Navigating Pesticide Regulatory Landscapes: Insights from SE Asia

Dr. Piyatida (Tung) Pukclai, knoell

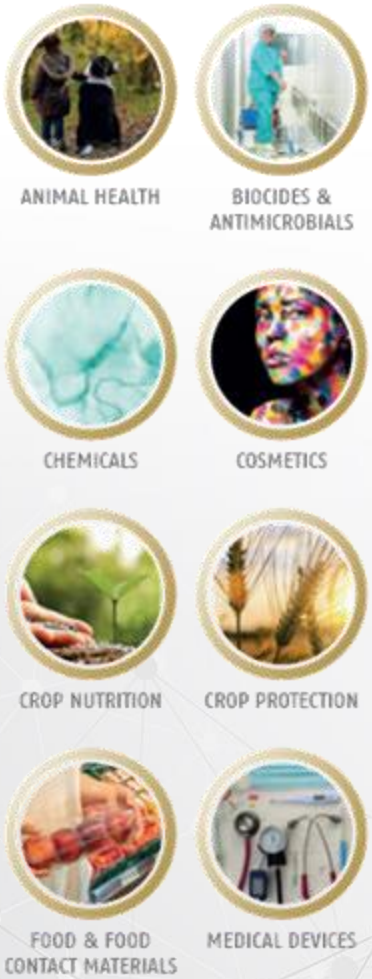
Navigating Pesticide Regulatory Landscapes: Insights from SE Asia

Dr. Piyatida (Tung) Pukclai

knoell

Regional Sales & Regulatory Policy Manager (Asia-Pacific)

- Regional Sales & Regulatory Policy Manager (Asia-Pacific) for knoell
- Responsible for registrations, monitors and reviews scientific data, new regulatory policies, and guidance developments in the Asian region
- Specializes in plant pathology and biological controls that reduce the use of chemical agriculture and improve the efficiency of plants or microorganisms.



Think globally, act locally
Your go-to partner for registration –worldwide

Leading provider of regulatory services and risk assessments	> 25 years, privately owned
Global regulatory compliance solutions	Range of critical regulatory areas covered
Experts from a variety of scientific disciplines	> 650 experts > 30 languages > 20 locations on 3 continents
In-country registration and field studies	Own companies plus network of cooperation partners

Regulatory diversity across several Asia countries: 2024

AgriBusiness GLOBAL Trade Summit

Country	Pesticides	Fertilizers	Biostimulants
Thailand	Hazardous Substance Act	Fertilizer Act	Consumer Protection Act B.E. 2522 and the amendment (No.2) B.E. 2541
Malaysia	Pesticides Act 1974	Plant Quarantine Act 1976 and Plant Quarantine Regulations 1981 (amended 2005)	Plant Quarantine Act 1976 and Plant Quarantine Regulations 1981 (amended 2005)
Indonesia	Regulation No. 43 of 2019	Regulation No. 01 of 2019	Regulation No. 01 of 2019
Philippines	Presidential Decree No. 1144	Presidential Decree No. 1144	Presidential Decree No. 1144
Vietnam	Circular No. 21/2015/TT-BNNPTNT	Decree No. 108/2017/ND-CP	Decree No. 108/2017/ND-CP
Singapore	The Control of Plants Act (Registration of Pesticides) Rules	The Control of Plants Act (Registration of Pesticides) Rules	The Control of Plants Act (Registration of Pesticides) Rules
Myanmar	Pesticides Law	The Fertilizer Law	The Fertilizer Law
Cambodia	Law on the Management of Pesticides and Fertilizers 2012	Law on the Management of Pesticides and Fertilizers 2012	based on the claims
Lao PDR	Regulation on Control of Pesticides in Lao PDR No. 2860/MAF	Decision No. 2169/MAF and Order No. 2592/MAF	based on the claims

Typical registration steps

- ✓ Checking status of target product (category, concentration, formulation, usage, claims)
- ✓ The pre-registration meeting (Can be registered? Which category? Who can be a license holder? etc.)
- ✓ Application form with instructions (Tiered approach to data requirements)
- ✓ Check list for completeness of dossier
- ✓ Submission of registration application and a draft of label
- ✓ Technical and scientific evaluation by registration committee
- ✓ Bio-efficacy trials and evaluation of the results
- ✓ Registration decision
- ✓ Publication and dissemination of registration decision

Thailand

Authority: The Pesticide Registration Division (**PRD**), Department of Agriculture (DOA)

