	Technical Concen-trate (TK)	
CHAPTER 1: **IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES (Refer to GP1/2015)**								
Part A : Requirement On Technical Active Ingredient (TGAI)								
1.1 Manufacturer name and contact information	√	√	√	√	√	√	√	
1.2 ISO common name and synonym	√	√	√	√	√	√	√	
1.3 Chemical name	√	√	√	√	√	√	√	
1.4 Existing CAS and CIPAC number	√	√	√	√	√	√	√	
1.5 Identity and composition	√	√	√	√	√	√	√	
1.6 Specification of purity of active ingredient	√	√	√	√	√	√	√	**Must** comply with **FAO Standards.**
1.7 Molecular formula, molecular mass and molecular structure	√	√	√	√	√	√	√	
1.8 Method of manufacturing process *(starting material, pathway, byproducts and impurities)* and quality control.	√	√	√	√	√	√	√	Endorsed by QA Manager.
1.9 Identity, content, structural formula of isomer, impurities and additive.	√	√	√	√	√	√	√	
1.10 Data on five batch analysis including the profile of impurities and chromatogram.	√	√	√	√	√	√	√	**Must** comply with the standards of **Good Laboratory Practices (GLP).**
1.11 Safety Data Sheet (SDS).	√	√	√	√	√	√	√	Trade name stated on SDS **must be the same** with registered product.

Chapter	General Use Pattern							Notes
	Food Commodity	**Non-Food Commodity**	**Indoor/ Household**	**Outdoor/ Public Health**	**Forestry**	**Technical Material (TC)**	**Technical Concentrate (TK)**	
1.12 Physical and chemical properties: *a) Appearance* • *Physical state, color or odor* *b) Melting point* *c) Boiling point* *d) Specific gravity/ density* *e) pH* *f) Volatile point* *g) Vapour pressure* *h) Flash point* *i) Solubility in water* *j) Solubility in organic solvents* *k) n-octanol/water partition coefficient* *l) Hydrolysis rate, photolysis (under stated conditions)* *m) K_{ow}* *n) Dissociation constant (pKa, pKb)*	√	√	√	√	√	√	√	**Must** comply with the standards of **Good Laboratory Practices (GLP).** Notes: Item *(a – n)* : if applicable depending on active ingredient or physical state
Part B : Requirement On The Formulation *(if relevant)* (FORMULATION/ FINISHED PRODUCT)	Data for technical grade of active ingredient (TGAI) is required on cases where TGAI is not registered with Pesticides Board but its formulated product (ready-made) is directly imported and is intended to be registered.							
1.13 Manufacturer name and contact information	√	√	√	√	√	-	-	
1.14 Detail qualitative and quantitative information of the composition of preparation	√	√	√	√	√	-	-	Endorsed by QA Manager.
1.15 Method of manufacturing process *(material used and condition required)*	√	√	√	√	√	-	-	Endorsed by QA Manager.
1.16 Type of formulation and function	√	√	√	√	√	-	-	

Chapter	General Use Pattern							Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	Technical Concen-trate (TK)	
1.17 Physical and chemical properties: *a) Appearance* • *Physical state (for all formulation)* *b) Corrosiveness* *c) Flammability (if applicable)* *d) Known compatibility with other chemicals (only to be performed when tank mix is recommended on the label)* *e) Oxidation/reduction: chemical incompatibility (only to be performed when tank mix is recommended on the label)* *f) Rate of release, or release/retention index, of active ingredient (for slow-release granules (CG), slow-release capsule suspensions (CS), long lasting insecticidal nets (LN).* *g) "Free" active ingredient (For slow release granules (e.g: encapsulated granules, CG) and slow release capsule suspensions (CS).* *h) By-products of manufacture or storage (all specifications where relevant impurities may be associated with active ingredient* *i) Acidity or alkalinity and if necessary pH* *j) Explosivity*	√	√	√	√	√	-	-	Notes: Item *(a – j)* : if applicable depending on active ingredient or type of formulation

