GUIDEBOOK ON THE REGISTRATION OF PESTICIDES AND REPELLENTS AGAINST VECTORS

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GLOSSARY OF TERMS

Terms	Description
Active ingredient (A.I.)	Any substance contained in a pesticide or vector repellent which is responsible for the effect that the pesticide or vector repellent has on vectors.
Acute toxicity	The potential for a substance to result in adverse effects to an organism soon after exposure. The acute toxicity of a compound is established through scientifically verifiable data from animal studies or human exposure tests.
Botanical active ingredient	Any substance derived from plants that is responsible for the pesticide or repellent effect on the vectors. The substance can be obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/ or extractions. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified or altered by chemical and/or microbial processes.
Botanical product	A product containing botanical active ingredient(s).
Chemical product	A product containing a synthetic chemical and/ or a biochemical as the active ingredient(s).
Chronic toxicity	The potential for a substance to result in adverse effects to an organism after long-term exposure. The chronic toxicity of a compound is established through scientifically verifiable data from animal studies or human exposure tests.
Contaminant	An unexpected substance or material, or a mixture, occurring by any means in a technical or formulated pesticide. See also Impurity.
Dealer	Dealer would include the importer, manufacturer, distributor and/or seller of a pesticide or vector repellent.
Dermal/skin sensitization	Immunological response to previous exposure to a substance which results in an inflammatory skin reaction.
Dossier	Data package that is submitted by an applicant, in a structured manner, in support of an application for registration of pesticide or repellent product.
Formulant	Any substance, other than an active ingredient(s), intentionally incorporated in a formulation. Also known as an inert ingredient.
Formulation	The combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application.
Impurity	A by-product arising from the manufacture of the active ingredient or derived from the active ingredient during formulation or storage. For the purposes of this Guidebook, the definition does not include impurities derived solely from formulants or other additives, before or during storage. See also Contaminant.
Microbial product	Product containing a microorganism and any associated metabolites/toxins as the active ingredient.
Microbial active ingredient	A microorganism (protozoan, fungus, bacterium, virus, or other microscopic self-replicating biotic entity) (revised ISPM Pub. No. 3. IPPC, 2005) and any associated metabolites, to which the effects of pest control are attributed (OECD, 2008). A microbial active ingredient may contain viable and/ or non-viable microorganisms. It can contain relevant metabolites/toxins produced during cell proliferation (growth), material from the growth medium, provided none of these components have been intentionally altered.

Novel product	Product that fulfils one of the following: a) Formulated with new active ingredient: an active ingredient is considered to be "new" if it is not found in the current registry of vector control products maintained by NEA; or b) Its application may significantly modify the safety and efficacy of an existing active ingredient within the same product, for example nano-pesticides.
Pesticide	Any solid, liquid or gaseous substance or mixture or preparation of such substances which contains one or more active ingredients and which is used for vector control, but does not include any fumigant controlled under the Hydrogen Cyanide (Fumigation) Act (Cap. 132).
Primary skin irritant	Substance which produces direct skin inflammation on contact.
Product (or pesticide product or repellent product)	End-use product (active ingredient(s) and formulant(s)) in the form in which it is packaged and sold.
Relevant impurity	A by-product of the manufacture or storage of a pesticide which, compared with the active ingredient, is toxicologically significant to health or the environment, affects the stability of the pesticide, or causes any other adverse effect.
Repellent	Any solid, liquid or gaseous substance or mixture or preparation of such substances which contains one or more active ingredients and which is used or intended to be used for repelling vectors.
Residual effect	Duration of protection and effectiveness afforded by each application.
Significant impurity	Impurity level exceeding 0.1% of weight of the active ingredient.
Toxicity	Inherent property of an agent to cause an adverse biological effect.

SECTION ONE: INTRODUCTION

1.1 Control of Vectors and Pesticides Act (CVPA)

All pesticide and repellent products intended for use against the five vectors (i.e. mosquitoes, flies, rodents, cockroaches and rat fleas) in Singapore are required to be registered with the National Environment Agency (NEA). It is an offence under the Control of Vectors and Pesticides Act (CVPA) for any person to advertise, sell or supply vector control pesticides and repellents which are not registered. The maximum fine for an offence is $20,000 and/or 3 months' jail for the first conviction, and $50,000 and/or 6 months' jail for subsequent convictions.

The main objectives of this registration are to ensure that the pesticide and repellent products sold in Singapore are:

(a) Effective for their intended use;
(b) Unlikely to pose undue hazards to the public and the environment; and
(c) Properly labelled.

It is the responsibility of the dealer to ensure the safety, efficacy and quality of the product.

1.2 Types of Pesticides and Repellents Required for Registration

1.2.1 Registration Based on Pesticide Hazard Classification

Pesticide and repellent products are registered under the following categories:

(a) For General Use: can be used by households directly. The formulated product should be "Unlikely to present acute hazard in normal use" (based on the "WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009").

(b) For Restricted Use: shall only be handled by licensed pest control operators. The formulated product may have high toxicity or concentration, and/or require further mixing/dilution and/or specialised equipment for the application of the product. All rodenticide products are required to be registered as "For Restricted Use".

A Hazardous Substances Licence/Permit issued by the Development Control & Licensing Division (National Environment Agency) is required, prior to registration, for pesticides or repellents containing any hazardous substance controlled under the Environmental Protection and Management Act (EPMA). Please refer to the NEA website for the latest list of hazardous substances controlled and requirements under the EPMA.

1.2.2 Pesticide Classification Based on Type of Active Ingredients

Pesticide and repellent products can be further classified into chemical, microbial, or botanical products, based on the type of active ingredients.

