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Vector Control in the Indo-Pacific: Regulatory Landscape

INNOVATIVE VECTOR CONTROL CONSORTIUM

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Contents

Regulatory Pathways

1. Introduction:

Pesticides are invaluable in their use in the control of pests in Agriculture, Veterinary, Industrial and Public Health. Largely, Pesticides are primarily used in the control of pests in Agriculture, especially Insecticides. Since the discovery DDT and its effectiveness in the control of mosquitoes – the Malaria vector, the use of insecticides has been increasingly used in Public Health to combat disease-causing insect vectors.

Insecticides have been rampantly used in Agriculture and in all the fields wherein its usefulness has been established. Due to its unchecked extensive use, regulatory checks and balances were devised to streamline the use of insecticidal intervention tools as well as bring in quality products for the end user to achieve superior control of the intended pests, as well as avoid fallouts such as insecticide resistance.

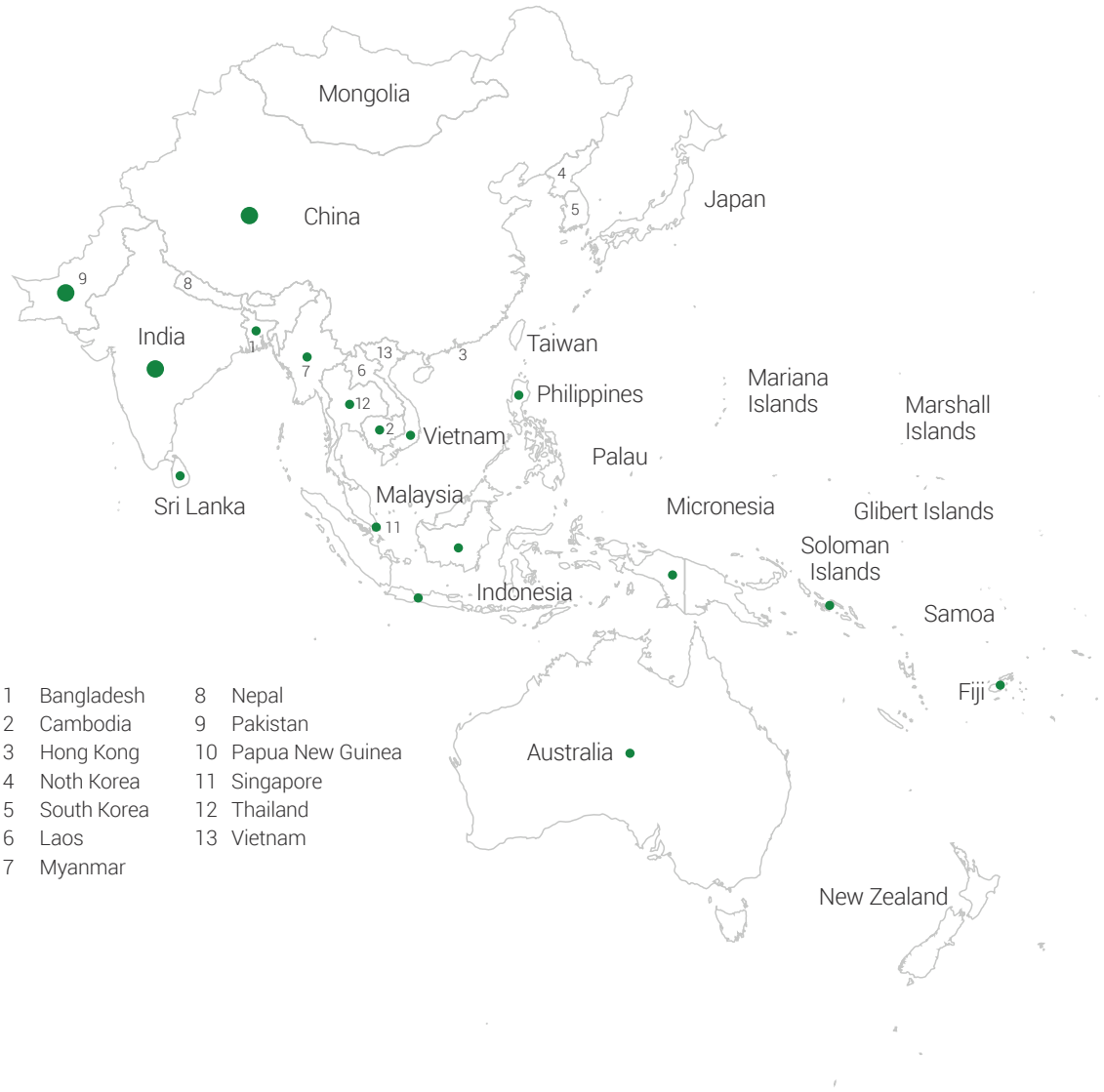
Regulatory Mechanisms for Pesticides have been devised to ensure that the efficacy, human safety and environmental safety parameters have been adequately evaluated and only those pesticides that have been able to meet these standards and specifications are able to be registered before being permitted to be used in close proximity to human beings.

Over the years, regulatory processes and guidelines have been systematically evolving to make them more robust as well as to expedite the processes so as to have newer and novel intervention tools for the control of pests, especially those involved with human health.

2. Regulatory landscape profile – Asia – Pacific Region:

The Asia – Pacific region has varying degrees of robustness and stringency in the regulatory processes for pesticides. The pesticides for use in public health for control of vectors are regulated primarily under the Ministry of Agriculture in many countries in the region and under the Ministry of Health regulator in a few countries.

The following brief is to provide a snapshot of the regulatory process in the Asia – Pacific region, providing a glimpse of the regulatory process in each country of the region.



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South Asia

India	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Central Insecticides Board & Registration Committee (CIBRC) under MOA.[1] **Ease of Registration:** Process is time consuming. Public Health Products are accorded priority. Lengthy in-country testing of public health pesticides. **Timelines for Regulatory Approval:** 10 - 12 months for VCP Provisional registration Additional 12 – 15 months for Full registration **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. For registration purposes, WHOPES is not mandatory. **Manufacturing of VCPs:** Yes, manufacturing capabilities exist. Currently VCP produced. **VCPs used in Vector Control:** Mass scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs. Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, Several ISO 17025 and GLP accredited laboratories as well as WHO collaborating centers are available.

Pakistan	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Under MOA.[2] http://www.plantprotection.gov.pk/ **Ease of Registration:** Process is not expedited. It can be time consuming to secure registrations. Fast track registration is only for identical products **Timelines for Regulatory Approval:** 10 – 12 months for VCP. Pesticides for agriculture can take up to 18 – 24 months. **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended depending on the requirement by malaria programs and donors. **Manufacturing of VCPs:** Yes, manufacturing capabilities exist. Currently VCP produced. **VCPs used in Vector Control:** Mass scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, GLP and ISO accredited testing facilities are available.

[1] India – Central Insecticides Board & Registration Committee (CIBRC) - http://ppqs.gov.in/divisions/cib-rc/about-cibrc

[2] Pakistan – Department of Plant Protection (DPP) - http://www.plantprotection.gov.pk/

Bangladesh	Country Brief
	**Registration**: Yes, Required for Public Health products **Authority:** Department of Agricultural Extension under the Ministry of Agriculture (MoA).[3] **Ease of Registration:** No priority of Public Health Pesticides. Registration process is not expedited. **Timelines for Regulatory Approval:** 8 – 10 months for Public Health Pesticides. In country evaluation is required for Public Health Pesticides **WHOPES / PQ Acceptance:** PHPs in Public Health programs should be WHOPES recommended. However, for regulatory approval WHOPES / PQ is not mandatory **Manufacturing of VCPs:** Currently, formulation facilities are available. There is manufacture of active ingredients but formulation industry is thriving. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Not many testing facilities available. Testing capacity limited. Only Government testing facilities.

Sri Lanka	Country Brief
	**Registration**: Yes, Required for Public Health products **Authority:** The regulatory authority for pesticides to be used in Agriculture and for public health use is under the Registrar of Pesticides, Seed Certification and Plant Protection Centre, Department of Agriculture, Ministry of Agriculture (MoA)[4] **Ease of Registration:** Registration process is not very complicated. Simple requirement for registration of products. Local trials are required for registration. **Timelines for Regulatory Approval:** 8 – 10 months for VCP. **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** No manufacturing capabilities. All pesticides are imported into Sri Lanka. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, government facilities are available but private GLP and ISO accredited facilities are limited.

[3] Bangladesh – Department of Agricultural Extension (DAE) – http://dae.portal.gov.bd/

[4] Sri Lanka – RoP, SCPPC, Ministry of Agriculture https://www.doa.gov.lk/SCPPC/index.php/en/institute/30-orp-2

Myanmar	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Pesticides Registration Board, Department of Plant Protection, Ministry of Agriculture (MoA)[5] **Ease of Registration:** Process for existing products is simple. Innovative products registration can be very lengthy and circuitous process. **Timelines for Regulatory Approval:** 6 – 8 months for a product in existing category. New Innovative products may take at least 15 – 18 months. **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** No manufacturing capacity. All products are imported into the country. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Testing facilities are vastly limited. Government laboratories. Capacity building is ongoing. Analytical equipment limited.

Country	Reg. Authority
India	Central Insecticides Board & Registration Committee (MoA)
Pakistan	Plant Protection Dept. (MoA)
Bangladesh	Plant Protection Wing & DAE, (MoA)
Sri Lanka	Department of Agriculture (MoA)
Myanmar	Pesticide Registration Board (PRB) – (MoA)
China	Institute for Control of Agrochemicals (ICAMA) – (MoA)

[5] Myanmar (Burma) – Pesticides Registration Board, DPP, MoA - http://ppdmyanmar.org/pesticide-registration-board/

East Asia

The main countries in East Asia are be China, Japan, South Korea and Korea DPR.

China	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Institute for Control of Agrochemicals (ICAMA) Ministry of Agriculture (MoA)[6] **Ease of Registration:** Process is stringent for imported products. **Timelines for Regulatory Approval:** 10 – 12 months for VCP **WHOPES / PQ Acceptance:** Not mandatory for registration of Public Health Pesticides. **Manufacturing of VCPs:** Yes, manufacturing capabilities exist. Currently VCP produced. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, Several ISO 17025 and GLP accredited laboratories as well as WHO collaborating centers are available

South East Asia

The South East Asian Region comprises of Singapore, Malaysia, Thailand, Indonesia, Vietnam, Cambodia, Laos PDR and Brunei.

Singapore	Country Brief
	**Registration**: Yes, Required for Public Health products **Authority:** National Environmental Agency (NEA)[7] under the Ministry of Environment regulates pesticides for household and public health use. **Ease of Registration:** Process is very simple, pragmatic and quite fast. **Timelines for Regulatory Approval:** 2 – 3 months for VCP **WHOPES / PQ Acceptance:** PQ listing is not mandatory for PHP approval process but VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** Manufacturing facilities are not available. Most of the products are imported into the country. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, several high-quality ISO 17025 and GLP accredited laboratories are available

[6] China – Institute for Control of Agrochemicals – MoA – http://english.agri.gov.cn/

[7] Singapore – National Environmental Agency (NEA) - https://www.nea.gov.sg/our-services/pest-control/overview

Malaysia	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Department of Agriculture, Ministry of Agriculture and Agro-based Industry (MoA)[8] **Ease of Registration:** Process is stringent. However, regulatory authority accepts data from other countries thereby avoiding unnecessary in-country trials. Adequate guidelines exist **Timelines for Regulatory Approval:** 10 – 12 months for VCP **WHOPES / PQ Acceptance:** For registration WHOPES / PQ listing is not mandatory but VCPs in Public Health programs should be WHOPES / PQ listing recommended. **Manufacturing of VCPs:** Yes, there are good manufacturing facilities available. Many formulation units available. One of the leading exporters of pesticides in the region. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, Several ISO 17025 and GLP accredited laboratories as well as WHO collaborating centers are available

Thailand	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Hazardous substances control division[9] under Food and Drugs Administration, Ministry of Health. **Ease of Registration:** Process is time consuming. Very stringent and elaborate process to secure registration of Public Health Pesticides. Technical capability is **Timelines for Regulatory Approval:** 6 – 8 months for VCP **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** Yes, manufacturing capabilities exist. Currently VCP produced. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, Several ISO 17025 and GLP accredited laboratories as well as WHO collaborating centers are available

[8] Malaysia – Ministry of Agriculture – http://www.doa.gov.my/

[9] Thailand – Hazardous Substances Controls Division, FDA, MoH -

Indonesia	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Department of Agriculture, Ministry of Agriculture (MoA)[10] **Ease of Registration:** Process is very lengthy. In-country testing is mandatory and time consuming. Lack of transparency in the regulatory process is an issue. **Timelines for Regulatory Approval:** 12 – 15 months for VCP **WHOPES / PQ Acceptance:** For registration of household pesticides, there is no need for WHOPES / PQ listing but VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** Yes, pesticide formulation capacity exists. No LLIN manufacturing. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Testing facilities available. GLP and ISO 17025 accredited laboratories are present.