Chapter	General Use Pattern							Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	Technical Concen-trate (TK)	
1.18 Specific Properties/ Test Related to Use: *a) Wettability* *b) Persistent foaming* *c) Suspensibility* *d) Wet sieve test* *e) Dry sieve test* *f) Emulsion stability* *g) Dilution stability* *h) Flowability* *i) Pourrability* *j) Dustability* *k) Distribution and - adherence to seed* *l) Others*	√	√	√	√	√	-	-	Please refer to **Appendix I, II, III** in Summary Data. **Must** comply with **FAO Standards.**
1.19 Storage stability test *(FAO Accelerated Storage Test Procedures may be employed)*	√	√	√	√	√	-	-	Comply with the standards of **Good Laboratory Practices (GLP) / ISO 17025.**
1.20 Specifications of the product *(indicate whether it meets any specifications e.g. Malaysian Standard, FAO/WHO specification or others)*	√	√	√	√	√	-	-	
1.21 Safety Data Sheet (SDS)	√	√	√	√	√	-	-	Trade name stated on SDS **must be the same** with registered product.
1.22 Packaging *(including packaging material and its compliance to any standards or specifications)*	√	√	√	√	√	-	-	
1.23 Data on five batch analysis of the active ingredient including chromatogram	√	√	√	√	√	-	-	Compulsory**.**

Chapter	General Use Pattern							Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	Technical Concen-trate (TK)	
CHAPTER 2 : **METHOD OF ANALYSIS (Refer to GP1/2015)**								
2.1 Validated methods of analysis of active ingredient in the technical material	-	-	-	-	-	√	√	
2.2 Validated method of analysis of active ingredient content in the formulation	√	√	√	√	√	-	-	
2.3 Validated methods of analysis of content of impurities in the technical material and formulation.	√	√	√	√	√	√	√	
2.4 Validated methods of analysis for residue of the active ingredient and all important metabolites in all relevant matrix of the crops.	√	-	-	-	-	-	-	
2.5 Validated methods of analysis for residue of the active ingredient and all important metabolites in environmental media.	√	√	-	√	√	-	-	
2.6 Analytical standard should not be shared among registered products.	√	√	√	√	√	√	√	

Chapter	General Use Pattern						Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	
<u>CHAPTER 3</u> : **IMPACT ON HUMAN AND ANIMAL (MAMMALIAN TOXICOLOGICAL DATA) (Refer to GP2/93)**							
Part A : Requirement On Technical Active Ingredient (TGAI)							**MUST** comply with the Standards od **Good Laboratory Practices (GLP).**
3.1 Acute toxicological data							
3.1.1 Acute oral studies *(in rats)*	√	√	√	√	√	√	Not required if test material is a gas or highly volatile.
3.1.2 Acute dermal studies *(in rats)*	√	√	√	√	√	√	Not required if test material is a gas or highly volatile. Not required if test material is highly corrosive to skin or has pH of < 2 or > 11.5.
3.1.3 Acute inhalation studies *(in rats)*	√	√	√	√	√	√	Required if the end-use product consists of, or under the conditions of use will result in, a respirable material *(e.g. gas, vapour, aerosol, or particulate)*.
3.1.4 Skin irritation studies *(in rabbits)*	√	√	√	√	√	√	Not required if the pesticide is a gas or highly volatile liquid, or if it is corrosive to skin or has a pH of < 2 or > 11.5.
3.1.5 Eyes irritation studies *(in rabbits)*	√	√	√	√	√	√	Not required if the pesticide is corrosive to the eye, or has a pH of < 2 or > 11.5.
3.1.6 Dermal sensitisation study *(in guinea pigs)*	√	√	√	√	√	√	Not required if the pesticide is corrosive to skin or has a pH of < 2 or > 11.5.
3.1.7 Acute delayed neurotoxicity in hens *(for organophophates and carbamates)*	√	√	√	√	√	√	Required for active ingredient under group organophosphates and carbamates.

Chapter	General Use Pattern						Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	
3.2 Sub-acute toxicological data							Not required for commodity pesticide, unless acute toxicity profile indicates that there is a strong possibility that sub-acute exposure can result in significant negative effects.
3.2.1 Repeated dose 21 or 28 days dermal toxicity *(in rats)*	√	√	√	√	√	√	
3.2.2 Repeated dose 28 days oral delayed neurotoxicity in hens *(organophosphates and carbamates if triggered by findings of acute delayed neurotoxicity)*	√	√	√	√	√	√	Required for active ingredient under group organophosphate and carbamates.
3.2.3 Sub-acute 90 days dietary feeding study *(in rats)*	√	√	√	√	√	√	
3.3 Chronic toxicological data							Not required for commodity pesticide, unless acute and sub-chronic toxicity profile indicates that there is a strong possibility that chronic exposure can result in significants negative effects.
3.3.1 Chronic dietary feeding study *(24 monts in rats, 18 months in mouse and 1 year in dogs)*	√	√	√	√	√	√	
3.3.2 Oncogenicity *(carcinogenicity) study (not less than 24 months for rats and 18 months for mouse. This study can be combined with chronic feeding study, if appropriate)*	√	√	√	√	√	√	
3.4 Supplemental toxicological data							Not required for commodity, unless its toxicity profile/ use recommendations indicates that there is a strong possibility that exposure can result in long-terms significant negative effects in relation to the aspects as stated below.
3.4.1 Teratogenicity study *(2 species, one rodent and one non-rodent)*	√	√	√	√	√	√	