1.2.3 Pesticide and Repellent Products Not Required for Registration under CVPA

The following products, unless specifically required by NEA, are not subjected to registration with NEA prior to advertising, sale or supply of the products:

(a) Fumigants, which are controlled under the Hydrogen Cyanide (Fumigation) Act;
(b) Pesticides/repellents imported solely for re-export purpose;
(c) Pesticides/repellents solely for agricultural and/ or for gardening use (please seek advice from the SFA (Singapore Food Agency) on the registration of agricultural pesticides);
(d) Pesticides/repellents that do not target the five mentioned vectors (i.e. mosquitoes, flies, rodents, cockroaches and rat fleas);
(e) Pesticides/repellents whose mode of action is physical in nature (e.g. light and ultra-sound);
(f) Repellents formulated with botanical active ingredients.

It is the responsibility of the dealer to ensure the safety, efficacy and quality of the products. These products shall not contain any ingredients of toxicological concern, including but not limited to carcinogens, mutagens and reproductive toxic agents.

1.3 Product Register

Please refer to the NEA website for the list of pesticides and repellents registered with NEA.

SECTION TWO: PROCEDURES FOR THE REGISTRATION OF PESTICIDES AND REPELLENTS

2.1 General Information on Submitting an Application

Any person who advertises, sells and/ or supplies any pesticide and/ or repellent products locally, and is registered under the Business Registration Act/ Accounting and Corporate Regulatory Authority (ACRA) to carry out business in Singapore, or in the case of a company, incorporated under the Companies Act, may apply for the registration.

The application form can be downloaded from the NEA website.

Each application form is for the registration of **one** pesticide/ repellent product only. **The completed application form together with all the relevant documents stated in Section 2.3 is to be emailed to NEA_VC_Licences@nea.gov.sg.**

The flow chart in Annex 1 shows how applications are processed by NEA.

2.2 Registration Fee

A non-refundable registration fee of $160 per pesticide/repellent product shall be paid once the registration is approved.

2.3 Data Requirement for Registration

The following documents are required to be submitted as part of the dossier for the registration of pesticide and repellent products. NEA reserves the right to ask for additional information for areas that need further evaluation.

(a) Application form with completed fields;

(b) A copy of the full Computer Information Business Profile from ACRA of Singapore;

(c) A copy of the applicant's NRIC/ work permit/ employment pass/ PR status/ re-entry permit;

(d) Approval from other relevant authorities (if any). For pesticides and/ or repellents containing any substance under the Second Schedule in the Environmental Protection and Management Act, a copy of the Hazardous Substances Licence/ Permit issued by the Development Control & Licensing Division (National Environment Agency) shall accompany the application;

(e) A copy of the proposed label of the product (please refer to Section 2.6 and Annex 2);

(f) Data to substantiate product claims of content, safety, efficacy and quality. Studies or tests shall be conducted in accordance with the principles of Good Laboratory Practice (GLP) and internationally recognized testing guidelines and methods, such as those published by the Organization for Economic Co-operation and Development (OECD), the Collaborative International Pesticides Analytical Council (CIPAC), Food and Agriculture Organization (FAO) and World Health Organization (WHO).

Failure to submit credible, valid and relevant data will result in the denial of registration. It is therefore crucial that all studies and test reports submitted be based on studies on the product and/or active ingredient(s), and must bear the source and origin from

where the documents are obtained. Documents, especially technical reports (e.g. Safety Data Sheet (SDS) and efficacy report of the product), that are self-generated or extracted from technical bulletins or from the internet, will not be accepted unless the reports are GLP-compliant.

The following is a brief description of the data to be provided to support an application for registration. Details of data requirements for registration of chemical, microbial and botanical pesticides and repellents are listed in Annex 5. Requests for data waivers shall be considered on a case-by-case basis and be based on the properties of the active ingredients and products

(i) Content

Data and information on the identity and composition of the formulated pesticide and/ or repellent product, including information on the active ingredient, inert ingredient, significant impurities (if any) and relevant impurities (if any).

(ii) Safety

Toxicity data of the formulated product and/or active ingredient(s) are required to be submitted to assess the potential risks to human health and environment from the pesticide or repellent intended for registration.

- Toxicity (potential human health impact): acute toxicity study reports are required for submission to assess the potential immediate hazard to human health. If adverse effects are noted in the acute studies, additional studies may be required to verify product safety. Should the full toxicity studies of the product be unavailable, toxicity values of the product may be calculated in accordance with international guidelines. For this purpose, please refer to "The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009" for more information. All data used in the calculation must be justified with supporting documents (e.g. toxicity study reports of the active ingredient(s) and/ or the proposed surrogate product with a similar composition).
- Ecotoxicity: data on the ecotoxicities of the product and its metabolites and degradants are required for submission to assess potential adverse effects on non-target organisms in the environment, which generally include birds, fish, arthropods, aquatic invertebrates and algae.

(iii) Product Efficacy

Bio-efficacy study reports shall be provided to demonstrate the efficacy of the product against the target vector(s) when used in accordance with the recommended direction of use. Efficacy field trials, if required, should be conducted under tropical climatic conditions similar to Singapore. Reports should include detailed descriptions of the objectives, experimental design for meeting such objectives, raw data and statistical results as well as discussion of appropriate data analysis.

Additional data may be required to confirm efficacy, depending on the physical form and intended use of the product. The active ingredient concentrations tested in the bio-efficacy studies should be equivalent to (or lower than) the application rate recommended on the label.

(iv) Quality

Methods of sample preparation and analysis of the formulated product shall be submitted to demonstrate the methods for the determination of active ingredient(s), significant impurities and relevant impurities, if applicable.