Vietnam	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Health and Environmental Agency (HEMA), MoH [11] **Ease of Registration:** Process of registration is not time consuming. Very limited data required. In country testing of products is mandatory. Mostly administrative review process and nothing technical. **Timelines for Regulatory Approval:** 6 - 8 months for VCP **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** Yes, manufacturing capabilities exist. Currently VCP produced. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, Several ISO 17025 accredited laboratories as well as WHO collaborating centers are available

[10] Indonesia – Department of Agriculture, Ministry of Agriculture (MoA) - http://www.pertanian.go.id/

[11] Health and Environmental Management Agency (HEMA), MoH - http://vihema.gov.vn/

Cambodia	Country Brief
	**Registration:** No, Public Health Pesticides do not require regulatory approval. However, strengthening of regulatory legislation to include Public Health pesticides is ongoing. **Authority:** Ministry of Agriculture, Forestry and Fisheries (MAFF)[12] **Ease of Registration:** Since, there is no regulations for Public Health Pesticides there is no **Timelines for Regulatory Approval:** Not applicable. **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** No manufacturing capacity in the country. All pesticides are imported. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Testing capability and capacity is not strong. There is very limited chemical analysis capacity but strengthening of testing is planned.

Country	Reg. Authority
Singapore	National Environmental Agency (NEA) - (MoE)
Malaysia	Department of Agriculture (MoA)
Thailand	Thai Food and Drug Administration (Thai FDA) - (MoH)
Indonesia	Department of Agriculture (MoA)
Vietnam	Health and Environmental Agency (HEMA) - (MoH)
Cambodia	Ministry of Agriculture, Forestry and Fisheries (MAFF) – (MoA)

[12] Ministry of Agriculture, Forestry and Fisheries (MAFF) - http://web.maff.gov.kh/?lang=en

Oceania

The countries in the Oceania region are Australia, Papua New Guinea, New Zealand, Fiji, Solomon Islands, Vanuatu and 17 other pacific islands.

Australia	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Australian Pesticides and Veterinary Medicines Authority (APVMA[13]), Ministry of Agriculture (MoA) **Ease of Registration:** Timelines are defined. Stringent regulatory authority. Streamlined requirements. **Timelines for Regulatory Approval:** Waiver requests available. Normally, 10 – 12 months for VCP **WHOPES / PQ Acceptance:** WHOPES / PQ listing is not mandatory. Country has own funding for Vector Control. WHOPES / PQ listing is preferred. **Manufacturing of VCPs:** Yes, manufacturing capabilities exist. Currently VCP produced. **VCPs used in Vector Control:** Mass Scale: Chemical Sprays (IRS, Fogging), Larvicides, LLINs Retail: Space sprays, Repellents, Mosquito coils, cards, mats **Testing capabilities:** Yes, Several ISO 17025 and GLP accredited laboratories are available

Papua New Guinea	Country Brief
	**Registration:** No regulatory process available specifically for Public Health Pesticides. Pesticides are required to obtain a permit under Environmental Contaminants Act. **Authority:** Ministry of Environment (MoE)[14] **Ease of Registration:** Permit only is required. No regulatory process. Simple requirements. **Timelines for Regulatory Approval:** 2 – 3 months for obtaining Permit to import **WHOPES / PQ Acceptance:** VCPs in Public Health programs should be WHOPES recommended. **Manufacturing of VCPs:** No manufacturing capacity in the country. Imported pesticides only. **VCPs used in Vector Control:** --- **Testing capabilities:** No GLP or ISO 17025 accredited labs. Capacity not present. Needs capacity building

[13] Australian Pesticides and Veterinary Medicines Authority - https://apvma.gov.au/

[14] Ministry of Environment - http://www.pngcepa.com/

Fiji	Country Brief
	**Registration:** Yes, Required for Public Health products **Authority:** Ministry of Agriculture, Fisheries and Forestry **Ease of Registration:** No clear guidelines for registration of pesticides. Not many requirements for registration. **Timelines for Regulatory Approval:** 10 – 12 months for VCP **WHOPES / PQ Acceptance:** No clarity on this. **Manufacturing of VCPs:** No manufacturing capacity. All pesticides are imported into the country **VCPs used in Vector Control:** Mosquito coils, vaporizers, IRS **Testing capabilities:** Not many testing facilities in the country. There is a need for better facilities and testing personnel capacity to be built.

Country	Reg. Authority
Australia	Australian Pesticides and Veterinary Medicines Authority (APVMA) – (MoA)
Papua New Guinea	Ministry of Environment (MoE)
Fiji	Ministry of Agriculture (MoA)

3. Objectives:

The main objectives of the regulatory pathways in the DFAT – IVCC Market Access and Market Landscape project is as follows: -

1. Map the regulatory requirements and processes in the focus countries.
2. Collate the information on the regulatory authority and the framework of regulations in the country for Vector Control Products
3. To compare and evaluate the registration processes in the various focus countries and their outlook on regulating Vector Control Products.
4. To ascertain the influence of WHO or other regional regulatory authorities in the registration process in the country
5. To analyse the barriers and the gaps in the regulatory process that hinder the registration of the products.

4. Methodology:

The methodology adopted for collating information on regulatory pathways was:

(i) a detailed questionnaire was developed taking into consideration all parameters of the regulatory processes
(ii) Questionnaires were shared with Vector control product manufacturers and suppliers, country agents / distributors, country regulatory contacts / experts
(iii) Information was also collected from country level regulatory websites, WHO portal, third party desk reviews.
(iv) the collected information was further validated by cross checking across industry and country level malaria elimination program leads

5. An introduction to the focus countries

5.1 Indonesia

Indonesia is an Archipelago with Agriculture being the main source of income. Vector Borne diseases have been prevalent in Indonesia amongst which Malaria and Dengue are widespread. There has been steady decline in the number of Malaria cases but the disease burden is still very high. Malaria transmission occurs year-round due to diversities in vectors, geographies and environment. Vector control is still one of the most important strategies in Malaria elimination. Use of Pesticides is high for the control of vectors. Insecticide resistance is observed but only on secondary insects. Insecticide registration is very important for use of pesticides in the country.

5.2 Vietnam

Vector borne diseases is prevalent in the central and southern provinces of the country. Whilst malarial incidences have steadily decreased there is an increase in the number of Aedes borne diseases. Undetected malaria parasites in central Vietnam and antimalarial drug resistance remain barriers to malaria elimination. Vietnam's success in malaria control and elimination is attributed to widespread distribution of insecticide-treated bed nets (ITNs) and later, long lasting insecticidal nets (LLINs), extensive community education, and diversified vector control interventions in high-risk populations

5.3 Malaysia

Malaysia has effectively reduced Malaria incidence by 73% in the past couple of years. There are a lot of imported malaria cases since there are a lot of migrant workers who bring malaria into the country. Integrated Vector Management (IVM) is the key in the control of vectors and in the country's plan for malaria elimination. The regulatory system in Malaysia is very robust with stringent guidelines in testing, review, implementation and monitoring of vector control tools. Moreover, the surveillance of mosquito populations is also very well planned and hence the country has been able to keep malaria outbreaks under control despite the migrant population and other unfavorable conditions.

5.4 Cambodia

The country is transitioning from malaria control to pre-elimination. Large number of Plasmodium vivax cases in the country. Drug resistance of the parasite is also a major factor to be considered in the country's quest for malaria elimination. Forest malaria is also another important factor increasing the difficulty in the process of elimination of the disease. Moreover, the regulatory process in the country is very lax and there is no testing capacity and capability.

5.5 Myanmar

Malaria is a major vector borne disease in the country. There is a lot of insecticide resistance and forest malaria in the country making the efforts taken in eliminating the disease difficult. The regulatory processes in the country are evolving but there is a need for capacity building and streamlining regulatory processes and testing facilities in the country.

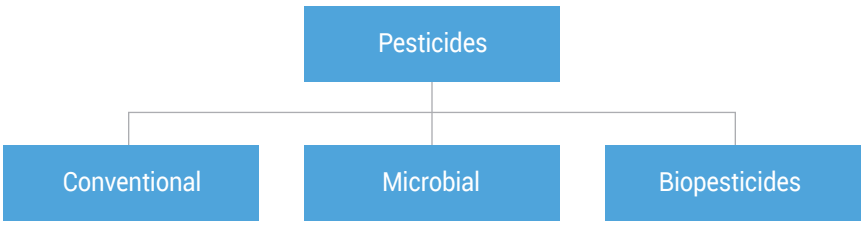
5.6 Papua New Guinea

The country has a very high malaria burden and funding allocation for intervention tools is also flawed. The regulatory process in the country is fragmented with no robust guidelines for regulating pesticide use for public health in the country.

6. Pesticide regulatory pathways in focus countries

The term "pesticides" includes Insecticides, Herbicides, Rodenticides, Antimicrobial products, Biopesticides, and other substances used to control a wide variety of pests. A pesticide product is defined as a pesticide in the particular form (including composition, packaging, and labelling) in which the pesticide is, or is intended to be, distributed or sold and includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.[15]

The pesticide registration process includes many common elements, but some aspects are specific to the pesticide category. The categories that are important for the registration process are:

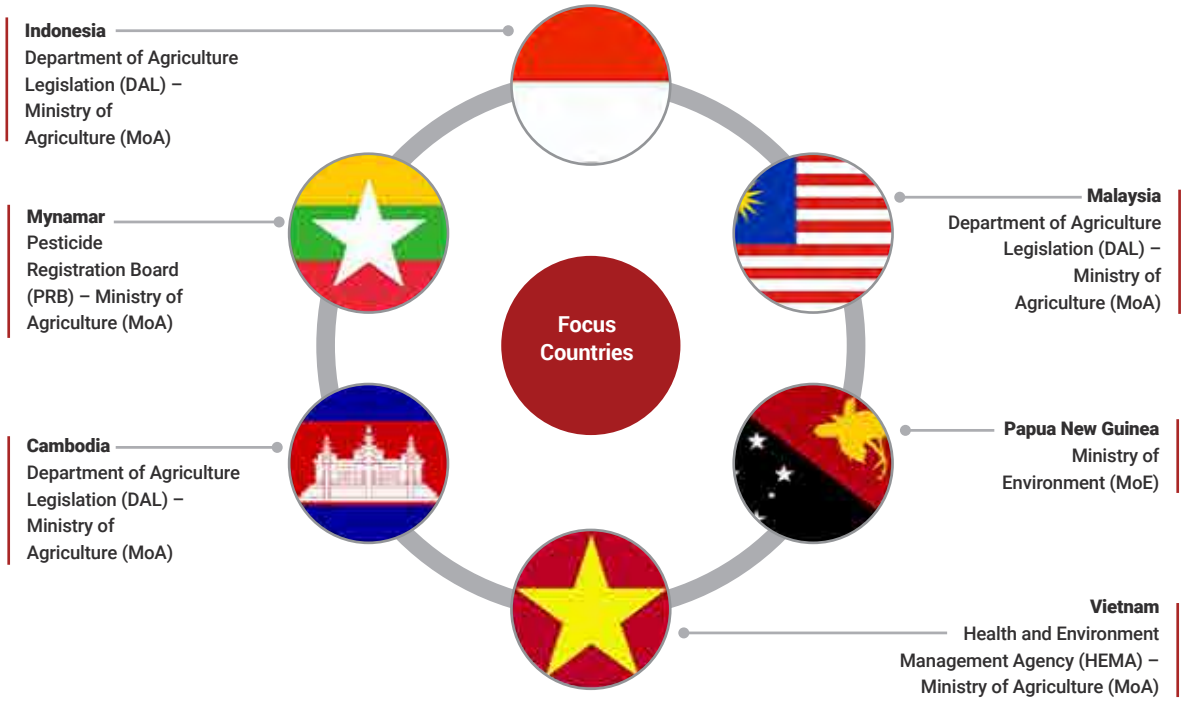


The registration process includes the following major steps for the first-time registration: (i) preparation and submission of the dossier by the applicant; (ii) initial administrative actions by the responsible authority; (iii) completeness check; (iv) technical and scientific evaluation; (v) preparation of summaries and conclusions; (vi) risk management and registration decision; (vii) publication and dissemination of registration decision; and (viii) label extension.[16]

