



by



SE Asia Regulatory Deep Dive

Exploring SE Asia's Biological Products Regulations

Piyatida (Tung) Pukclai, Ph.D.

Knowledge Hub by the Industry for the Industry

Regulatory diversity across several Asia countries: 2023

Country	Pesticides/ Biopesticides	Fertilizers/ Biofertilizers	Biostimulants	Soil Amendments
China	Regulations on the Management of Pesticides (State Council Decree 677)	MOA Order 32 (revises in 2004, 2017 and 2022)	Based on the claims (mainly registered as fertilizers)	Based on the claims (mainly registered as fertilizers)
Japan	Agricultural Chemicals Regulation Law	Fertilizer Control Law	based on the claims	based on the claims
Thailand	Hazardous Substance Act	Fertilizer Act	Consumer Protection Act B.E. 2522 and the amendment (No.2) B.E. 2541	Consumer Protection Act B.E. 2522 and the amendment (No.2) B.E. 2541
Malaysia	Pesticides Act	Plant Quarantine Act 1976 and Plant Quarantine Regulations 1981 (amended 2005)	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	Regulation No. 01 of 2019
Philippines	Presidential Decree No. 1144	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	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	The Control of Plants Act (Registration of Pesticides) Rules
Myanmar	Pesticides Law	The Fertilizer 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	Law on the Management of Pesticides and Fertilizers 2012
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	Decision No. 2169/MAF and Order No. 2592/MAF

Regulatory Hurdles



Controlling of formulations and concentrations. Registration of new formulation or new concentration takes a long time



Language barrier on regulations: guidelines are available in local language, communication with authority, communication with local companies



Insufficient information about the updates on laws & regulations for registration



Insufficient manpower and expertise of competent authority



Regulatory process and data requirements are challenging



Changes in regulatory science are very slow compared to science developments

Today's agenda

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Biopesticides

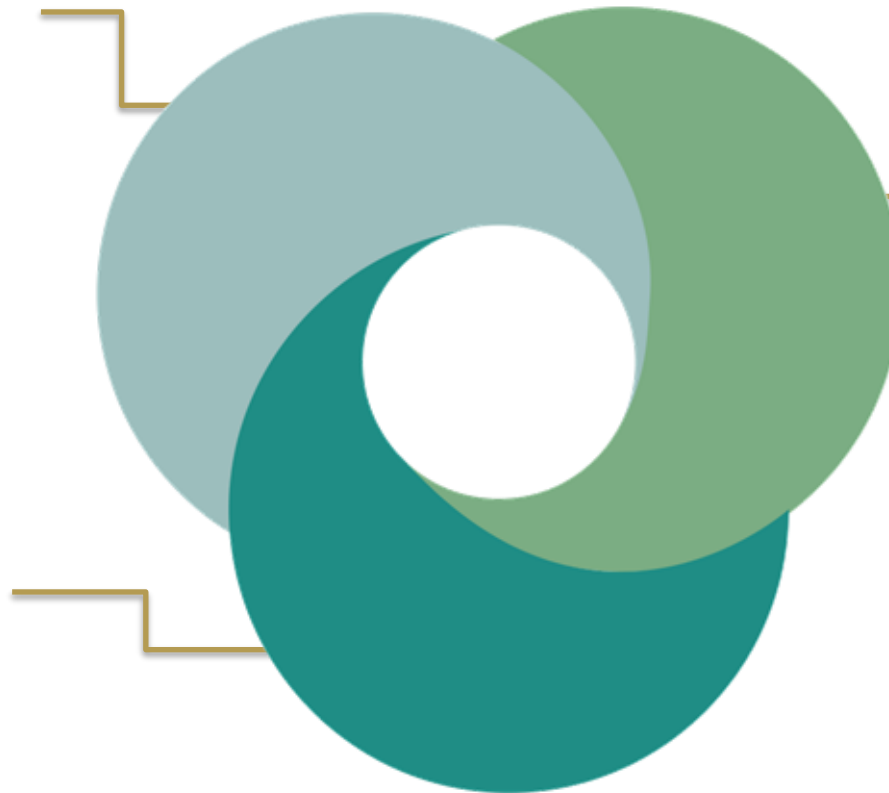
- Thailand
- The Philippines
- Vietnam
- Indonesia