Information on the product specification with quality criteria limits is to be furnished based on the respective analytical data (e.g. content of active ingredient(s), significant impurities and relevant impurities). For this purpose, please refer to "Manual on Development and Use of FAO and WHO Specifications for Pesticides 2016" for more information.

Certificate of analysis (COA) of at least 3 production batches shall be submitted to demonstrate composition consistency among batches, based on the recommended testing methodology.

(g) Applicant may be required to submit product samples with certified authentic analytical standards for analysis.

2.4 Registration of Novel Products

NEA considers the following products as novel:

(a) Products formulated with new active ingredient, i.e. an active ingredient which is not found in the current registry of vector control products maintained by NEA; or

(b) Products with new application (e.g. formulation type) that significantly modifies the safety and efficacy of an existing active ingredient within the product, for example nano-pesticides.

Application for registration of a novel product may be subjected to extensive data requirements for both active ingredient(s) and formulated product, which includes:

(a) Toxicological data, such as sub-chronic and chronic toxicity study reports, that characterise potential hazards to human health after prolonged or repeated exposure;

(b) Such other information as the Director-General of Public Health may require.

2.5 Registration Process

Each registration process includes two key stages, i.e. dossier screening stage and technical evaluation stage.

(a) Dossier screening stage:

(i) During this stage, the application dossier will be screened to assess whether all the required documents listed in Section 2.3 and Annex 5 have been included in the dossier;
(ii) If the submission is incomplete, the application dossier will be rejected. Subsequent data submissions will be considered as new applications;
(iii) Once the application dossier is complete with all the required documents, a technical evaluation will be conducted. This does not guarantee that an application will result in an approval for registration.

(b) Technical evaluation stage:

(i) Technical evaluation is conducted to assess the product content, safety, efficacy and quality;
(ii) Application dossiers will be assessed based on international guidelines (such as WHO Guidelines, USEPA Guidelines and EU Guidelines);
(iii) Additional information/ data may be requested for further clarification or verification of product claims of content, safety, quality and efficacy, which will require further evaluation and the evaluation time may vary depending on the submitted information/ data;
(iv) Common reasons for rejection of application at this stage include:

- Inconsistent information across different documents within the application dossier;
- Information provided does not define or characterise the product;
- Vague and inadequate data in supporting information, rendering interpretation and assessment impossible;
- Failure in submission of the requested additional information/ data during clarification.

Subsequent application for the same product, following a rejection, will be considered as a new application.

2.6 Product Label

A label shall be printed on or affixed to every container or package of the product. It shall be in English and preferably in one more official language of Singapore. The information required on a product label is listed below:

(a) Product/trade/brand name;
(b) Composition (% w/w) of the product (name and percentage of active ingredient(s), percentage of inert ingredients);
(c) Formulation type (please refer to Annex 3);
(d) WHO hazard classification (please refer to Annex 4);
(e) Hazard warning statement or symbol (please refer to Annex 4);
(f) Statement of classification (i.e. “For General Use” or “For Restricted Use”);
(g) Net weight or volume of product;
(h) Target pest(s);
(i) Date of manufacture;
(j) Date of expiry or shelf-life;
(k) Residual period (if any);
(l) Toxicological effect(s) on non-target organism(s) (e.g. fish, birds);
(m) Safety precaution(s);
(n) Directions of use;
(o) Storage and disposal information;
(p) Practical treatment statement(s) and guide to doctor in case of poisoning;
(q) Names and addresses of manufacturer and importer;
(r) NEA registration mark (comprising a registration number and logo, please refer to Annex 2 for details);
(s) Such other information as the Director-General Public Health may require.

Applicants are advised **not** to proceed with the printing of the product labels until the product labels have been approved.

Product containers and packages come in different shapes and sizes. Under normal circumstances, the labels must contain all the required information (see Section 2.6 above-mentioned (a) to (s)).

However, if there are space constraints, the following essential information is required to appear conspicuously on the package/ container:

(a) Brand name;
(b) NEA registration mark;
(c) Composition (% w/w) of the product;
(d) Formulation type;
(e) Directions of use;
(f) WHO hazard classification;
(g) Hazard warning statement or symbol;
(h) Statement of classification;
(i) Net weight or volume of the product;
(j) Target pest(s);
(k) Date of manufacture;
(l) Date of expiry or shelf-life;
(m) Residual period (if any).

The remaining information can appear in a separate leaflet/ brochure enclosed or attached to the package.

Figure 1: Sample of Label Without Separate Leaflet for "Restricted Use" Product

SIDE PANEL

PRECAUTIONARY STATEMENTS
WARNING

HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)

DO NOT BREATHE SPRAY MIST. DO NOT GET IN EYES. AVOID CONTACT WITH SKIN.
FOR EMERGENCY ASSISTANCE, PLEASE CALL XXXXXXX.

PHYSICAL OR CHEMICAL HAZARDS

WARNING - Flammable! KEEP AWAY FROM HEAT OR OPEN FLAME.

ENVIRONMENT HAZARDS

KEEP OUT of any body of water. DO NOT APPLY where runoff is likely to occur. DO NOT CONTAMINATE WATER by cleaning of equipment or disposal of wastes.

TOXICOLOGICAL EFFECT(S) ON NON-TARGET ORGANISMS

This product is toxic to fish / birds / bees.

PRACTICAL TREATMENT

IF SWALLOWED - Induce vomiting by giving a tablespoon of salt in a glass of warm water. Repeat until vomitus is clear. Call a physician immediately.
IF INHALED - Remove to fresh air. Call a physician immediately.
IF IN EYES - Flush eyes with plenty of water for at least 15 minutes. Call a physician immediately.
IF ON SKIN - In case of contact, remove contaminated clothing & immediately wash skin with soap & water.