[15] USEPA

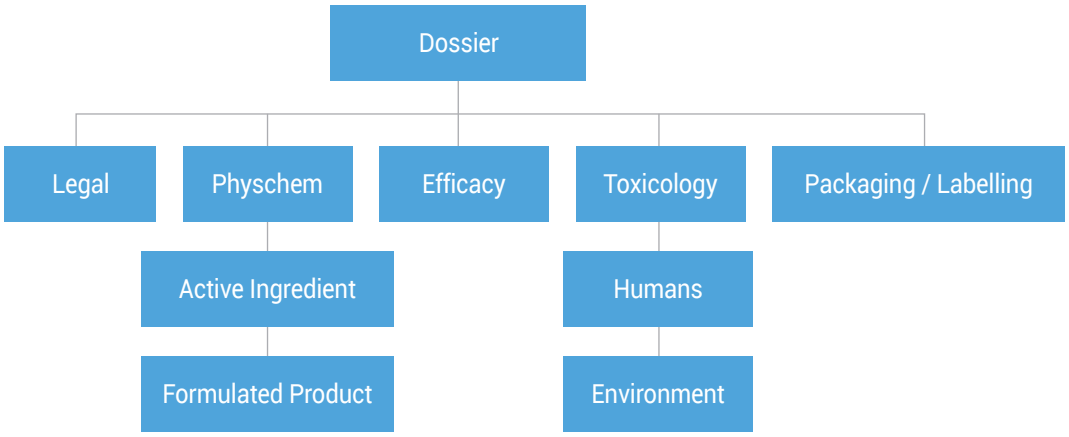
[16] WHO Guidelines on Pesticides Legislations - https://www.who.int/whopes/resources/9789241509671/en/

6.1 Regulatory Authority



6.2 Dossier Requirements

Product Registration is a careful evaluation of weighing the pesticides potential benefits of use vis-à-vis the potential adverse effects. A pesticidal product is evaluated for its (i) Quality (ii) Effectiveness against target pests (iii) Safety to Humans and (iv) Safety to non-target and environment and if its potential outweighs the adverse effects, then the product is approved for use. Therefore, for evaluation of product leading to regulatory approval, the following are components of the dossier.



6.2.1 Legal

These are administrative documents that are required to prove the authenticity of the registrant and the product. Under the legal part of the dossier the requirements are:

- Application form
- Company Registration Certificate
- Local Entity / Representative registration certificate
- Agreement with local representative
- Letter of Supply from Active Ingredient supplier
- Letter of Access
- Registration Certificates of the product registered in other countries
- Trademark registration

The above are commonly required documents but it is not the same in all the countries. There are differences in the requirement. Attachment in **Appendix 2** provides details on specific country requirements.

6.2.2 Physiochemical

This component of the dossier comes under the technical requirement part. Herein, the required data is for the (i) Active Ingredient in the product and (ii) the end use or formulated product. The data requirements are related to product chemistry apply for technical material or formulated product. It includes data on physical characteristics of the technical material and/or formulated products. Additionally, it includes data on chemical information of technical and/or formulated products. They also include providing information about impurities, submitting an analytical method for enforcement and more.

- Physical Identity such as physical nature, Formulation type, colour,
- Chemical Identity such as nomenclature, CAS Registry number
- Chemical parameters such as Solubility, Specific Gravity, Melting Point, Boiling Point,
- 5 batch analysis of the active ingredient
- Impurity profile
- Storage Stability – Accelerated and or Real time
- Manufacturing process
- Analytical and validation methods
- Analytical Reports

Despite the commonality in the requirements, several countries in the region have their own list of requirements for physiochemical parameters. Some countries insist on test reports from GLP accredited laboratories and in some countries the tests are to be conducted from ISO 17025 accredited labs only; in other countries there is no specific requirement.

Additionally, regulatory authorities in the region do direct the applicant to any specific guideline or specification such as WHO (more relevant for public health pesticides), OECD or OPPTS guidelines for generating data. The attachment in **Appendix 3** provides details on specific country requirements.

6.2.3 Efficacy

Product performance data are provided as a mechanism to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure does not occur. Specific performance standards are used to validate the efficacy data in the public health areas, including:

Evaluation of pesticidal product is an essential part of the registration process. Proof of bio-effectiveness of the product on its intended target pest(s) is a mandatory component in the approval of a product to be used in a country. Pesticides, for use in Agriculture is tested for its effectiveness in institutes / laboratories on crops and pests for which its effectiveness is claimed on the label. The same yardstick is used for vector control products. The WHO has framed several guidelines for evaluating various vector control products such as Insecticides for IRS, Larvicide, Spatial sprays, LLINs, Mosquito coils, Vaporizers, repellents, Aerosols, Biological insecticides. However, many countries in the region insist on in-country evaluation of the product for its effectiveness regardless of the data available to adequately prove effectiveness of the product on the target pest. Moreover, some of the countries in the region do not specify the appropriate evaluation guideline to be followed and leave it to the manufacturer or the testing institute to decide upon the guideline to be followed. Attachment in **Appendix 4** provides details on specific country requirements.

6.2.4 Toxicological

Data required to assess hazards to humans and domestic animals are derived from a variety of acute, sub-chronic, and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism. The information required to assess hazards to non-target organisms is derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system that progresses from the basic laboratory tests to the applied field tests.

The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause harmful effects and to determine whether further testing is required. A purpose common to all data requirements is to help determine the need for (and appropriate wording for) precautionary label statements to minimize the potential harm to non-target organisms.

6.2.5 Packaging & Labelling

A pesticide product's label is of utmost importance as the label is the primary mechanism to inform the end-user about how to use and apply the product to achieve the product's useful functions, as well as which precautions must be followed to protect both human health and the environment.

6.3 Types of Registration

Registration approval in countries comes in various categories. The categories of registration approval commonly granted in the region are (i) Full registration (ii) Provisional or Conditional Registration.

Under Full registration, the approval is granted for a defined period in some countries with no limit to the volume of pesticide that can be imported during the validity of the registration. The full registration in some countries is for a period of 3 years or 5 years. After this period, the registration is renewable for another period of 3 years or 5 years.

Provisional or conditional registration is valid for a period of 1 year or 2 years depending on the country. The provisional registration is granted for this specific period, and during this period additional data required for registration leading to full registration is to be generated. A limited volume is also permitted to be sold during this period. However, during this period of provision registration validity, the permitted volume cannot be exceeded. There is no renewal of provisional registration.

Country	Full Registration	Provisional / Conditional
Indonesia	5 years	2 years (No commercial)
Malaysia	5 years	No Provisional registration
Vietnam	5 years	No Provisional registration
Myanmar	10 years	5 years
Cambodia	No regulation for Public Health Pesticides	No regulation for Public Health Pesticides
Papua New Guinea	Permit – 1 year	No Provisional Permit

6.4 Cost of Registration

Cost of Registration differs from country to country in the region. The cost of registration includes (i) Cost of application (ii) Cost of registration (iii) Cost of in-country trials (if required) and (iv) Cost of Import Permit (if Product has to be imported into the country).

Though cost of registration in terms of application fees and registration fees are nominal, the cost gets inflated because of mandatory in-country efficacy trials in some countries in the region.

6.5 Flowchart on registration processes – country-wise

The registration process is a flow of different phases and it varies from country to country. From the time of submission of dossier to the final decision on the registration request, the process is known as registration process. The dossier goes through various stages such as pre-scrutiny, evaluation of dossier, evaluation of trial reports and then experts committee approval and final approval of ministerial board and grant of registration certificate.

The detailed flowchart examples are provided in **Appendix 5**.

6.6 Validity of Registration Certificates

As described in Section 6.3 – Types of registration, the validity of registration certificates may vary from country to country. Normally, for Full registration the validity is for a period of 3 years or 5 years in the focus countries. In countries, where provisional / conditional registration is granted, the validity is for a period of 1 or 2 years. More details on this can be referred under Section 6.3.

6.7 Requirements for Experimental Use Permits (EUP)[17]

Experimental Use Permit (EUP) or Trials Permit (TPs) are granted to a registrant to facilitate the importation of a small quantity of the pesticide to be registered or for any trial to be conducted by an institute or company for research purposes. EUP is granted on the basis of an application to be provided by the registrant of the product or by the trial scientist who is interested in importing an unregistered pesticide for the purposes of research.

Country specific EUP processes are detailed in **Appendix 6**.

6.8 Post Registration Requirement

Once the registration is approved and a certificate is issued as proof of registration, the registrant is eligible for importing, stocking and selling of the Vector Control Product. However, each activity has to be authorized by the regulatory department in the country. Following regulatory approval, if the product is imported, then an Import Permit is to be obtained. For Selling and Stocking the pesticide in different provinces or states, a Selling and Stocking License is to be obtained. In addition to this monitoring and reporting of pesticide imports and sales should also be done on an annual basis.

Import Permit: An import permit is a mandatory requirement for a foreign manufacturer who has secured a registration in the country and now is ready to import the product into the country. To facilitate the import of the product, the registrant has to apply for an import permit to the respective regulatory department. The main document required for import permit to be granted is the Certificate of Registration (CoR).

Selling and Stocking License: A local manufacturer of Vector Control products or an importer of vector control products has to fulfil another statutory requirement – Stocking and Selling permit / license. This is a permit to be accorded by the respective regulatory authority who grants the registration or an allied ministry under which local trading laws come under. Only with a stocking and selling license would the product be allowed to be placed in pesticide shops or retail outlets.

Reporting: One of the most important activities which is normally required on an annual basis is for the pesticide manufacturer, supplier, registrant, importer or distributor to file an annual report on the volume of pesticide manufactured, re-formulated, imported, re-packaged or in stock to the regulatory authority, either on a prescribed form or online. The regulatory authority can then maintain a check on the pesticides that are being manufactured or shipped into the country. This is an important tool in providing information to the appropriate authority to curb unregulated pesticides in the market.

6.9 Pesticides and Public Health Programs

In country level public Health programs, the use of pesticides is an indispensable tool for vector control. However, for inclusion as a recommended vector control product the pesticide should have regulatory approval in the country for use against the intended target pest. In addition to this it is also mandatory to be in the WHO (World Health Organization) Pre-Qualified List.

It is not mandatory to be under the WHO PQ list for registration of product for use in Vector Control in the country but to be included in Public Health Programs for procurement by country level funded vector borne disease control programs or global donor funded disease control programs, the product should be PQ listed. Many focus countries in the region are not aware of the change from WHOPES to WHO PQ. Country regulatory authorities who do not keep abreast with changes happening in the guidelines for vector control should be made aware of this significant change.

Various Country level Vector borne disease programs and have their specific requirements for vector control products as per their Vector Borne diseases Program.

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[17] Source: http://www.pertanian.go.id/ - INDONESIA ; http://vihema.gov.vn/ - VIETNAM ; http://ppdmyanmar.org/ - MYANMAR; http://www.doa.gov.my/index.php/pages/view/302?mid=141 – MALAYSIA

6.10 Importance of SRA and International bodies in country regulatory processes

The regulatory authorities in the focus countries do not have any cooperation with any Stringent Regulatory Authorities (SRA), such as US EPA or the EU, nor have any collaborative registration process between the regulatory authorities in the countries. In addition to this, the regulatory authorities in this region such as CIBRC (India), ICAMA (China), NEA (Singapore), APVMA (Australia), MAFF (Japan) do not have any influence in expediting the registration in the focus countries.

Therefore, there is no significant influence by any other regional or global regulatory authority on the registration process in the region.

6.11 Regulations on Pest Control Operators (PCOs)

Pest Control Operators play an important part in the control of vectors causing life threatening diseases such as Malaria, Dengue, Zika, Chikungunya and other mosquito borne diseases. Pest control operators are trained to handle hazardous chemical pesticides that play an indispensable role in vector control programs.

The Pest Control Operators (PCOs) are trained to handle and use pesticides in the restricted pesticides list. It is pertinent to provide quality training to personnel on safe handling of pesticides, proper spraying of the pesticide on target areas and safe disposal of pesticides. The PCOs are also trained on first aid and the use of Personal Protective Equipment (PPE).

In the focus countries in the region, some of the countries such as Malaysia and Indonesia have robust training procedures for Pest control operators whereas in some of the other countries the training and certification is not very structured.

Proper training and sharing of information are lacking in many countries in the region and due to this proper and effective delivery of insecticides on the target areas and insects is not done. Proper training and periodic inspection would ensure effective delivery of insecticides and thereby an effective control of insect pests.