Website: https://www.doa.go.th/ard/

Online submission: Yes

Regulation: Hazardous Substance Act

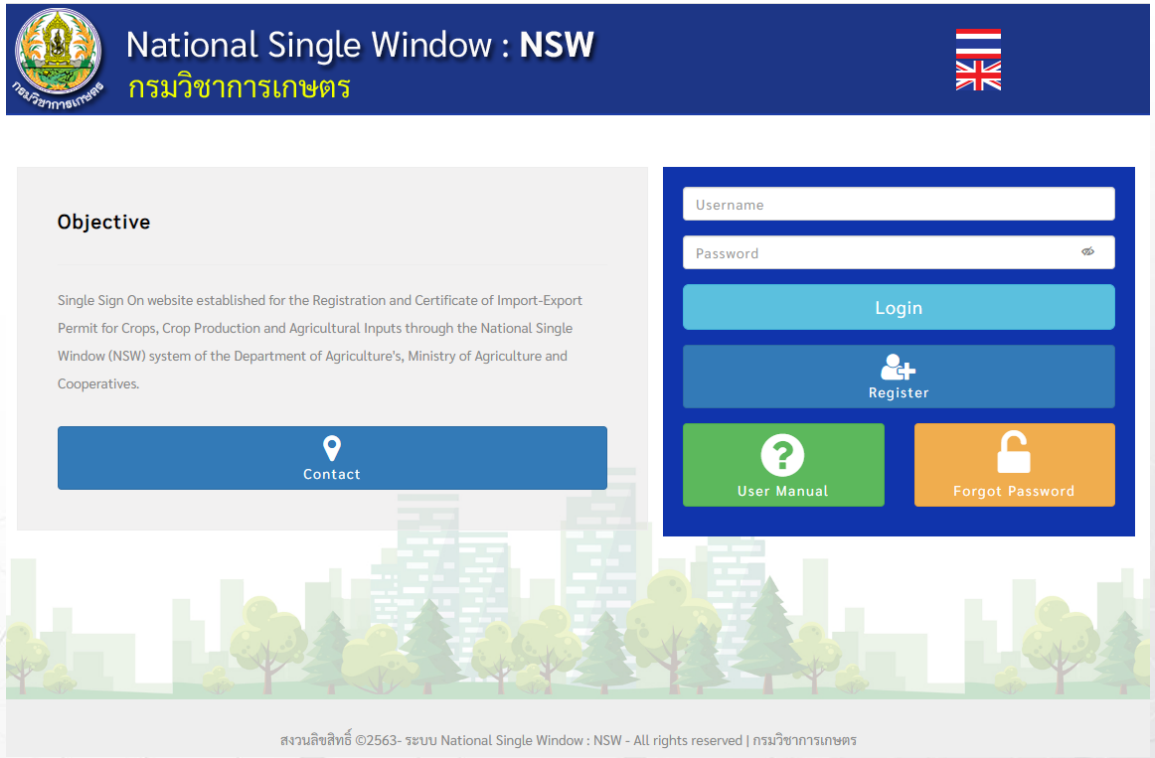
Registration holder: Local entity only
(local manufacturer, local importer, etc.)

Data requirements: Available in Thai and English

Local efficacy trials: required

Overall registration timeframe: 2 – 2.5 years

Registration validity: 6 years



- To register plant protection products in Thailand, ensure compliance with approved concentrations and formulations.

ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน

- ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน พ.ศ. ๒๕๕๔
- ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน (ฉบับที่ ๒) พ.ศ. ๒๕๕๖
- ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน (ฉบับที่ ๓) พ.ศ. ๒๕๕๖
- ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน (ฉบับที่ ๔) พ.ศ. ๒๕๕๗
- ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน (ฉบับที่ ๕) พ.ศ. ๒๕๕๗
- ประกาศกรมวิชาการเกษตร เรื่อง กำหนดอัตราความเข้มข้นในแต่ละสูตรของวัตถุอันตรายที่รับขึ้นทะเบียน (ฉบับที่ ๖) พ.ศ. ๒๕๖๐

- Exemptions apply for plant growth regulators, plant extracts, biological products, and pheromones. If the desired product information is not available in the National Single Window (NSW) system, companies can notify officials to request the addition of the required list.

Registration process

- Three phases of the registration process
  - Phase I registration (Trials clearance)
  - Phase II registration (Provisional clearance)
  - Phase III registration (Full registration)

- Registration process starts with:
  1. Creating a "Trade name" and requesting a trade name approval
  2. Submit Phase I registration dossier and bio-efficacy protocol
  3. Submit the sample import permit

SCAN ME!