MEDICAL TREATMENT

TO PHYSICIAN: XXX is a reversible cholinesterase inhibitor. Do not use oximes such as 2-PAM. Give Atropine 2 mg. Intravenously or subcutanously. If in eye instill one drop of Homatrophine.

MAIN PANEL

FOR RESTRICTED USE
SINNEA-X-XXX/XXX/XXXX

XXX

EMULSIFIABLE CONCENTRATE

ACTIVE INGREDIENT: XXXXXXXX % w/w

INERT INGREDIENTS: XX.XX% w/w

WARNING

KEEP OUT OF REACH OF CHILDREN
WHO CLASS II
Moderately Hazardous

IMPORTED BY XXXXXXXXX
XXXXXXXXX
TEL NO : XXXXXXX
FAX NO : XXXXXXX

MANUFACTURED BY : XXXXXXXXX
XXXXXXXXX

DATE OF MFG : XX - XX - XXXX
DATE OF EXPIRY : XX - XX - XXXX

SIDE PANEL

DIRECTIONS FOR RESTRICTED USE

LAWN INSECT CONTROL: TO CONTROL INSECTS LISTED BELOW, apply RECOMMENDED RATES. For Fleas, Ticks and Mites, which are commonly found near the house and may enter the house, spray a 5 ft. band of soil around the house, as well as the house foundation wall to a height of 2-3 ft. Repeat application if necessary.

INSECTS	RATE/ 100 m^2	water	REMARKS
FLIES	XX m^3	XX L	Mow grass & water well before treatment but delay application until grass is dry. Do not water again until necessary.
FLEAS	XX m^3	XX L	Do not apply to animals.
ROACHES	XX m^3	XX L	Make a 0.2% finished spray. Make spot applications as a coarse spray where insects

STORAGE & DISPOSAL

STORAGE - Do not store next to food or other articles intended for consumption by humans or animals.
DISPOSAL - Do not reuse container. Contact licensed industrial waste collector for proper disposal.

Figure 2: Sample of Label With Separate Leaflet for "General Use" Product

MAIN LABEL

FOR GENERAL USE
SINNEA-X-XXX/XXX/XXXX

XXX XX%w/w

INSECTICIDE

This product contains :
XXXXXXXX X.XX% w/w XXXXXXXX X.XX% w/w

EFFECTIVE AGAINST
cockroaches and ants.
The toxicity of this product to non-target organisms has not been determined.

KEEP OUT OF REACH OF CHILDREN
CAUTION
Unlikely to Present Acute Hazard in Normal Use

IMPORTED BY:
xxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxx

DATE OF MFG XX-XX-XX
DATE OF EXP XX-XX-XX

DIRECTIONS FOR USE

FRONT (separate leaflet)

FOR GENERAL USE
SINNEA-X-XXX/XXX/XXXX

XXX

INSECTICIDE
XX%w/w

ACTIVE INGREDIENTS: XXXXX X.XX% w/w
XXXX X.XX% w/w

INERT INGREDIENTS: .XX% w/w

KEEP OUT OF REACH OF CHILDREN

CAUTION

Unlikely to Present Acute Hazard in Normal Use

EFFECTIVE AGAINST.

SAFETY PRECAUTIONS

(SEE OVERLEAF)

BACK (separate leaflet)

PRACTICAL TREATMENT
IF SWALLOWED - Induce vomiting by giving a tablespoon of salt in a glass of warm water. Repeat until vomitus is clear. Call a physician immediately.
IF IN EYES - Flush eyes with plenty of water for at least 15 minutes. Call a physician immediately.
IF ON SKIN - In case of contact, remove contaminated clothing & immediately wash skin with soap & water.

STORAGE AND DISPOSAL

IMPORTED BY:
XXXXXXXXXXX
XXXXXXXXXXX
TEL. NO. XXXXXXX
FAX NO. XXXXXXX

MANUFACTURED BY:
XXXXXXXXXXX
XXXXXXXXXXX

DATE OF MANUFACTURE:

DATE OF EXPIRY:

Figure 3: Sample of Label Without Separate Leaflet For "General Use" Product

SIDE PANEL

TARGET PESTS

A fast acting, non-staining insect killer effective against flying and crawling insects, such as cockroaches, fleas, mites and mosquitoes.

TOXICOLOGY EFFECT(S) ON NON-TARGET ORGANISMS

Product is toxic to fish / birds / pets.

SAFETY PRECAUTIONS

AVOID CONTACT WITH SKIN & EYES. AVOID INHALATION OF SPRAY MIST. DO NOT SPRAY DIRECTLY ON HUMANS, FOOD, OR FOOD UTENSILS. CONTAINER IS PRESSURISED. DO NOT PUNCTURE / THROW INTO FIRE. DO NOT EXPOSE TO TEMPERATURE ABOVE 65^0C (150^0F). DO NOT SPRAY ON PLASTICS.

PRACTICAL TREATMENT

IF SWALLOWED - Induce vomiting by giving a tablespoon of salt in a glass of warm water. Repeat until vomitus is clear. Call a physician immediately.
IF INHALED - Remove to fresh air. Call a physician immediately.
IF IN EYES - Flush eyes with plenty of water for at least 15 minutes. Call a physician immediately.
IF ON SKIN - In case of contact, remove contaminated clothing & immediately wash skin with soap & water.