6.12 Regulations on disposal of pesticides

Disposal of pesticides that have expired or used should be carried out in a proper manner. Disposal is an important issue especially in mass distribution of LLINs or mass spraying of pesticides. In many of the focus countries disposal plans are not properly framed and there are no clear guidelines provided. It is left to the discretion of the manufacturers as well as the end users.

6.13 Comparison of registration process in the focus countries vis-à-vis African registration process

Parameter	Indo-Pacific	Sub Saharan African
Regulatory Authority	Primarily Ministry of Agriculture (MoA) regulates Pesticides for Public Health use.	Predominantly, Regulatory authority in Eastern Africa is under Ministry of Agriculture. In Western Africa especially in CILSS countries though regulations would be under MoA, authorizations have to be obtained from MoH too.
Harmonization	No regional harmonization between regulatory authorities	There are several regulatory harmonization processes in Sub Saharan Africa. SEARCH – East Africa SADC – South Africa CILSS – West Africa
Role of WHO Specifications	Not mandatory for registration.	Mandatory in many countries.
In Country testing	Several countries insist on in-country evaluation of efficacy & chemical content for registration	Many regulatory authorities in East Africa insist on in-country evaluation of efficacy In West Africa, in-country evaluation is not mandatory. Other regional country evaluation or WHO recommendation would suffice.
Testing Facilities	Several countries have good GLP / ISO certified testing facilities whereas in some countries testing capacity and capability is severely challenged	Very limited GLP / ISO certified laboratories / testing facilities in Sub Saharan Africa except in a few countries
Registration Timelines	Timelines depends on testing period and review time. In some countries the timelines can be very lengthy spanning over 15 – 20 months and some countries it is 3 – 6 months	Timelines would be based on testing and review period. Average time for regulatory approval would be 6 – 8 months. However, in some countries, the need for long in-country trials and slow review process may make the regulatory approval process very long – 18 – 20 months
Types of registration	Full / Provisional / EUP	Full / Provisional / EUP
Manufacturing capability	Good manufacturing capability in many countries. However, some countries depend on importation of pesticides	Manufacturing capability is not available. All types of pesticides are imported into Africa.
Pest Control Operators	Better PCO training and certifications in many countries	Un-regulated PCO certification needs to be strengthened.
Validity of certificate	3, 5, 10 or indefinite period (till recall) Renewal of registration available	1 – 3 years only. Renewal of registration available
Labelling	Globally Harmonized System of Labelling guidelines followed. Labelling in English / Country specific language (1 or more)	Guidelines not specific. Labelling in English / Country specific language
Post Registration Inspection	Post registration inspection of goods is not required in many countries. Import permit may have to be obtained	Inspection of consignments prior to import is mandatory in many countries. 3rd party inspection agencies conduct inspection on behalf of country. Import permits are mandatory in some countries but not prevalent.

7. Identified Gaps in Regulatory Processes in Focus Countries:

The regulatory systems in all countries have certain gaps and grey areas and that's the reason there are constant attempts on streamlining the process as well as work on legislations are ongoing. Some of the gaps that have been broadly identified are as follows:

1. Fragmented Registration Process:

The countries in the region are in the process of strengthening pesticide legislation in line with international standards. There are continuous efforts by the governments to bring in newer regulations and systems. Despite, the several efforts undertaken to streamline the registration process and with advances in the processes, there are several areas of lacunae.

There are great differences between the countries in the region. The pesticide regulations are more lopsided towards regulating for use in Agriculture and the strengthening of legislations for pesticides in use for other areas especially Public Health Use is meted out with little or no change.

2. No Standardized guidelines and specifications:

There are no specific guidelines recommended for public health pesticides in many of the countries in the region. There are no guidance documents available for specific categories of vector control products. The end use products range from indoor products such as mosquito coils, vaporizers / emanators, Indoor residual sprays of insecticides, aerosols / spatial repellents, insecticide treated mosquito nets and outdoor products such as insecticides used for outdoor residual sprays etc. Each product would require specific physical and chemical characteristics and specifications, specific testing requirements, toxicological requirements, packaging and labelling requirements. However, this specific guidance document is lacking in almost all the regulatory authorities. More disabling is the lack of a provision in the legislation to provide justification or request for waiving tests that are irrelevant for a particular type of pesticide. Since the regulatory authorities in many of the countries are under the Ministry of Agriculture, very little about the products and pests in public health domain is known to the regulatory authority. Due to this lack of awareness, the requirements for public health pesticides are also squeezed into the regulatory template that is more suitable for pesticides used in Agriculture.

3. Mandatory In-country efficacy testing:

Evaluation of pesticides proving their efficacy on the intended target pests are a mandatory part in the registration process of the product. However, there are requirements in some countries in the region to conduct efficacy testing of Public Health pesticides that have been adequately tested and proven for its efficacy either as part of WHOPES full recommendation / PQ listing or in a country in the region. There are a few countries among the focus countries such as Indonesia and Vietnam wherein local testing of product efficacy is mandatory for registration of the product in the country. In Indonesia, the testing has to be done in Government approved testing institutes. In Vietnam, the testing has to be done in NIMPE. Regional trial data are not considered for regulatory approval. In Malaysia, trial data from any region with similar climatic conditions are accepted for registration. In Myanmar, due to the lack of efficacy testing facilities, reports of trials conducted following international protocols are accepted. However, in-country chemical analysis of the end use product is mandatory in all the countries.

The mandatory testing of efficacy in the region adds to the cost of the registration and also adds to the delay of the product being approved for use in the country.

Unwarranted in-country evaluation of the efficacy of pesticidal products for use in Public Health which have already been adequately tested for their effectiveness is something that can be avoided but are still mandatory requirements in some countries in the region.

4. Lengthy Registration Process:

Registration timelines are the time taken from the submission of application along with dossier to the time the registration is approved leading to issuance of registration certificate. Timelines include – dossier check, review of documents, in-country efficacy testing, quality testing, chemical analysis, review of test reports, technical committee recommendation, pesticide board approval and issuance of registration certificate.

There are various processes that take time in product registration steps. The registration process in some countries such as Indonesia take a minimum of 12 – 15 months whereas in some countries such as Vietnam the process takes about 6 months. The reasons for lengthy registration processes are due to some of the following reasons:

a. In-country trials
b. Increased workload – Lower Capacity
c. Complicated document requirement
d. Less transparency in process

5. Lack of Enforcement and Implementation:

The gap between the letter of the Law and implementation of the same is very wide. There is a lack of coordination between the various ministries in the countries in the region. The regulations are by the Ministry of Agriculture predominantly but without the cooperation of the other ministries such as Ministry of Health, Ministry of Industries, Ministry of Commerce, Ministry of Environment etc. there is no proper enforcement or implementation of the legislation.

Without proper enforcement and implementation of the legislation, there are many gaps in monitoring of pesticide imports, sale of unregistered pesticides, sale of counterfeit pesticides and thereby the availability of good quality pesticide is seriously hampered. As a consequence, there is no motivation or encouragement for genuine manufacturers and suppliers and directly impedes the vector control operations in the country.

8. Vector Control Toolbox from Regulatory Perspective:

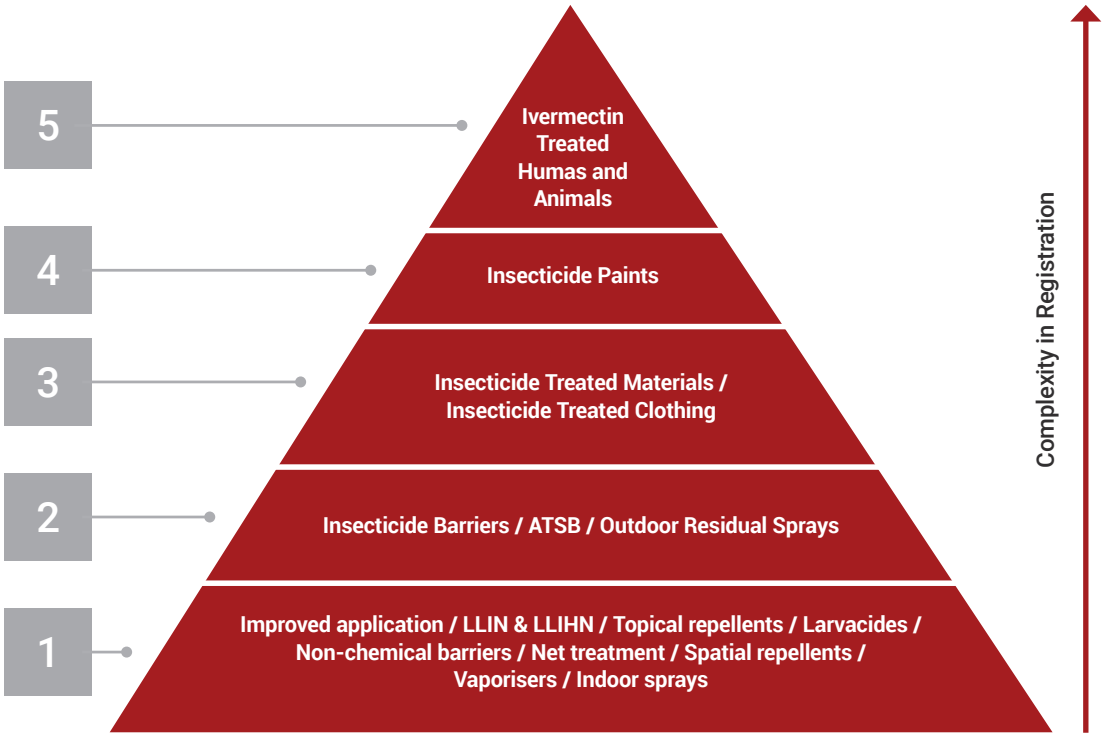
University of California and San Francisco (UCSF) have mapped the technical landscape of the DFAT – IVCC project and in this landscaping study, the disease burden, vector dynamics and distribution, epidemiology, behavior of end users and availability and suitability of vector control products have been detailed.

The landscaping study has identified that based on people's extended outdoor activities and the behavior of the main disease-mosquito vectors being more concentrated outdoors, several products have been identified on parameters such as these.

The following are the main products that have been identified from the landscaping work conducted by UCSF and further screened by DFAT and IVCC.

1. LLIN (LLIN & LLIHN)
2. Indoor Residual Sprays
3. Outdoor Residual Sprays
4. Topical Repellents
5. Forest packs
6. Space Sprays
7. Insecticide treated screens
8. Insecticide treated paints
9. ATSB (Attractive Toxic Sugar Baits)
10. Ivermectin treated Livestock
11. Ivermectin treated Humans

The above list contains the comprehensive list of product categories that have been identified by UCSF in their technical landscape analysis.



The bottom (1) layer of products such as LLIN / LLIHN, Topical repellents, Larvicides, Spatial repellents, Conventional net treatments, Spatial repellents, Vaporizers, IRS are all registered as recommended public Health products in the various countries in the region. There are several registered vaporizers, coils and topical repellents in the various focus countries in the region. These are registered to be sold in retail markets. Apart from these, several brands of LLINs and Chemical pesticides have been registered and approved to be used in mass distribution under various Vector borne diseases control programs.

So, these are potentially products that are available for easy adoption and induction into the public health programs appropriate for specific countries as per the need identified by technical landscape and the challenges identified in the market access profiling of the country. Based on the funding source and need suitable product mix can be picked up from the tool box and provided to the end users.

The second level (2) of products such as Insecticides Barriers i.e. materials treated with insecticides such as Insecticidal screens, Attractive Toxic Sugar Baits (ATSB), Outdoor residual sprays are some products which have not been registered. However, the complexity of registration of these products are less and can be easily considered for registration with some minimal data generated. Since Outdoor residual sprays would have to have additional environmental safety studies and stability studies done there would be some time to be factored in for the registration of this product. Insecticide barriers in the form of a net would be a label extension of indoor nets but this too would have some additional data generated.

Since, vector control success depends on integrated vector management and a steady supply of innovative intervention tools, it is important to start working on securing specifications and country specific registrations for these products. However, it is also important that the regulatory processes in the countries would create legislations to fast track certain low risk products or use extension of certain existing products.

The third level (3) of products consists of Insecticide treated clothing and Insecticide treated materials. There are no categories created for these products but some commercial products have been tested and approved for use especially by military in some countries. These products would be of much importance for forest dwellers and migrant population – a scenario which is very common in this focus region. However, the regulatory requirements should be made less complex for these products and the regulatory authorities in the focus countries should take help from international regulatory authorities who have experience in working on such products.

Since, the regulatory authorities are mostly from Ministry of Agriculture, the onus would be with the Vector Borne Diseases Control programs under the Ministry of Health who would have to work closely with the regulators in making them understand the importance of these newer innovative products.