Registration Process

Overall timeframe:
2 – 2.5 years

1. Get trade name approval via NSW
2. Submit Phase I registration dossier and bio-efficacy protocol
3. Submit the sample import permit
4. Import of sample for efficacy trial and sample analysis
5. Efficacy trials and DOA Inspection
6. Phase III Registration Process
7. Artwork Preparation and Submission
8. Sub-Committee Evaluation
9. Certificate Issuance

The Philippines

Authority: The Fertilizer and Pesticide Authority (**FPA**), Department of Agriculture (DOA)

Website: https://fpa.da.gov.ph/NW/index.php

Online submission: Yes

Regulation: Presidential Decree No. 1144 (PD.1144)

Registration holder: Local entity only (local manufacturer, local importer, etc.)

Data requirements: Available in English

Local efficacy trials: required

Overall registration timeframe: 2 – 3 years

Registration validity: 3 years

- Only local companies registered by the Securities and Exchange Commission (SEC) to do business in the Philippines and duly licensed by FPA may apply for registration of pesticide products in the Philippines.
- Foreign suppliers or local subsidiaries of foreign-based pesticide companies registered under the SEC as regional liaison offices (PD 218) are not allowed to register products.
- In practice, the applicant or registrant shall be the importer, distributor or the local subsidiary of a foreign-based pesticide company

Classification of Pesticides

I. **Chemical Pesticides** i.e., Agriculture/ Home Garden/ Turf Use, and Other Chemical Pesticides

II. **Biorational Pesticides** i.e.,

1) Biochemical pest control agents: Semiochemical (pheromone, kairomone, allomone), Hormone, Natural plant regulator, Enzyme
2) Microbial pest control agents: Bacteria, Fungi, Protozoa, Virus
3) Plant-incorporated protectants (PIP): Single, Combined/ Stacked such as *Bacillus thuringiensis* (Bt)

Registration process

- There are 2 steps of registration

1. **Conditional Registration**
    - It is granted upon the fulfilment of minimum requirements. The applicant receives a status report indicating conditional registration, along with an assigned product registration number.
    - Conversion to full registration is possible within 1 year if all conditions and requirements are satisfactorily met. However, no renewal or extension of conditional registration is permitted, except in cases of force majeure or fortuitous events or when efficacy trials or other tests necessitate a timeframe exceeding 1 year.
    - Failure to meet the agreed-upon requirements for Conditional Registration may lead to the suspension of the registration.
2. **Full Registration**
    - It is granted when the applicant has satisfactorily completed all the requirements regarding bio-efficacy, protection of the environment, safety to humans and animals. A certificate of registration is issued to the applicant.

Experimental Use Permits (EUP)

- For pesticide products intended for registration, efficacy testing under local conditions is mandatory.
- An Experimental Use Permit (EUP) is required for field testing, ensuring adherence to approved protocols and protecting human health and the environment. Crop destruction is mandated in certain EUPs unless specific data is available.
- There are 4 types of EUPs, each suitable for different testing scenarios:

1. **EUP IA:** For coded compounds and formulations tested within the FPA-licensed company research station. Data generated is used for research purpose only and not intended for registration.
2. **EUP IB:** For coded compounds and formulations tested outside the company research station but in a licensed testing site, conforming to FPA-approved protocol. Data generated is used for research purpose only and not intended for registration.
3. **EUP II:** For pesticides in the pre-market stage, requiring prior approval due to increased exposure. The bio-efficacy and residue data generated may be used for registration purpose.
4. **EUP III:** For registered pesticides tested for additional uses or label expansion.

- No EUP is needed if the crop and pest uses are registered, and the tested dose is lower than the registered dose.
- All EUP trials should be conducted **by FPA-accredited researchers**, following approved protocols.

Registration process

1. Local companies registered by the SEC to do business in the Philippines and duly licensed by the FPA must schedule a face-to-face appointment with the Pesticide Registration Division (PRD) and shall have submitted advance the EUP application through the electronic system.

2. Submit the hard copies of the EUP application to the PRD and receive the accomplished bill form

3. Pay the corresponding government fee, present the receipt to the PRD, secure the receiving copy of the EUP application and wait for the updates from PRD through email (20-30 working days approx.)

4. The EUP shall be conducted by researchers accredited by FPA following the standard protocols for biological efficacy testing.

5. The EUP trial results will be used for registration.

Note: Application for EUP II shall be filed at least 6 months prior to the start of the experiment.