MEDICAL TREATMENT

TREATMENT ACCORDING TO SYMPTOMS. IN CASE OF EMERGENCY, PLEASE CALL TELEPHONE NO. XXXXXXX

MAIN PANEL

FOR GENERAL USE

SINNEA-X-XXX/XXX/XXXX

XXX

OIL-BASED AEROSOL

KEEP OUT OF REACH OF CHILDREN

CAUTION

Unlikely to Present Acute Hazard in Normal Use

ACTIVE INGREDIENTS:

XXXXXXXX	X.XX% w/w
XXXXXXXX	X.XX% w/w

INERT INGREDIENTS: X.XX% w/w

NET CONTENTS XXX ml

SIDE PANEL

DIRECTIONS FOR USE

Close all doors & windows. Press button & spray upwards throughout the room for 5-10 seconds. Leave doors & windows closed for 10 minutes. For individual

STORAGE & DISPOSAL

STORAGE - Do not store next to food or other articles intended for consumption by humans or animals.

DISPOSAL - Do not reuse container. Do not litter.

IMPORTED BY
XXXXXXXXXXX
XXXXXXXXXXX
XXXXXXXXXXX
XXXXXXXXXXX
TEL NO : XXXXXXX
FAX NO : XXXXXXX

MANUFACTURED BY
XXXXXXXXXXX
XXXXXXXXXXX
XXXXXXXXXXX
XXXXXXXXXXX

DATE OF MANUFACTURE:

DATE OF EXPIRY:

2.7 Other Information on the Product

In addition to the detailed requirements described in Sections 2.3 and 2.6, the applicant shall consider providing the following to users or first responders to guide the use of the product in a safe manner. NEA may request for the following data or information on a case-by-case basis or if the use description demonstrates significant potential exposure and/ or if toxicity tests or published data indicate concern.

(a) Physical and chemical compatibility with other products;
(b) Procedures to clean equipment and protective clothing of the user of the pesticide and verification methods to determine effectiveness of the cleaning procedures;
(c) Information of combustion by-products likely to be generated in case of fire;
(d) Detailed procedures in the event of an accident during transport, storage or use, including: neutralisation procedures, containment of spillages, decontamination of areas, vehicles and buildings, disposal of damaged packaging, absorbents and other materials, protection of emergency workers and bystanders, and first-aid measures;
(e) Operator and bystander exposure – monitoring procedures and hypersensitivity monitoring procedures;
(f) Medical management; and
(g) Necessary waiting periods for re-entry, recommended protective measures to reduce occupational exposure.

2.8 Successful Application

Every individual product supplied, imported or manufactured by a supplier, importer or manufacturer for sale in the local market will be issued a certificate of registration of pesticide/ repellent product with a unique registration number upon successful application.

The registered pesticide/ repellent product will also be reflected within the product register published on NEA's website (please refer to Section 1.3).

SECTION THREE: POST-REGISTRATION PROCESS

3.1 Post-Registration Surveillance

NEA may conduct post-registration surveillance to assess whether the registered products continue to comply with the required safety, quality control and labelling standards. The registrants may also be required to submit, at their own expense, the sealed samples to an accredited laboratory for the purpose of analysis. The reports of analysis (either original or certified true copy) shall be submitted to NEA thereafter.

3.2 Registration Amendment

Any changes to a registered product, such as changes to its importer, manufacturer and/ or active ingredient, registrant's particulars, product formulation type, direction of use, target pest, efficacy claims, product composition, packaging size, storage and disposal statements, label claims and design, and product name, shall be submitted to NEA through an application to amend the registration. Where necessary, NEA may request additional information/ data, for evaluation of the amendment request. The application for amended registration shall be approved by NEA before the modified product can be legally distributed or sold.

3.3 Duty of Applicant to Inform NEA of Product Withdrawal

The applicant is responsible for notifying NEA if the product has been withdrawn from sale from the market in Singapore.