The fourth level (4) of product(s) are insecticide paints – this is an innovative product which would be of great help in reducing vector burden inside the houses and can be safer and aesthetic alternative for indoor residual sprays. However, the product needs extensive testing and proof of concept to be established. Nevertheless, there are specifications to be finalized and then data requirements need to be finalized.

The regulatory landscape for this product on a complexity scale would be high and the regulators need to be quick to formulate guidelines for registration.

The fifth level (5) level would probably be regulated under Animal Health Directorate or human Directorate. This is a complex level of regulation.

9. Pathways into the Future:

The regulatory pathways landscape has been constantly being upgraded with new legislations and making the regulations more robust and more adaptable. However, the changes have not been rapid and there is much to be changed and for these changes, the following would be pathways that can be taken into consideration.

1. Regional Harmonization:

There is a need to harmonize the regulatory processes in the various countries in the region. There have been many attempts and workshops on the harmonization of regulatory processes and the changes in the legislations and processes can be to some extent be attributed to these programs. However, there needs to be a systematic look at the various aspects of regulatory process in the region and the various countries in the region to bring about a homogeneous harmonization.

In this direction, the ASEAN harmonization work has been initiated in the year 2018 and work is under progress to bring about harmonized regulatory processes for Pesticides used in various categories. There is also work done by programs such as VCAP (Vector Control Platform for Asia Pacific) spearheaded by APLMA, Unitaid and APMEN in the South East Asian Region.

2. Standardized Guidelines:

The guidelines for various intended use of pesticides need to be streamlined and standardized. The current guidelines in some countries for pesticide registration is a standard guideline – in terms of studies required for pesticides to be registered for use in Agriculture, Public Health / Household, Veterinary, Industrial etc. Currently in some countries there is no specific guidelines and testing methods provided for specific use categories. There is no reference to WHO guidelines which have been standardized for different use categories of Public Health Pesticides. There are specifications and study guidelines including risk assessments for Mosquito coils, vaporizers, Indoor residual sprays, LLINs, spatial sprays, Larvicides, fogging etc. but these guidelines are not referred nor recommended in the guidelines for registrations of public health pesticides in many of the focus countries.

Moreover, in some countries such as Vietnam there is no guidelines for registration of microbial pesticides to be used in Public Health. This situation gives a platform for low quality microbial intervention tools to be used in the country. This situation of not having any regulation is more harmful than a situation wherein there is slack in the regulatory process.

3. Acceptance of Regional trials:

Some countries in the region insist on in country testing of public health pesticides and data generated in institutes approved by the regulatory authority, before registration is granted. This requirement is despite the fact that the product would already be tested adequately and listed in Pre-Qualified (PQ) list or the product has been tested in the country in the region. Only some regulatory authorities in the region accept regional trial like Malaysia, Singapore etc. whilst in some countries such as Vietnam, Indonesia insist on local bio-efficacy trials. This disparity in the regulatory requirements is to be standardized and acceptance of trials conducted in any country in the region following international or standardized trial protocols should be accepted. Moreover, when trials have been conducted on the product especially for PQ listing and the product has been comprehensively tested, the need for repetitive in-country evaluation not only increases cost but also the time to market these valuable tools for protecting human lives against deadly vector borne diseases.

Harmonization of guidelines and processes would help in regional countries accept regional trials regardless of which country the trials have been conducted.

4. Prioritization of Public Health Pesticides:

Many of the countries in the region do not have any specific legislation to promote the registration of pesticides used for public health by providing special categories such as reduced risk or minor use pesticides. Moreover, there are no provisions for accordance of priority for public health pesticides by taking into consideration the need of these products quickly so that their use in saving human lives could be expedited. Therefore, there should be legislations enacted in the act wherein priority in evaluation, scrutiny and approval of public health pesticides especially to be used in mass distribution under malaria elimination programs should be done. This would help manufacturers and malaria / dengue elimination / control programs to avail a fast track regulatory mechanism and thereby have newer products.

5. Strengthening analytical and testing facilities:

The focus countries in the region had varying capacity and capability of testing facilities in the country. Some of the countries such as Malaysia have highly evolved facilities in terms of entomological and chemical testing. Several laboratories are ISO 17025 and GLP accredited in Malaysia. In Vietnam, many ISO 17025 accredited laboratories are available but very few GLP accredited laboratories are available. In Indonesia, the testing is all to be done by government approved laboratories. However, there are several private testing laboratories which are ISO 17025 accredited. Myanmar, Cambodia and Papua New Guinea needs to have their capacity and capability improved. There is a need for improving the equipment and facilities for testing and also for upgrading the capabilities of personnel in testing and evaluation of products.

6. Coordination and Cooperation of policy makers:

The regulatory mechanism is only effective as long as proper implementation of the regulations are enforced properly. For the implementation of the regulatory mechanism there should be proper cooperation and coordination with the different governmental department. In many countries, the ministry of Agriculture is the regulatory authority regulating pesticide registration, but the importance of other ministries such as Ministry of Health, Ministry of Commerce, Ministry of Trade, Ministry of Environment for proper implementation of the legislation in terms of testing, monitoring, surveillance, import of unregistered pesticides, manufacturing license of pesticides, selling license of pesticides, disposal and use of pesticides. These are monitored by different government entities under different ministries and only if there is seamless coordination between the ministries the legislation can be enacted properly and regulatory processes will be able to implement the intended process.

Unfortunately, this is less evolved in some countries and it has to be streamlined so that implementation could be done effectively.

10. Potential Advocacy Groups / Influencers:

1. ASEAN Harmonization

The regulatory processes in the region has to be harmonized so that the guidelines, testing, review, labelling, monitoring and implementation would be uniform across the various countries whereby the registration of public health products would be seamless across boundaries making it easier for innovative vector control tools be introduced for the control of vector borne diseases.

ASEAN (Association of South East Asian Nations) is in the process of developing detailed harmonized guidelines for registration of pesticides in South East Asian Region. This would enable swifter and robust registration of pesticides for use in various fields.

2. Regional / Global Malaria Programs

The regulatory processes in the various countries can be bolstered by the regional and global malaria programs who could impress upon the regulatory authorities on the need for quicker approval process in the various countries. The launch of VCAP (Vector Control Platform for Asia Pacific) is a good forum for sensitizing the regulatory authorities on the need for streamlined regional regulatory processes in the various countries in the Asia Pacific region. This could be good platform for countries outside the ASEAN region for regulatory process up-gradation and also for capacity building.

3. Donors

Donors can play a pivotal role in funding for effective malaria control in different countries based on the capacity of the country as well as the disease burden in the country. Donors also wield significant powers in influencing policy changes in the country especially when the need for innovative intervention tools are required.

4. Manufacturing companies

Due to diversity in vector population, population dynamics, resistance issues manufacturing companies should be constantly be innovating to discover newer vector control products. However, one of limiting factors to innovation is the sluggish pace at which some of the country regulations allow new innovations into the market. This discourages manufacturers from investing time and money on innovations for vector control products. Therefore, the manufacturing companies should influence policy makers to consider streamlining regulations for hastening regulatory processes for public health pesticides.

5. Country Level Governmental bodies

Though the regulatory processes in the country level have representations from various ministries such as Ministry of Health (MoH), Ministry of Commerce (MoC), Ministry of Environment (MoE), Ministry of Industry and Trade (MoIT) in the regulatory processes. However, the co-operation and coordination between the various ministries is very slack and needs a much better robust cooperation. If a seamless cooperation exists between the various ministries then there would better sharing of information and also coordination of the various ministries in the strengthening of the legislations as well as better implementation of the legislations.

Appendices

Appendix 1

Regulatory pathways summary

Vietnam / Indonesia / Myanmar / Malaysia / Cambodia / Papua New Guinea

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
1.	**Registration Requirement [Whether registration in country is mandatory or not]**	Mandatory for Household use pesticides under MoH and Agricultural Pesticides under MoA. Microbial Pesticides are not regulated under MoH. Reg. validity – 5 years – Renewable	Registration for Pesticides for household use / vector control is regulated under MoA. Biological Pesticides are also regulated under the MoA. Reg. Validity – 5 years – Renewable	Registration for pesticides for household use / vector control is regulated under MoA. Reg. Validity – 10 years – Renewable	Registration for all household pesticides and public health use pesticides are under MoA. Registration validity – 5 years. Renewable	There are no requirements for registration of pesticides for public health use. Allows import of products recommended by WHO / PQ listed	The Environmental contaminants Act governs pesticide usage. Need to obtain a permit for pesticides being imported into the country. Validity of Permit – 1 year. Renewable.
2.	**Ease of Regulatory Process [How stringent are the regulatory processes in country] (Scale 1 – 10*) *Scale given below the table**	Dossier requirement is simple. In-country trials are mandatory. Scale: 5	Lengthy registration process with long delays in securing registration. Scale: 8	Process can be very long since registration committee doesn't meet regularly. New Products process can be very lengthy Scale: 6	Systems for registration are place. Guidelines are available. Justifications are acceptable. Scale: 4	No specific requirement for registration of pesticides to be used in Public Health. Rating given on import permit instead of registration Scale: 2	Simple process to obtain permit. Requirements are minimal. Rating is given on import permit Scale: 2
3.	**Regulatory authority [Name and address of the regulatory authority regulating VCP]**	HEMA (Health & Environmental Management Agency) Ministry of Health – MoH	Ministry of Agriculture - MoA	Plant Registration Board (PRB) under the Plant Protection Department (PPD) under the Ministry of Agriculture (MoA)	Pesticide Board under the Ministry of Agriculture (MoA)	Pesticides are regulated by Ministry of Agricultural, Forestry and Fisheries (MAFF) for Ag. Use.	Ministry of Environment (MoE)
4.	**Timeline for approval [How long does regulatory process take for placing product in market]**	6 – 12 months depending on the product i.e. for Mosquito coils, vaporizers the registration timeline would be around 5 – 7 months and the rest would be 8 – 12 months.	18 – 24 months depending on the product and the complexity of the registration	6 – 8 months Process can become very long if it is an innovative product	8 – 12 months	No regulatory process. Hence no timelines	Securing a permit to import pesticide is about 1 – 2 months
5.	**Registration Holder [Is registration given to foreign entity or for local entity only]**	Local Representative / Local Entity	Local company or a local agent for a foreign company.	Local distributor or legal entity	Local legal entity or distributor should be the registrant	Any entity or individual interested in importing can import the product	Any local entity or supplier of pesticide can apply for permit
6.	**Data Requirement [Broad requirement of data for VCP registration in country]**	Standard data required – Company registration certificate, LoA, LoS, Physiochemical, Bio-efficacy, Toxicological and Labelling.	Standard data required – Company registration, trademark registration, LoA, LoS, Physiochemical, Efficacy, Toxicological and Labelling.	Standard data required. Local distributor Company certificate	Standard physiochemical, Toxicological, packaging and labeling is required. Efficacy trials from region is acceptable.	None	Environmental risk assessment, labels, SDS and other country registration certificates.
7.	**Harmonization of Process [Is there any regional harmonization of regulatory process]**	No harmonization of data or regulatory process	No harmonization of data or regulatory process	No harmonization of data or regulatory process	No harmonization of data or regulatory process	No harmonization of data or regulatory process	No harmonization of data or regulatory process
8.	**Online Process [Is there provision for online processing of VCP registration]**	Online submission of various applications – Registration & Licensing is available	Online submission of registration available in the regulatory system.	No provision for online submission	Yes, online submission provision is available	No online process is available	No online process is available
9.	**Registration Fees [What is the total cost of registration including trial cost]**	Cost of Registration – 450 USD Cost of trials – 10000 – 15000 USD Additionally, for PH Programs studies are to be done in North, Central and South Provinces	Cost of Registration 600 USD Cost of Trials - ~15000 – 20000 USD	Chemical analysis – 200 USD / unit Cost of Registration – 3200 USD for Full registration and 1300 USD for Provisional Reg. EUP – 650 USD	Cost of registration – 750 USD	None	Cost of Permit – 40 USD