Chapter	General Use Pattern						Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	
3.4.2 Reproductive study *(2 generations of rodents and one litter).*	√	√	√	√	√	√	
3.4.3 Mutagenicity study *(at least in 3 battery of tests to detect gene mutation, chromosomal aberration and genotoxic (micronucleus test) effects)*	√	√	√	√	√	√	
3.4.4 Metabolic study *(at least one species)*	√	√	√	√	√	√	
3.5 Human toxicology data *(such as industrial exposure data, accidental data or volunteer data)*	√*	√*	√*	√*	√*	√*	If available. Particularly needed are poisoning data and information on antidotes.
3.6 Toxicological information of every ingredient, synergist, and major or important impurity of the pesticides.	√*	√*	√*	√*	√*	√*	If available.
Part B : Requirement On The Formulation (FORMULATION/ FINISHED PRODUCT) *(if applicable)*							**MUST** comply with the Standards of **Good Laboratory Practices (GLP).**
3.7 Acute oral toxicity study *(in rats)*	√	√	√	√	√	_	
3.8 Acute dermal toxicity study *(in rats)*	√	√	√	√	√	_	
3.9 Skin irritation study *(in rabbits)*	√	√	√	√	√	_	
3.10 Eye irritation study *(in rabbits)*	√	√	√	√	√	_	
3.11 Skin sensitisation study *(in guinea pigs)*	√	√	√	√	√	_	
3.12 Acute inhalation study in rats *(if applicable)*	√	√	√	√	√	_	

Chapter	General Use Pattern						Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	
<u>CHAPTER 4</u> : **RESIDUE (Refer to GP4/2012) :** All reports submitted must be very recent and shall **not be more than 15 years** from the date of submission.							**Residue data is required.**
4.1 Definitions of the residue to Maximum Residue Limits (MRLs)	√	-	-	-	-	-	
4.2 Detailed reports on supervised residue trial on recommended crops based on accepted protocols *(e.g. FAO Manual on the Submission and Evaluation of Pesticide Residue Data for the Estimation of Maximum Residue Limits in Food and Feed, FAO, UN 2002)*. Studies conducted under similar climatic conditions may be submitted.	√	-	-	-	-	-	At least **three (3)** field experiments done at different sites must be submitted. For a **major crop**, which is oil palm, cocoa, paddy and black pepper, at least one field experiment must be generated under local conditions. * Residue data is not required for young oil palm (< 2 years), seed treatment, seedling stage, and pre-planting stage.
4.3 Residue analytical method with chromatograms for standard, control, sample and recovery test.	√	-	-	-	-	-	Analytical method by crop.
4.4 Information on metabolism or degradation of the active ingredient in crops or plants.	√	-	-	-	-	-	**Mandatory** for proprietari a.i
4.5 Acceptable Daily Intake (ADI) of the pesticide in mg/kg body weight.	√	-	-	-	-	-	ADI by a.i
4.6 Proposed Pre-harvest interval (PHI) or Pre-Slaughter Interval (PSI).	√	-	-	-	-	-	PHI by crop.
4.7 Proposed Maximum Residue Limits (MRLs) calculated based on Dietary Risk Assessment of the pesticide.	√	-	-	-	-	-	Proposed MRL by crop.
4.8 Maximum Residue Limits (MRLs) from other countries that have registered the pesticide.	√	-	-	-	-	-	MRL by crop.