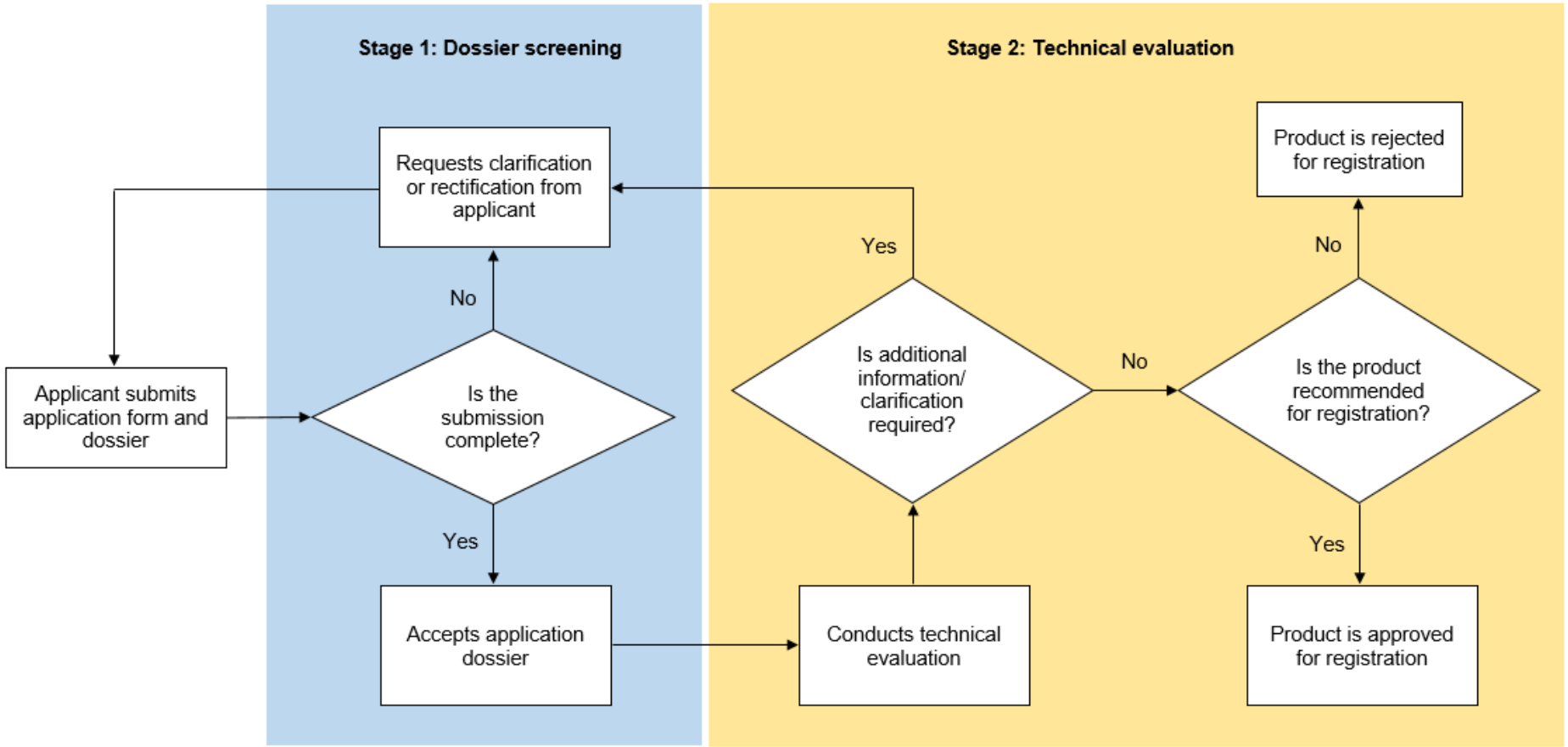
SECTION FOUR: CANCELLATION OF REGISTRATION AND REMOVAL OF REGISTRATION MARKS

Under Section 10 of the CVPA, a registration will be cancelled by NEA if a registered pesticide/ repellent:

(a) Is subsequently found to be hazardous or if the hazards arising from its use outweigh the advantages;
(b) Is not being prepared in accordance with the particulars registered in respect of the product;
(c) No longer conforms to prescribed standards;
(d) Is no longer available for purchase in Singapore;
(e) Has been registered upon false information provided by the registrant;
(f) The registrant has failed to comply with any of the conditions subject to which the product has been registered, or he/ she has intervened or failed to comply with the provisions of the Act or regulations;
(g) Container or package or the label printed/affixed does not comply with the prescribed requirements;
(h) Is being advertised in a manner that is deemed to be false, misleading or deceptive.

Upon the cancellation of the registration of a product, the Director General of Public Health may require the registrant to remove, cancel or obliterate the registration mark from every container and package of the product. The registrant may also be required to recall all stocks and to cease the sale, supply or distribution of the product within a specified timeframe.

Annex 1: Overall Process for the Registration of Pesticide and Repellent Product



Annex 2: NEA Registration Mark

Under Section 8 of the CVPA, a pesticide/ repellent that has been successfully registered shall be required to clearly show a registration mark in a conspicuous position on the label of every container or package of the product. The registration mark comprises:

i) A unique registration number in the form of "SINNEA-X-XXX/XXX/XXXX"; and
ii) A registration logo.

The registration logo is made up of a double-tick atop two rings of varying thicknesses, and the words "NEA REGISTERED VECTOR CONTROL PRODUCT". There are 3 versions of the registration mark which registrants may choose to use:

Figure 4: Acceptable Colour Schemes: Registration Mark

Full-Colour	One-Colour (Black)	One-Colour (White)
		

Applicants may refer to the registration mark usage guidelines for more details on the NEA website.

Annex 3: Codes for Formulations (Catalogue of Pesticide Formulation Types and International Coding System)

AE	Aerosol dispenser	KL	Combi-pack liquid/liquid*
AL	Other liquids to applied undiluted	KN	Cold fogging concentrate
AP	All other products to be applied undiluted	KP	Combi-pack solid/solid*
BR	Briquette	LN	Long-lasting insecticidal net
CB	Bait concentrate	LS	Solution for seed treatment
CP	Contact powder	MC	Mosquito coil
CS	Capsule suspension	ME	Microemulsion
DC	Dispersible concentrate	OD	Oil dispersion
DP	Dustable powder	OF	Oil miscible flowable concentrate (oil miscible suspension)
DS	Powder for dry seed treatment		
DT	Tablets for direct application	OL	Oil miscible liquid
EC	Emulsifiable concentrate	OP	Oil dispersible powder
EG	Emulsifiable granule	PA	Paste
EO	Emulsion, water in oil	PR	Plant Rodlet
EP	Emulsifiable powder	PS	Seed coated with a pesticide
ES	Emulsion for seed treatment	RB	Bait (ready for use)
EW	Emulsion, oil in water	SC	Suspension concentrate (= flowable concentrate)
FS	Flowable concentrate for seed treatment	SD	Suspension concentrate for direct application
FU	Smoke generator	SE	Suspo-emulsion
GA	Gas	SG	Water soluble granule
GE	Gas generating product	SL	Soluble concentrate
GL	Emulsifiable gel	SO	Spreading oil
GR	Granule	SP	Water soluble powder
GS	Grease	ST	Water soluble tablets
GW	Water soluble gel	SU	Ultra-low volume (ULV) suspension
HN	Hot fogging concentrate	TB	Tablet
KK	Combi-pack solid/liquid*	TC	Technical material

* Special two-letter code for twin-packs

TK	Technical concentrate	WT	Water dispersible tablets
UL	Ultra-low volume (ULV) liquid	XX	Others
VP	Vapour releasing product	ZC	A mixed formulation of CS and SC
WG	Water dispersible granule	ZE	A mixed formulation of CS and SE
WP	Wettable powder	ZW	A mixed formulation of CS and EW
WS	Water dispersible powder for slurry treatment		

For record keeping purposes, the suffix “SB” should be added to the formulation code, if the material is packaged in a sealed water soluble bag (e.g. WP-SB).