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
10.	**Technical (active substance) Reg. [Should active substance be registered before VCP is registered]**	The regulatory authority does not register Technical (a.s.) material. They have a list of approved Technical substances and VCPs are to be from these active substances.	Information on Technical (a.s.) material needs to be submitted along with the dossier for formulated product. Technical product registration is available.	Technical (a.i.) material registration process is not a capability under the registration department.	Yes, Technical (a.i.) material registration is required.	None	There is no requirement for Technical (active substance) registration required.
11.	**Technical Equivalence (a.s.) [Is there a provision to have equivalence for technical material]**	No Technical equivalence provision available	No Technical equivalence is available.	No Technical equivalence provision is available.	Technical equivalence provision is available in for comparative Technical grade	No Technical equivalence provision is available.	No Technical equivalence provision is available.
12.	**'Me Too' / Identical Registration [Can a registration be obtained for already approved VCP]**	No identical or 'me too' registration provision	No identical or 'me-too' registration provision	No identical or 'me-too' registration provision	Identical registration process is not available in the country.	No identical or 'me-too' registration provision	No identical or 'me-too' registration provision
13.	**Country Specific Labelling [Is there a country specific labelling for VCP products]**	The requirement for the labelling is not specific but reference is made to GHS. Preferred language on the label is Vietnamese. If main label is in foreign language then secondary label should be in Vietnamese	The labelling requirements to be followed are provided in the Pesticide Act. Labelling generally follows the GHS or FAO guideline. Indonesian language required.	Nothing specific but standard labelling requirement. FAO labelling guidelines referred to. Language required is Burmese.	Yes, labelling requirement are clearly defined by regulatory authority. GHS labeling guidelines are followed. Labels should have 3 languages describing safety procedures	Labelling required for pesticides used in agriculture. Since no registration of PHP labelling not required.	No country specific labeling is required.
14.	**VCP approved [What are the broad categories of VCP approved in-country] The approved lists of each country are annexed in Appendix**	There is no specific list of approved VCPs available. There is however, a list of banned and prohibited list of pesticides available.	There is specific list of pesticides with trade name of the product, company name available.	List of approved pesticides available which includes Public Health Use pesticides.	Vector control products are registered under Household pesticides category and is separately listed in registered products list	For Public Health Programs all PQ listed products are allowed.	No specific list of pesticides used for Public Health use.
15.	**VCP in Public Health Programs [What are the VCPs in Public Health Programs in the country]**	PH programs pesticides should be WHOPES / PQ listed since most of the	Yes, a list of pesticides in PH programs is also available.	Public Health Pesticides are listed in the list of approved public Health pesticides	Yes, PH pesticides are listed as PCO or Household pesticides	All PQ listed products are allowed in Public Health Programs.	None
16.	**Biological Vector Control Products [Are Biological VCPs to be registered in the country]**	Registration not required for Biological VCP. Hence there is no list	Registration is required for Biological products too and this is also listed in the list of registered pesticides	Yes, Biological Vector Control Products are also registered under the regulatory department.	Microbial pesticides are registered under the same regulatory authority.	No specific guidelines or registration requirement for Biological Vector Control Products.	No specific guidelines for Biological Vector Control products
17.	**Emergency Situations [Are unregistered products or are registrations fast tracked during exigencies]**	There is no provision for Emergency regulatory approval process under the regulatory authority	There are no provisions for an emergency approval process.	No specific provisions for emergency use registration	There are no specific provisions for unregistered pesticides to be approved for emergency.	No specific guidelines.	No specific guidelines.
18.	**Retail Markets [Are approved VCPs allowed to be sold in retail markets?]**	Retail Markets [Are approved VCPs allowed to be sold in retail markets?]	Specific licensing to be obtained for retailing pesticides. Retail license to be obtained from DoH and is valid for 4 years.	Retail permit to be obtained as a separate license to sell pesticides in retail shops	Retail permit / licensing is mandatory for placing pesticides in retail markets.	No specific requirement for getting retail permit for public health products	No specific requirement for retail permit for public health pesticides
19.	**Insecticides Banned [Are any VCP banned or not registered in-country due to restrictive processes]**	All Class 1a and 1b pesticides as per the WHO toxicological classification are banned and cannot be registered.	All Class 1a and Ib pesticides as per the WHO toxicological classification are banned and cannot be registered.	All Class 1a and Ib pesticides as per the WHO toxicological classification are banned and cannot be registered. (POP & PIC List Pesticides)	Highly hazardous pesticides are also registered. Commodity & Proprietary pesticides. Different costs for registration of different toxicity class	All Class 1a and Ib pesticides as per the WHO toxicological classification are banned and cannot be registered.	No specific list of banned pesticides.

*Scale 1 – 10 with 1 – very easy / no regulations & 10 – very strict; The ease is measured cumulatively based on time taken, data required, processes involved etc.

Source: http://www.pertanian.go.id/ - INDONESIA ; http://vihema.gov.vn/ - VIETNAM ; http://ppdmyanmar.org/ - MYANMAR; http://www.doa.gov.my/index.php/pages/view/302?mid=141 – MALAYSIA; http://web.maff.gov.kh/contactus?lang=en – CAMBODIA; http://www.pngcepa.com/ - PA-PUA NEW GUINEA

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
20.	**Are Local trials required? [Are local trials required for in-country regulatory approval]**	Yes, both chemical and efficacy trials are to be conducted in country as part of registration process	Yes, both chemical and efficacy trials are to be conducted in country as part of registration process	In country chemical analysis is required. Efficacy trials are not mandatory. Country capacity to conduct trials limited.	Bio-efficacy trials are required as part of registration but in country trials are not mandatory. Regional trials are accepted	No local trial is required for public health products.	No local trial data is required.
21.	**Is GLP data mandatory? [Should data be generated in facilities with GLP accreditation]**	No, GLP is not mandatory but study on efficacy as well as chemical content must be done under ISO 17025 accredited labs.	GLP data not required for physiochemical or efficacy data. But Toxicological data is to be conducted in GLP accredited labs	GLP data not mandatory.	Yes, toxicological data and physiochemical data are to be done in GLP certified labs	Not applicable	No specific requirement is given
22.	**Testing facilities capability [Are there any international or GLP accredited facilities in country]**	There are several ISO 17025 labs accredited to conduct chemical content. However, ISO 17025 labs conducting efficacy are limited.	MoA has a list of approved labs for conducting efficacy trials. The country also has several GLP and ISO accredited labs.	Limited testing capability	There are many testing facilities for efficacy, chemical analysis and toxicological studies. WHO collaborating center is also available	In country testing is severely limited. No efficacy testing facility. Chemical analysis facility available.	Limited testing capability
23.	**Cost of Local trials [What is the cost of conducting local trials]**	~10000 – 15000 USD	~15000 – 20000 USD	200 - 300 USD (Analytical studies)	Regional trial data is acceptable Local trial cost would be around 10000 USD	No local testing	No local testing
24.	**Institutes approved for Local trials [What institutes in country are approved for local trials]**	NIMPE – National Institute for Malariology, Parasitology and Entomology IMPE	A list of approved institutes by the MoA	National Agricultural Laboratory (NAL)	Regional trial data is acceptable. In country testing facility such as USM is readily acceptable.	No testing capacity or capability	No testing capacity or capability

Source: Regional Regulatory Authorities, Pesticide Manufacturers, WHO – https://www.who.int/whopes/resources/by_year/en/; https://www.who.int/pq-vector-control/en/

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
25.	**FAO-WHO JMPS Specification [Is it mandatory or a requirement for Technical (a.i.) to have JMPS specs]**	It is not mandatory for the technical to have FAO-WHO specification to be considered for registration under household use category or for PH programs	FAO specifications is referred but is not a mandatory requirement.	FAO specifications are preferred but not mandatory.	FAO / WHO specifications are recommended for PHP products. However, it is not mandatory for registration.	WHO approved products are permitted for im-port into the country for public health programs.	FAO / WHO specification is not referred.
26.	**Stringent Regulatory Authority [Would stringent regulatory authority registration waive in country registration]**	SRA registration does not expedite nor waive registration requirement	SRA registration does not expedite nor waive registration requirement	SRA registration does not expedite nor waive registration requirement.	SRA registration does not expedite nor waive registration requirement	SRA registration has no bearing on regulatory processes. There are no registrations for PHPs	SRA registration has no bearing on regulatory processes. Only permits are required.
27.	**WHOPES / PQ Recommendation [Is there waiver of regulatory process if VCP is WHOPES / PQ recommended]**	WHOPES or PQ listing does not waive registration requirement.	No waiver or fast tracking of registration	No waiver or fast track registration process	No waiver or fast track registration process	No registration of PH pesticides.	Not applicable
28.	**WHOPES / PQ mandatory [Is WHOPES / PQ listing mandatory for approval of VCP]**	For country registration of VCP WHOPES recommendation / PQ listing is not mandatory. Registration is done despite PQ status. Public Health Programs consider only PQ listed products	Not mandatory for registration Public Health Programs consider only PQ listed products	Not mandatory for registration Public Health Programs consider only PQ listed products	Not mandatory for registration Public Health Programs consider only PQ listed products	Public Health Programs consider only WHOPES/PQ listed products	Public Health Programs consider only WHOPES/PQ listed products
29.	**Regional Influencers [Any regional influencers on in-country registration process]**	A registration with a regional regulatory authority does not influence the registration process in the country.	No regional influencer or registration scheme that can influence registration process. Registration in the region can be favorable	No regional influencer or registration scheme that can influence registration process. Registration in the region can be favorable.	No regional influencer of registration scheme	No regional influencer – No regulatory requirement	Registration under APVMA (Australian Reg. Authority) would hasten the process.
30.	**Collaborative Registration [Does the country RA collaborate with any other Registration Authority]**	There is no collaborative registration process under which the regulatory authority is part off.	No collaborative registration process	No collaborative registration process	No collaborative registration process	No collaborative registration process	No collaborative registration process

Source: Regional Regulatory Authorities, Pesticide Manufacturers, WHO – https://www.who.int/whopes/resources/by_year/en/; https://www.who.int/pq-vector-control/en/

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
31.	**In-Country Manufacturing [Is there manufacturing of VCP's in the country]**	In country manufacturing of household pesticides such as LLINs and other retail products are predominant	Pesticide re-packaging is done extensively. Mosquito coils, vaporizers are manufactured but no capability to manufacture LLINs or other chemical pesticides	No manufacturing capability. Pesticides are all imported into the country.	Yes, capacity if there for formulation. No manufacturing of LLINs.	No manufacturing capability. Pesticides are all imported into the country.	No manufacturing capability. Pesticides are all imported into the country.
32.	**Manufacturing Licenses [Is there a need for obtaining manufacturing license to manufacturing VCPs]**	Manufacturing license is to be obtained prior to manufacturing of formulations, repackaging of pesticides.	Manufacturing license is to be obtained for formulation, repackaging of pesticides	Manufacturing license to be obtained if formulation or repackaging of pesticides is to be done	Yes, manufacturing license is to be obtained if any formulating or repackaging is done	No manufacturing capacity	No manufacturing capacity
33.	**Marketing Licenses [Is there a need to obtain marketing licenses in different states or provinces in-country]**	Marketing licenses are not required. Registration certificate is enough for marketing.	Selling and Storage License needs to be obtained. Public Health Pesticides have to obtain permit from Department of Health, MoH	Selling and Storage License to be obtained prior to stocking and selling of pesticides in shops	Yes, selling and storage license is to be obtained prior to stocking and selling of pesticides.	No specific marketing license required	No specific marketing license required
34.	**Pre / Post Shipment Inspection [Is pre-or post-shipment inspection of VCPs mandatory by 3rd party accreditations req,]**	Not a requirement for registration. But donors and or implementing agencies in country would insist on 3rd party inspections	Not a requirement for registration. But donors and or implementing agencies in country would insist on 3rd party inspections	Not a requirement for registration. But donors and or implementing agencies in country would insist on 3rd party inspections	No specific requirement. But donors and implementing agencies might insist on inspection	Donors and implementing agencies might insist on inspection	Donors and implementing agencies might insist on inspection
35.	**Certifications / PCO [Any other in-country certifications to be obtained for VCPs]**	Licensing of Pest Control Operators are limited. PCOs have to apply for a license. Restricted pesticides application can be done by licensed applicators.	No quality certification program for registered pesticides. Licensing not very structured. PCOs have to obtain license before undertaking any pesticide application	Certified licensed applicator is the one responsible for PCO work Applicator training certificate and First aid training license essential.	Robust certifying process exists in the country.	Semi regulated and not proper	No specific process or regulatory requirement.