Chapter	General Use Pattern						Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	
<u>CHAPTER 5</u> : **FATE AND BEHAVIOUR IN THE ENVIRONMENT (Refer to GP2/93)**							
5.1 Definition of the residue relevant to the environment	√	√	√*	√	√	√	
5.2 Degradation and dissipation studies *(hydrolysis, photolysis in water and soil)*	√	√	√*	√	√	√	
5.3 Metabolism studies *(in water and soil for both aerobic and anaerobic conditions)*	√	√	√*	√	√	√	
5.4 Mobility studies *(leaching and adsorption or desorption studies, volatility in laboratory and field)*	√	√	√*	√	√	√	
5.5 Fate and behavior in air	√	√	√*	√	√	√	
5.6 Bioaccumulation study in fish	√	√	√*	√	√	√	
<u>CHAPTER 6</u> : **EFFECTS ON NON TARGET SPECIES (Refer to GP2/93)**							
6.1 Effects on terrestrial vertebrates *(including acute oral toxicity to avian species e.g. pigeon, quail, pheasant, or duck)*	√	√	-	√	√	√	
6.2 Effects on aquatic species							
6.2.1. Acute LC_{50}, 96 hours exposure on the suitable fish species	√	√	-	√	√	√	
6.2.2. Acute LC_{50}, 48 hours exposure on one suitable fish-food species *(e.g. daphnia)*	√	√	-	√	√	√	
6.3 Effects on bees and other arthropod species *(including acute oral LD_{50}, and contact toxicity on honey bees)*	√	√	-	√	√	√	
6.4 Effects on earthworms and other soil macro-organisms *(including acute toxicity on earthworms)*	√	√	-	√	√	√	
6.5 Effects on other non-target organisms *(flora and fauna)*	√	√	-	√	√	√	

Chapter	General Use Pattern						Notes
	Food Com-modity	Non-Food Com-modity	Indoor/ House-hold	Out-door/ Public Health	Forestry	Technical Material (TC)	
<u>CHAPTER 7</u> : **EFFICACY DATA AND INFORMATION (Refer to GP3/93)** • All reports submitted must be very recent and shall **not be more than 15 years** from the date of submission. • Not required for HERBICIDE if the active ingredient and its formulation is listed in GP5**.** *Please refer latest circular dated 26 February 2013. • Journal data on bio-efficacy trial is acceptable.							
7.1 Local Bio-efficacy trials on the recommended crops based on the accepted protocols *(e.g. FAO Harmonized Bio-efficacy Protocols). Trials conducted under similar climatic regime and cultural practices may be used for minor crops)*	√*	√	-	-	√	-	* Not required for veterinary products. - **Must** submit bio-efficacy trial data **for each crop.** - For a **major crop**, which is oil palm, cocoa, paddy and rubber, **one field experiment** (with multiple replicates) must submit bio-efficacy trial generated under **local conditions.** - For non-major crop, bio-efficacy trial from overseas is acceptable.
7.2 Phytotoxicity assessment on crops based on accepted protocols *(e.g. FAO Guidelines for Phytotoxicity Assessment)*	√*	√	-	-	√	-	* Not required for veterinary products.
7.3 Effects on natural Enemies	√*	√	-	-	√	-	* Not required for veterinary products.
7.4 Information on potential occurrence to resistance	√	√	-	-	√	-	
7.5 Comparative study using Malaysian Standard or other internationality accepted protocols for all non-agriculture pesticides	√*	-	√	√	-	-	* Not required for agricultural products.
7.6 Information on mode of action and its grouping.	√	√	√*	-	√	-	* Not required for household pesticides.
7.7 Propose use(s) and Recommendation in tabulated form - tabulated format - statement format	√	√	√*	√	√	-	*Depending on the type of usage. Refer to *Garis Panduan Pelabelan*.

[**KEY** : (√) = Required; (√*) = Conditionally required and (-) = Not required]

EXAMPLES OF GENERAL USE PATTERNS

Food Commodity ▪ Agricultural crops for human consumption ▪ Veterinary	**Indoor / Household** ▪ Household Pesticides ▪ Household Insecticides ▪ Rodenticides for household use ▪ Pet animals pesticides ▪ Termite control inside buildings ▪ Commercial and industrial uses - Eating establishment - Transportation facilities - Building and structures	**Forestry** ▪ Forest trees including dead trees, logs and stumps ▪ Forest tree nurseries ▪ Non-ornamental trees including rubber trees
Non-food Commodity ▪ Crop for smoking ▪ Medicinal crops ▪ Ornamental plants ▪ Lawn and turf grasses ▪ General soil treatments ▪ Recreational areas ▪ Roads, tracks and paved areas	**Outdoor** ▪ Wood treatments ▪ Antifouling treatments ▪ Public health ▪ Preservative ▪ Termite control outside buildings ▪ Domestic ornamental platings	**Technical Material** ▪ Technical material for manufacturing purposes