Annex 4: WHO Hazard Classification - Acute LD_{50} Values of Formulated Products

Classification and Signal Wording	Pictorial Reference for Each Class	Acute LD_{50} for Rat (mg/kg body weight)*	
		ORAL	DERMAL
Extremely Hazardous **CLASS Ia** **"DANGER – POISON"**		< 5	< 50
Highly Hazardous **CLASS Ib** **"DANGER – POISON"**		5-50	50-200
Moderately Hazardous **CLASS II** **"WARNING"**		50-2000	200-2000
Slightly Hazardous **CLASS III** **"CAUTION"**		Over 2000	Over 2000
Unlikely to present acute hazard in normal use **CLASS U** **"CAUTION"**		5000 or higher	

*For toxicities other than acute oral and dermal toxicities, GHS hazard classification will be adopted to classify the formulated products.

Annex 5: Data Requirements for Pesticides and Repellents

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
1	**CONTENT**					
1.1	Manufacturer of the product, including company name, address, contact person, telephone/ mobile number, and email	MR Product	MR Product	MR Product		C, M, B
1.2	Manufacturer(s) of the technical grade active ingredient(s), including company name, address, contact person, telephone/ mobile number, and email	MR Product	MR Product	MR Product		C, M, B
1.3	Trade name of the product	MR Product	MR Product	MR Product		C, M, B
1.4	Formulation type and code	MR Product	MR Product	MR Product		C, M, B
1.5	Chemical name and CAS No. of the active ingredient	MR Product	MR Product	MR Product		C, B
1.6	Scientific name of microorganism (MCPA) to species level or a level sufficient to show taxonomic relation to known microorganisms, especially pathogens. Include trade names, common names and developmental code names (if any)	MR Product	MR Product	MR Product		M
1.7	Composition (in terms of g/kg or g/L or % w/w) of the product, indicating the function of each inert ingredient and presence of impurities (if any)	MR Product	MR Product	MR Product		C, M, B

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
1.8	Detailed taxonomic description of the botanical material used, including scientific name of source material and part of plant used	MR Product	MR Product	MR Product		B
1.9	For mutants or genetically modified strains, indicate all known differences between the modified microorganisms and the parent wild strains	NR	NR	MR Product		M
1.10	Intended use of the product	MR Product	MR Product	MR Product		C, M, B
1.11	Target pest(s)	MR Product	MR Product	MR Product		C, M, B
1.12	Mode of action	NR Product	NR Product	CR Product		C, M, B
Physical-Chemical Properties						
1.13	Melting-point	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C
1.14	Boiling-point	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C
1.15	Relative density	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.16	Vapour pressure	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.17	Description of physical state, colour and odour	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.18	Partition coefficient	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
1.19	Flammability	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.20	Flash point	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.21	Explosivity	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.22	Oxidizing properties	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.23	pH	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.24	Stability in water, hydrolysis rate, photochemical degradation, and identity of breakdown products	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.25	Solubility in water	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
1.26	Solubility in organic solvents	CR A.I. or Product	CR A.I. or Product	CR A.I. & Product		C, M, B
Microbial Characteristics						
1.27	Origin of the isolate; method of isolation; preservation and maintenance of strain during development; historical information on testing and use of the strain; history of use of closely related strains or species; Description of any unusual morphological, physiological, pesticidal or resistance characteristics of the MPCA which differ from classical description of the species	NR	NR	MR A.I. or Product		M

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
1.28	Natural occurrence of the microorganism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence	NR	NR	MR A.I. or Product		M
1.29	Available information on host specificity; possible effects on species closely related to the target pest	NR	NR	MR A.I. or Product		M
1.30	Potential of the microorganism to produce secondary compounds (metabolites) that are of concern for human health and/or the environment	NR	NR	MR A.I. or Product		M
1.31	Description of any plasmids or other extra chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, etc.	NR	NR	MR A.I. or Product		M
1.32	Genetic stability (mutation rate of traits related to the mode of action)	NR	NR	MR A.I. or Product		M
1.33	Detailed discussion of relationship of microorganism to any known human dermatophyte	NR	NR	MR A.I. or Product		M
1.34	Resistance/sensitivity to antibiotics/antimicrobial agents used in human or veterinary medicine	NR	NR	MR A.I. or Product		M
2	**SAFETY (HUMAN HEALTH)**					
2.1	Acute oral toxicity	MR A.I. or Product	MR A.I. or Product	MR A.I. & Product		C, M, B
2.2	Acute dermal toxicity	MR	MR	MR		C, M, B

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
		A.I. or Product	A.I. or Product	A.I. & Product		
2.3	Acute inhalation toxicity	MR A.I. or Product	MR A.I. or Product	MR A.I. & Product	Required only if the product consists of, or under conditions of use will result in, a respirable material (e.g. gas, vapour, aerosol, or particulate).	C, M, B
2.4	Primary eye irritation	MR A.I. or Product	MR A.I. or Product	MR A.I. & Product		C, M, B
2.5	Primary dermal irritation	MR A.I. or Product	MR A.I. or Product	MR A.I. & Product		C, M, B
2.6	Dermal sensitization	MR A.I. or Product	MR A.I. or Product	MR A.I. & Product		C, M, B
2.7	Acute neurotoxicity	NR	NR	CR A.I. or Product	Required if adverse effects or toxicity concerns from other data point to a health risk.	C, M, B
2.8	28-day delayed neurotoxicity	NR	NR	CR A.I. or Product	Required if results of acute neurotoxicity study indicate significant statistical or biological effects or if other available data indicate the potential	C, M, B