Source: http://www.pertanian.go.id/ - INDONESIA ; http://vihema.gov.vn/ - VIETNAM ; http://ppdmyanmar.org/ - MYANMAR; http://www.doa.gov.my/index.php/pages/view/302?mid=141 – MALAYSIA; http://web.maff.gov.kh/contactus?lang=en – CAMBODIA; http://www.pngcepa.com/ - PA-PUA NEW GUINEA

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
36.	**Core group responsible [Which group is responsible for all vector control activities in Public Health]**	Ministry of Health	Directorate General for Communicable Diseases and Environmental Health, the Directorate for Vector Borne and Zoonotic Diseases, and the Sub-directorate for Vector Control, MoH	Vector Borne Diseases Control under Department of Public Health under Ministry of Health	Vector Borne diseases control under Ministry of Health	CNM – Cambodia National Malaria program	National Malaria Program
37.	**National Guidance Document [Is there a National Guidance document to procure VCPs]**	National Malaria Control Program National Dengue Control Program (The National Strategy for Malaria Control and Elimination)	National Malaria Elimination Action Plan Procurement is done by Malaria Sub Directorate.	National Malaria Control Program (National Plan for Malaria Elimination in Myanmar 2016-2030)	National Vector Borne Diseases Control Program monitors all vector borne diseases	Yes, National malaria elimination Policy document exists	National Malaria Program governs all policies regarding malaria control.
38.	**Global Donors [Which are the Global Donors active in the country]**	Global Fund PMI	Global Fund Government funding	Global Fund – UNOPS being the principal recipient of the fund. PMI, Save the Children, JICA	Exclusively country funding only.	Global Fund, PMI, Country funding	International Donor funding is limited despite high disease burden.
39.	**Guidance document on disposal [Is there a guidance document on the disposal of used VCPs]**	No clear guidance document existing on the disposal of VCPs.	Disposal document is provided as part of the MoA legislation on Pesticide registration.	No specific guidance on disposal of Vector Control Products.	No detailed guidance document available on disposal. Standard disposal methods defined.	No specific guidance on disposal of vector control products	No specific guidance on disposal of vector control products

Source: http://www.searo.who.int/entity/malaria/data/en/

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
40.	**Resistance Status [What is the resistance status of mosquito vectors]**	Pyrethroids resistance observed.	Pyrethroids and Carbamates resistance observed	Pyrethroids, OPs and OCs Resistance observed	Resistance to Pyrethroids is prevalent.	Pyrethroids, OPs and OCs Resistance observed	Pyrethroids resistance observed.
41.	**IRM Policies [Are there any active Insecticide Resistance Management policies in-country]**	NIMPE & IMPE do annual resistance monitoring in 3 sites (Northern, Central and Southern provinces) For inclusion in PHP programs, trials have to be done in North, Central and South provinces)	No routine surveillance IRM Policy on monitoring and reporting.	No annual country IRM Policy on monitoring and reporting. National Malaria Control Program has stressed the importance of IRM. However segmented monitoring is followed.	Country wide resistance monitoring is structured and actively	No resistance monitoring system in the country. Capacity is missing.	No resistance monitoring system in the country. Capacity is missing.
42.	**IVM Policies [Are there any Integrated Vector Management policies in-country]**	No country IVM Policy. MoH and MoA are planning to implement guidelines for correct use of PHPs. This is yet to be put in place.	No country IVM Policy as part of the Vector control program.	IVM is not formally a part of National Malaria Elimination Program. No country IVM Policy. National Malaria Control Program has stressed the importance of IVM	IVM policy is adequately incorporated in the Vector Borne diseases program.	No structured country IVM policy.	No structured IVM policy in the malaria program.

Source: http://www.searo.who.int/entity/malaria/data/en/ ; http://www.searo.who.int/entity/malaria/documents/myanmar_mpr/en/

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
43.	**Comparative VCP Regulations [What is the comparison / differences in the regulatory process in Africa vs Asia]**	The regulatory process is under the MoH and this is similar to the regulatory mechanisms followed in some West African countries by the Ministry of Health.	Regulatory process in MoA can be considered similar to East African Regulatory bodies – SEARCH Countries	Regulatory systems are evolving in Myanmar. There are guidance documents on the regulatory processes for Agrochemicals. The system can be on par to some evolving regulations in Africa.	Regulatory processes are well structured with robust guidelines and legislations.	Many African countries depend upon WHO / PQ listing for permitting Public Health pesticides. The regulations in Cambodia are similar to that.	The regulatory requirements are similar to the countries wherein WHOPES / PQ listing is acceptable.

Source: JVP analysis

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
44.	**Gaps in Regulatory Process [What are the gaps / barriers in the regulatory processes that delay or hinder registration of new products]**	1. Regulatory system is under the Ministry of Health with limited inputs from Ministry of Agriculture. 2. No specific regulatory requirement for various categories of VCPs. Biological VCPs are not regulated. 3. In country efficacy testing is mandatory making registration process quite long. 4. WHO Guidelines not implemented for regulating VCPs 5. Additional trials required for inclusion into PH Programs 6. Harmonization lacking	1. Lengthy registration process 2. In country efficacy testing is mandatory. 3. No specific guidelines for different types of Public health pesticides. 4. No priority accorded for Public Health Pesticides 5. No expedited registration process for Public health pesticides 6. WHO Guidelines not implemented for regulating VCPs	1. Lacks specific guidance documents to be followed. 2.. Lacks quality control processes 3. No in-country testing facilities 4. IVM Policies are lacking. 5. FAO / WHO guidelines not utilized 6. Limited cooperation between ministries	1. Lack of Prioritization PHP registration	1.No regulations / registration process for Public Health Pesticides. 2. Limited Capacity for quality control and testing 3. Enforcement / Monitoring of illegal pesticide trade very scarce.	1. No perceptible regulatory system exists. 2.. Guidelines very vague. 3. Legislation does not exist for pesticides.

S.No.	Parameters	Vietnam	Indonesia	Myanmar	Malaysia	Cambodia	Papua New Guinea
45.	**Advocacy [Who / Which groups or agencies that can potentially do advocacy in the region]**	WHO / FAO Donor agencies Regional Disease Control partnership – APLMA, APMEN, MHDC Manufacturers and Suppliers of VCPs ASEAN & ADB					

Appendix 2

Legal:

Indonesia:

1. Requires Free Sales Certificate (Registration in the country of Origin)
2. Requires registration of trademark in trademark registry

Vietnam:

1. Requires Free Sales Certificate (Registration in the country of Origin) – Legalized in the Vietnamese embassy in the country of origin.
2. All documents should be translated into Vietnamese

Appendix 3

Physical and Chemical:

Myanmar:

1. Requires payment of analytical test fees and this should be attached along with the application form with samples for the application to be accepted.

Indonesia:

1. Analytical test report should be from GLP accredited test lab.

Vietnam:

1. Analytical test report should be from an ISO 17025 accredited lab

Appendix 4

Bio-efficacy:

Malaysia:

1. Regional test reports are accepted – if done following internationally accepted test protocols
2. Regional testing should be done in countries which have similar pest profile and climatic conditions

Indonesia:

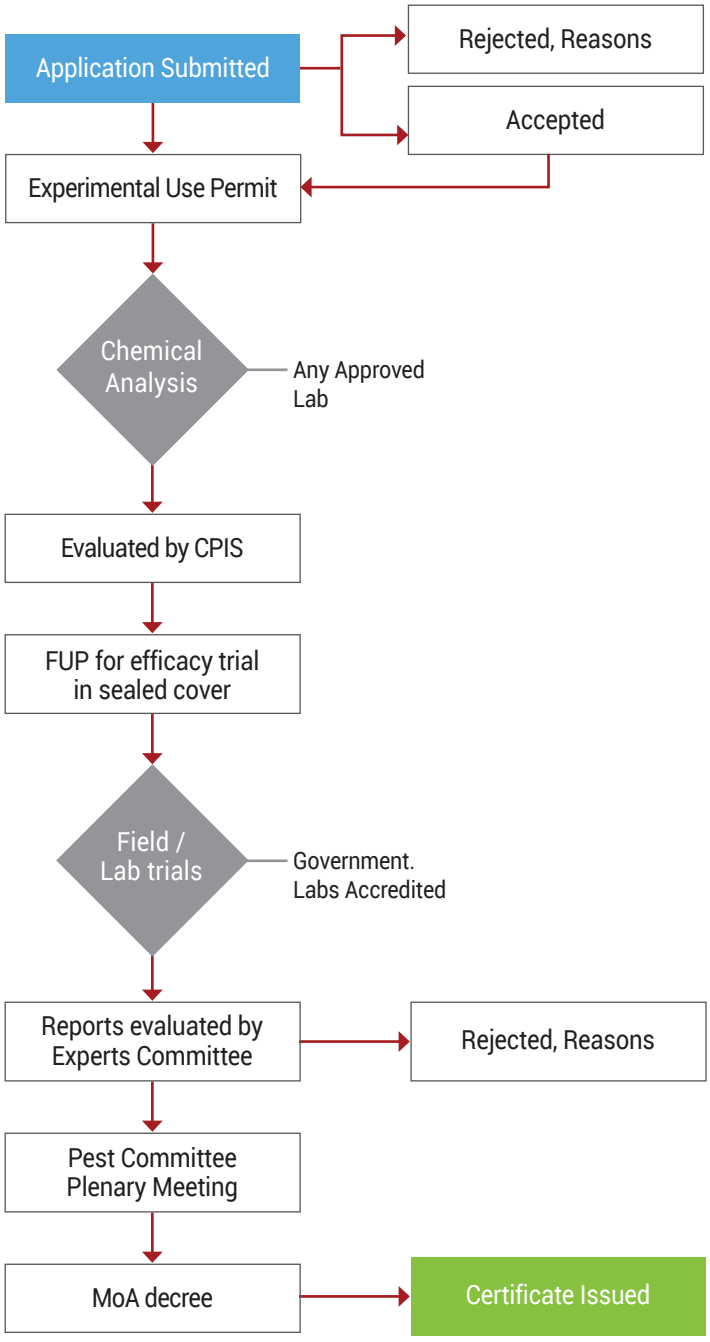
1. In country testing is mandatory. Other country data is not acceptable and the need for in country trials is not waived off.
2. Trials need to be done in one of the trial institutes approved by the Ministry of Agriculture to conduct efficacy testing of Public Health Pesticides

Vietnam:

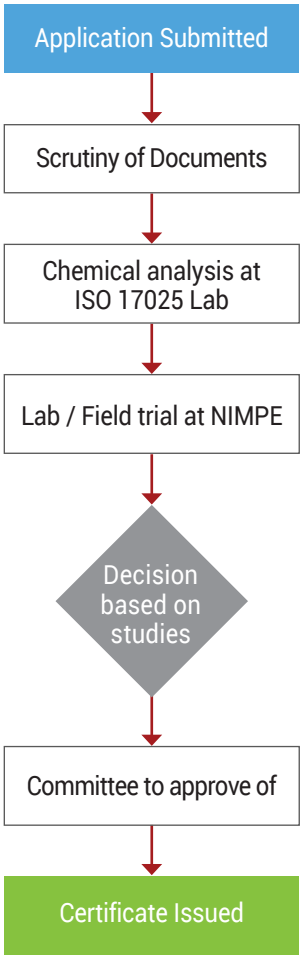
1. In country evaluation of public Health pesticides is mandatory
2. Testing has to be done in ISO 17025 accredited labs and that too from NIMPE (National Institute for Malariology, Parasitology and Epidemiology)

Appendix 5

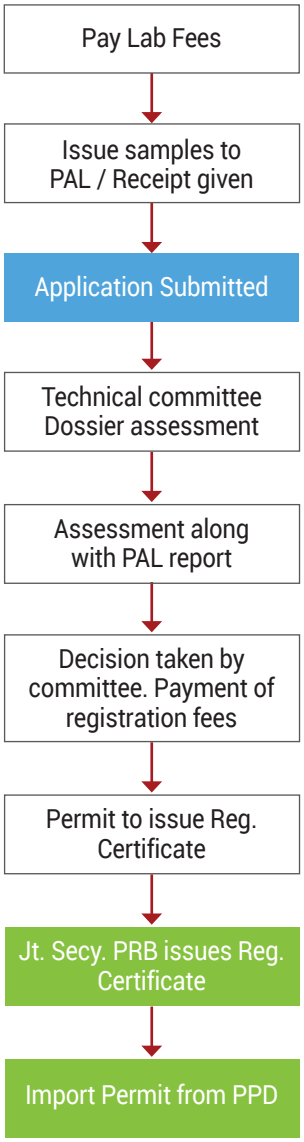
Flow Chart of Registration Process in focus countries:



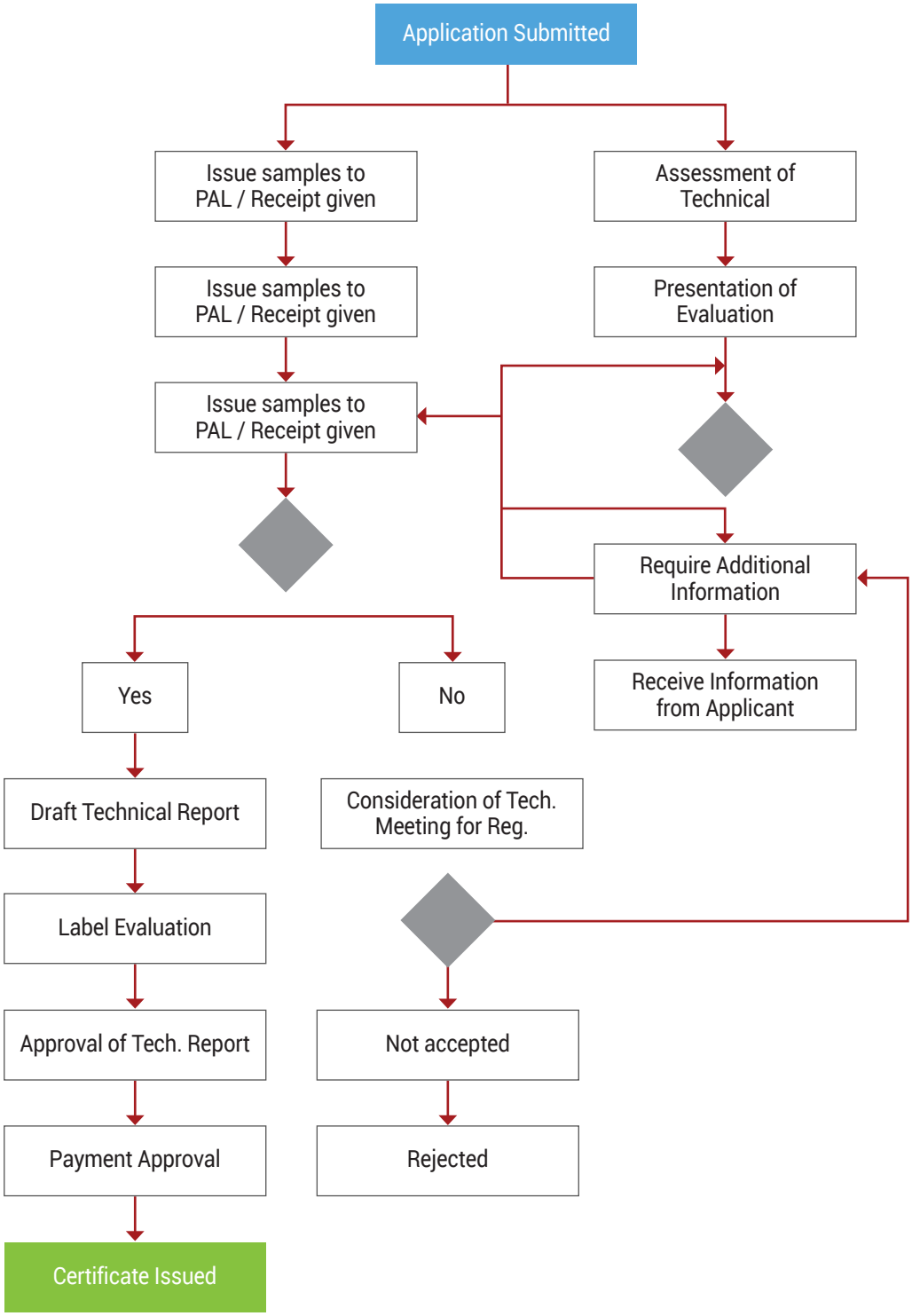
Indonesia



Vietnam



Myanmar


Application Submitted
Issue samples to PAL / Receipt given
Assessment of Technical
Issue samples to PAL / Receipt given
Presentation of Evaluation
Issue samples to PAL / Receipt given
Require Additional Information
Yes
No
Receive Information from Applicant
Draft Technical Report
Consideration of Tech. Meeting for Reg.
Label Evaluation
Approval of Tech. Report
Not accepted
Payment Approval
Rejected
Certificate Issued

Appendix 6

Experimental Use Permit (EUP):

MALAYSIA

Need Experimental Use Permit?	Yes, Experimental Use Permit is mandatory for import of unregistered pesticides for conducting trials leading to the registration of the product or for research purposes
Application Form?	Form A
Procedure for obtaining?	Application form in prescribed form be submitted to the Pesticides Board along with prescribed fees. Board, if satisfied, will lay some conditions such as import quantity, disposal process and then permit for a limited one-time import for the requested use only – such as research, trials for registration etc. A permit issued under Section 14 of Pesticides Act, 1974 cannot be breached of its conditions.
Timeline for securing permit?	1 – 2 months
Penalties?	1. If a pesticide is imported under this permit and is used for any other purpose other than educational or research purpose is liable for prosecution with imprisonment for three (3) years or fine of fifty thousand (50,000) Ringgit. 2. If unregistered pesticide is imported into the country with-out an experimental use permit, the person is liable for imprisonment for six (6) years or a fine of fifty thousand (50,000) Ringgit.

MYANMAR

Need Experimental Use Permit?	Yes, Experimental Use Permit is mandatory for import of unregistered pesticides for conducting trials leading to the registration of the product or for research purposes
Application Form?	No prescribed form but a list of required data to accompany the application is prescribed
Procedure for obtaining?	Application with the following information on the pesticide need to be submitted for review by the Pesticide Registration Board (PRB)… 1. Trade Name 2. Physical Chemical Properties 3. Information on Technical Substance 4. Efficacy study reports – Laboratory 5. Specification 6. Toxicological Reports – Acute / WHO toxicity reports 7. Disposal guidelines
Timeline for securing permit?	2 months (longer if it is a new product)
Fee?	1000000 (MMK) = 656 USD
Validity of Permit	2 years
Penalties?	1. If a pesticide is imported without a permit, then for first of-fence a minimum of 1000 MMK = 0.66 USD to up to 5000 MMK = 4 USD 2. For second offence then the penalty will be 10000 MMK = 8 USD

INDONESIA

Need Experimental Use Permit?	Yes, Experimental Use Permit is mandatory for import of unregistered pesticides for conducting trials leading to the registration of the product or for research purposes
Application Form?	No prescribed form but a list of required data to accompany the application is prescribed
Procedure for obtaining?	Application with the following information on the pesticide need to be submitted for review by the Pesticide Registration Board (PRB)… 1. Business Trade License 2. Company Affidavits 3. Trade Name as in Trademark Registry 4. Letter of Supply (LoS) from the Technical Substance supplier 5. Letter of Access (LoA) for technical information 6. Information on Technical Substance 7. Certificate of Analysis (CoA) 8. Analytical Methods 9. Certificate of Composition 10. Completed Registration Form – FORM 5
Timeline for securing permit?	20 – 30 working days
Fee?	200 USD
Validity of Permit	Initially granted for a period of 1 year. This can be extended for up to 2 times (each 1 year)
Penalties?	

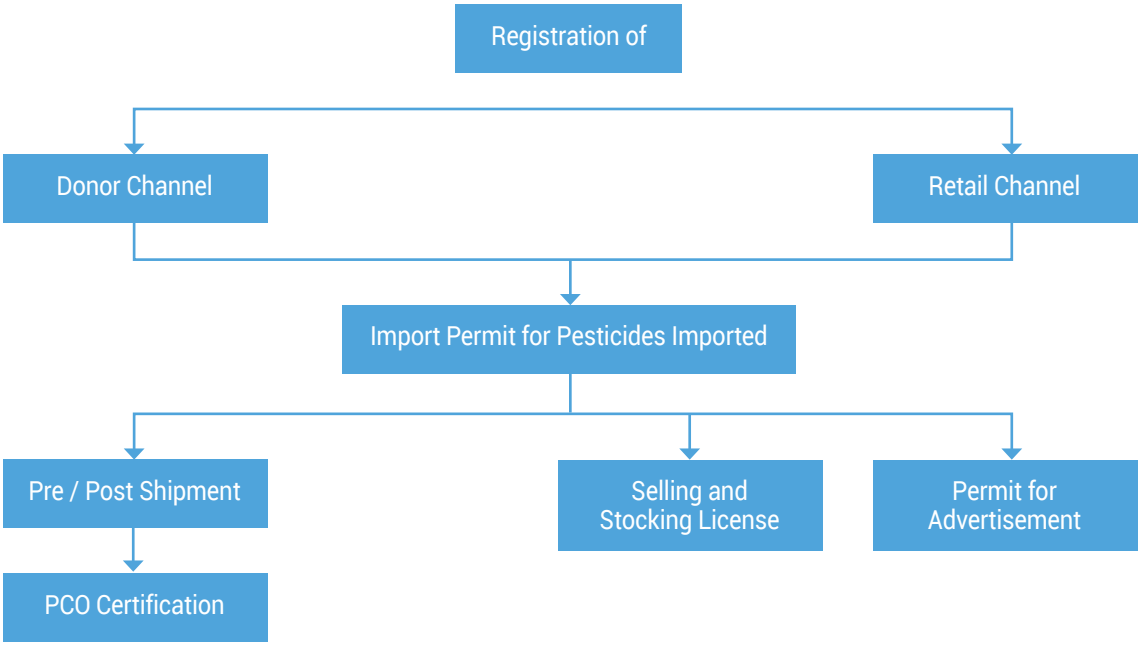
Appendix 7

Trial Institutes

S. No.	Country	Trial Institutes
1.	Indonesia	Directorate General of Disease Control & Env. Health, MoH, Indonesia Institute of Science (LIPI), Faculty of Veterinary Medicine, Ag. University, Bogor, Parasitology Division, Faculty of Medicine, Gadjah Mada University, Yog-yakarta Division of Entomology of Tropical Medicine, Gadjah Mada University, Yogyakarta Faculty of Agriculture, Bogor Ag. University, Bogor
2.	Vietnam	National Institute of Malariology, Parasitology and Epidemiology (NIM-PE)
3.	Malaysia	Ministry of Health University of Malaya, Sabah Universiti Sains Malaysia (USM), Penang
4.	Myanmar	National Agricultural Laboratory (NAL)
5.	Cambodia	No registration for Public Health Pesticides hence no requirement for testing. However, Testing facilities such USF, MSF available.
6.	Papua New Guinea	No government facility available for testing public health pesticides

Appendix 8

Registration Process for Pesticides – Donor Channel vis-à-vis Retail Channel



The pesticide registration process is the same regardless of whether the pesticide is for donor channel or for retail channel. The requirements for registration are the same for pesticides used in Donor and Retail channels. However, there are some differences in the requirements in a few countries in the pre-registration processes in some countries the requirements vary post registration.

Registration	In Vietnam, public health pesticides imported for distribution under donor funded programs do not need registration. Only an import permit is required. All other countries registration is mandatory and import permit is also mandatory.
Import Permit	Import permit is mandatory for import of pesticides for use in Public Health in all focus countries.
Pre/ Post Shipment Inspection	Post shipment inspection of LLINs is mandatory in Indonesia. But in other countries pre or post shipment inspection is mandatory for pesticides imported or supplied under donor funded projects. The inspection is insisted by donors or implementing agencies. Inspections are done by third party certifying bodies e.g. SGS, Intertek, Bureau Veritas, COTECNA, TUV etc.
Selling and Stocking License	Selling and Stocking license is mandatory for pesticides that need to be stocked and sold through retail channels. Technically, even pesticides procured for mass distribution and needs.
Permit to Advertise	Some countries have stringent rules on advertisement of pesticides and this includes pesticides used in public health especially through the retail channel. Countries such as Malaysia, Myanmar and Indonesia have requirements to obtain permission to advertise prior to airing advertisements of the products in media or publications.
Pest Control Operators Certification	PCO certification is part of the donor channel insecticide delivery. A trained and certified PCO is essential in effective vector control operation in public health programs.

Appendix 9

References:

1. Regulatory Authorities – Vietnam (1), Indonesia (1), Myanmar (1)
2. Country level public Health Distributors / agents – 5 numbers in Indonesia (2), Vietnam (1) and Myanmar (2)
3. Global Pesticide Manufacturers – Regional Managers / Business leads from 3 Major Agrochemical companies – Malaysia (2), Philippines (1)
4. Regional Malaria Program Partners – 3 from Singapore, Malaysia and Myanmar
5. LLIN Manufacturers – Regional Director level – 1, Factory Production In-Charge – 1, Regional Manager – 2 from 2 different companies based in India and Vietnam
6. Companies active in Retailing of Public Health Pesticides – Country head – 1 and Regional Manager - 2 based in Thailand and India
7. Regulatory Websites – Indonesia, Malaysia, Vietnam, Myanmar
8. Country level Malaria Program Managers – Cambodia (2), Myanmar (1) Indonesia (1)
9. WHO / FAO documents
10. Publications from various authors on regulatory processes in focus countries