Vietnam

Authority: The Plant Protection Department (**PPD**), Ministry of Agriculture and Rural Development (MARD)

Website: https://www.mard.gov.vn/en/Pages/default.aspx

Online submission: Yes

Regulation: Circular No 21/2015/TT-BNNPTNT

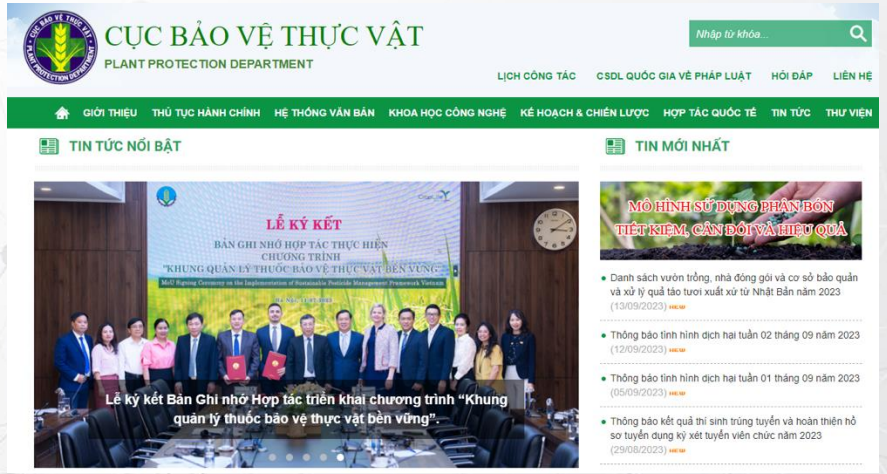
Registration holder: Local entity only (local manufacturer, local importer, etc.), or a representative offices or branches of foreign company with business license to carry out pesticide product business operations in Vietnam

Data requirements: Available in Vietnamese language

Local efficacy trials: required

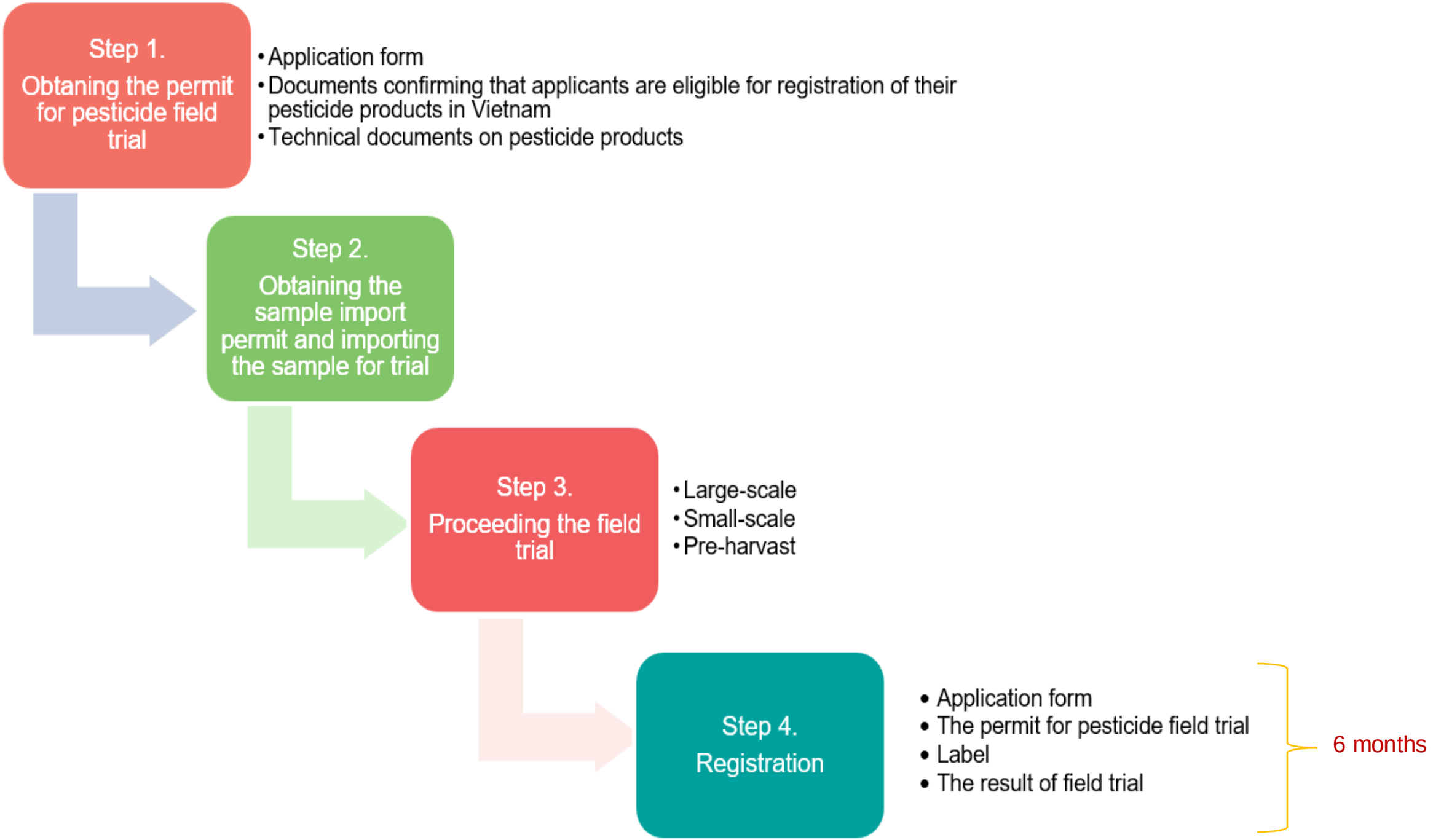
Overall registration timeframe: 2 – 3 years