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
					for this type of delayed neurotoxicity.	
2.9	90-day oral	NR	NR	CR A.I. or Product	Required if oral exposure could occur.	C, M, B
2.10	90-day dermal	NR	NR	CR A.I. or Product	Required if either of the following criteria is met: (i) Dermal route would be the primary route of exposure; or (ii) The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite is the toxic moiety.	C, M, B
2.11	90-day inhalation	NR	NR	CR A.I. or Product	Required if the product consists of, or under conditions of use will result in, a respirable material (e.g. gas, vapour, aerosol, or particulate).	C, M, B

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
2.12	Delayed neurotoxicity (acute)	NR	NR	CR A.I. or Product	Required if the test material is an organophosphorus substance or is structurally related to other substances that may cause the delayed neurotoxicity.	C, M, B
2.13	Chronic oral	NR	NR	CR A.I. or Product		C, M, B
2.14	Prenatal developmental toxicity	NR	NR	CR A.I. or Product		C, M, B
2.15	Developmental neurotoxicity	NR	NR	CR A.I. or Product		C, M, B
2.16	In vitro mammalian cell assay	NR	NR	CR A.I. or Product		C, M, B
2.17	In vivo cytogenetics	NR	NR	CR A.I. or Product		C, M, B
2.18	Metabolism and pharmacokinetics: Absorption, distribution, metabolism and excretion in mammals, with special reference to differences between laboratory animals and humans, kinetics, accumulation and half-lives.	NR	NR	CR A.I. or Product		C, B
2.19	Potential of microbial pest control agent to be hazardous to humans with consideration of its pathogenic potential,	NR	CR A.I. or Product	CR A.I. or Product		M

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
	its ability to infect and pattern of clearance, and its toxicological effects					
2.20	90-day neurotoxicity	NR	NR	CR A.I. or Product		C, M, B
2.21	Toxicity studies on metabolites	NR	NR	CR A.I. or Product		C, M, B
2.22	Dermal penetration	NR	NR	CR A.I. or Product	Required if use description demonstrates significant potential exposure and/or if toxicity tests or published data indicate a concern. Solid matrix dispensers are unlikely to present significant potential exposure, but some sprayed applications might.	C, M, B
2.23	Immunotoxicity	NR	NR	CR A.I. or Product		C, M, B
2.24	Carcinogenicity	NR	NR	CR A.I. or Product		C, B

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
3	**SAFETY (ECOTOXICITY)**					
.1	Acute avian oral toxicity	CR A.I. or Product	CR A.I. or Product	MR A.I. or Product	Study to be conducted on one passerine species and either one waterfowl species or one upland game bird species for outdoor uses. Data on waterfowl or upland game bird species are required for indoor uses.	C, M
3.2	Acute toxicity to freshwater fish	CR A.I. or Product	CR A.I. or Product	MR A.I. or Product	Study to be conducted using one warm-water fish.	C, M
3.3	Acute toxicity to freshwater invertebrates (*Daphnia magna*)	CR A.I. or Product	CR A.I. or Product	MR A.I. or Product	Study to be conducting using one freshwater aquatic invertebrate species.	C, M
3.4	Toxicity to fresh water algae	CR A.I. or Product	CR A.I. or Product	MR A.I. or Product		C, M
3.5	Monitoring data on fate and behaviour of the active ingredient and of relevant metabolites, degradation and reaction products	NR	NR	MR A.I. or Product		C, M

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
3.6	Degradation in aquatic systems: Aerobic and anaerobic aquatic metabolism	NR	NR	CR A.I. or Product		C, M
4	**EFFICACY**					
4.1	Laboratory bio-efficacy study, specifically data demonstrating efficacy against declared targeted vector(s)	MR Product	MR Product	MR A.I. & Product		C, M, B
4.2	Bio-efficacy data on residual effect (if claimed)	MR Product	MR Product	MR A.I. & Product		C, M, B
4.3	Field or semi-field bio-efficacy study, specifically data demonstrating efficacy against declared targeted vector(s)	CR Product	MR Product	MR A.I. & Product		C, M, B
5	**QUALITY**					
5.1	Safety Data Sheet of the product and the technical grade active ingredient(s)	MR A.I. & Product	MR A.I. & Product	MR A.I. & Product		C, M, B
5.2	Product Specification providing the quality criteria for the production and storage of the product, including acceptable tolerance of active ingredient(s), inert ingredient(s), and impurities (if any)	MR Product	MR Product	MR A.I. & Product		C, M, B
5.3	Certificate of Analysis from at least 3 production batches of product demonstrating composition consistency among batches	MR Product	MR Product	MR Product		C, M, B
5.4	Method of Analysis of the product	MR Product	MR Product	MR Product		C

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.

MR = Mandatory Requirement CR = Conditional Requirement on a case-by-case basis NR = No Requirement

S/N	Category	Chemical /Botanical/Microbial			Remarks	Applicability
	Requirement	Existing A.I.		New A.I.		Chemical (C) Microbial (M) Botanical (B)
		Existing Application	New Application*			
5.5	Test procedures and criteria, using best available technology, to characterise the strain or serotype	MR Product	MR Product	MR Product		M

* If new application (e.g. formulation type) significantly modifies the safety and efficacy of the active ingredient, dossier should comply with the data requirement for New A.I.