Registration validity: 5 years



Types of registration

1. **Supplementary Registration:**
   - Pertains to pesticides with trade names on the list but with expanded use scope, altered dosage, usage, formulation type, or modified active ingredient content.
   - Includes pesticides with active ingredients on the list but registered under different trade names.
2. **Full Registration:**
   - Involves pesticides with active ingredients not yet listed or those with new compositions registered abroad.
   - Encompasses pesticides with active ingredients not yet listed, invented domestically, and proposed by scientific councils for recognition.


Step 1.
Obtaning the permit for pesticide field trial
• Application form
• Documents confirming that applicants are eligible for registration of their pesticide products in Vietnam
• Technical documents on pesticide products
Step 2.
Obtaining the sample import permit and importing the sample for trial
Step 3.
Proceeding the field trial
• Large-scale
• Small-scale
• Pre-harvast
Step 4.
Registration
• Application form
• The permit for pesticide field trial
• Label
• The result of field trial
6 months

Registration of pesticides in SE Asia – What should we know?

3Ls

1. **L**ocal Entity Requirement
2. **L**ocal Efficacy Trials
3. **L**anguage and Regulatory Complexity

Registration of pesticides in SE Asia – What should we know?

1. Local Entity Requirement

- In Southeast Asian countries, pesticide registration typically requires a local entity as the registration holder.
- This ensures a local presence to manage regulatory needs and issues.
- The local entity must be a registered company authorized for pesticide operations.
- Verification is crucial to confirm the entity's eligibility to hold registration licenses.

2. Local Efficacy Trials

- Southeast Asian countries mandate local efficacy trials to validate pesticide effectiveness in local conditions.
- Trials are essential to demonstrate performance in specific climates, soils, and against local pests.
- Understanding country-specific requirements for trial protocols is vital, considering variations based on crop types.

Registration of pesticides in SE Asia – What should we know?

3. Language and Regulatory Complexity

- Each Southeast Asian country has its own pesticide registration laws, creating a complex regulatory landscape.
- Regulations differ significantly between countries, necessitating thorough understanding and compliance.
- Language barriers require translations and local expertise for navigating regulatory requirements.
- Formal written submissions are typically required for communication with regulatory authorities, often following regulatory meetings or reviews

What else should we know?

- ✓ Must check if the product can be registered or not (specific formulation and concentration)
- ✓ Information of storage facility may be required together with pesticide operator certificate (depends on the country)
- ✓ Type of registration e.g., imported product, repacking, export only, etc.
- ✓ How the local bio-efficacy trials will be conducted? By CRO, accredited research institute, etc.
- ✓ Current situation on the registration submission. Any suspension or pending? Phasing out of pesticides, etc.
- ✓ Overall process and rough cost estimation

Key Takeaways

Registration:

- It is crucial to have a thorough understanding of the regulatory requirements.
- Before proceeding with registration, it is important to verify the necessary administrative documents.
- It is also essential to keep track of the registration process and its timeframe.

Market opportunities

- New active ingredients, new formulations
- Biological products e.g., biopesticides, biostimulants, soil amendments, adjuvants
- Agricultural Drone Operation and pesticides for spraying drone applications
- Investment opportunities in climate-smart agriculture (CSA) technologies

AgriBusiness GLOBAL Trade Summit

THANK YOU!

Questions?

Contact info

Dr. Piyatida (Tung) Pukclai

Regional Sales & Regulatory Policy Manager (Asia-Pacific)

Phone: +66 (0) 83 4856565

Email: Piyatida.Pukclai@knoell.com

AgBusinessMedia AgriBusinessGlobal AgriBusinessGlobal