Biofertilizers

- Thailand
- The Philippines
- Vietnam
- Indonesia

Biostimulants & Soil Amendment

- Thailand





Navigating Regulations for Biopesticides in Selected Southeast Asian Countries

Biopesticide Regulations - THAILAND



- ▶ **Main regulation:** The Hazardous Substances Act
- ▶ **Authority:** the Pesticide Registration Division (**PRD**), Department of Agriculture (DOA)
- ▶ **Website:** <https://www.doa.go.th/ard/>
- ▶ **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.)
- ▶ **Data requirements for biopesticides:** Available in Thai and English
- ▶ **Local efficacy trials:** required
- ▶ **Overall registration timeframe:** 1.5 – 2 years
- ▶ **Evaluation process:** same as conventional pesticides but for specific biological pesticides, some tox data can be waived
- ▶ **Registration validity:** 6 years

Biopesticide Regulations - THAILAND



- ▶ Company shall have account for the registration submission
- ▶ Registration submission can be done via the DOA National Single Window (NSW): <https://nsw.doa.go.th/public/>

The screenshot shows the 'National Single Window : NSW' portal for the Department of Agriculture (กรมวิชาการเกษตร). The header includes the Thai coat of arms, the text 'กรมวิชาการเกษตร' (Department of Agriculture), and the Thai flag. The main content area is divided into two sections:

- Left Section (Information):**
 - วัตถุประสงค์ (Purpose):** เว็บไซต์ Single Sign On ใช้สำหรับการลงทะเบียนและขอใบรับรอง ใบอนุญาต นำเข้า-ส่งออก นำผ่านพืช ผลผลิตพืช และปัจจัยการผลิตทางการเกษตรผ่านระบบ National Single Window (NSW) ของกรมวิชาการเกษตร กระทรวงเกษตรและสหกรณ์ (The Single Sign On website is used for registration and requesting certificates, licenses, import-export, and transit of agricultural products and agricultural inputs through the National Single Window (NSW) system of the Department of Agriculture, Ministry of Agriculture and Cooperatives).
 - ติดต่อเจ้าหน้าที่ (Contact staff):** A button with a location pin icon.
- Right Section (Login/Registration):**
 - กรอกชื่อใช้งาน (Enter username):** A text input field.
 - กรอกรหัสผ่าน (Enter password):** A text input field with a toggle icon.
 - เข้าสู่ระบบ (Login):** A blue button.
 - คลิกที่นี่เพื่อลงทะเบียน (Click here to register):** A blue button with a user icon.
 - แนะนำการใช้งาน (User guide):** A green button with a question mark icon.
 - ขอรับเมล์รหัสผ่านอีกครั้ง / ลืมรหัสเข้าใช้งาน (Request password email / Forgot login password):** An orange button with a lock icon.

Biopesticide Regulations - THAILAND



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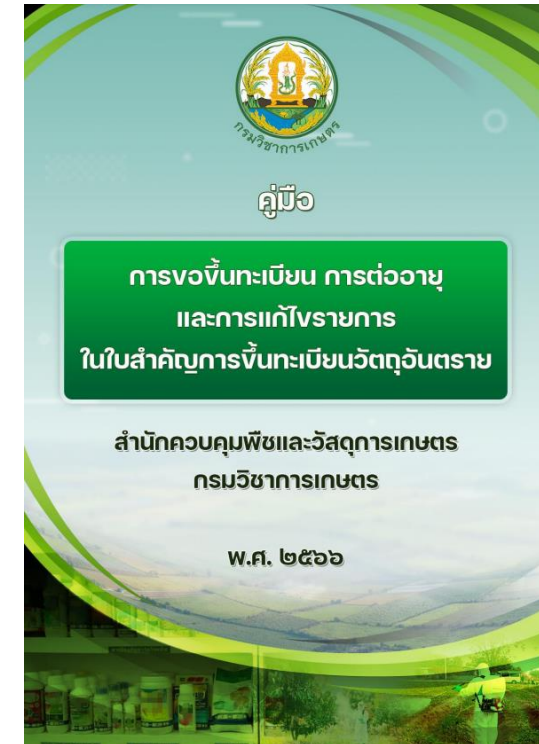
- ▶ Exemptions apply for plant **growth regulators**, **plant extracts**, **biological products**, and **pheromones**. If the desired product information is **not available** in the **National Single Window (NSW)** system, companies can notify officials to request the addition of the required list.

Requesting Inclusion of Concentrations and Formulations in NSW System

- ▶ Contact the DOA officer to add the concentrations and formulations
- ▶ Need to provide the name of the active substance
- ▶ A **group of compounds cannot** be used (for plant extract).
- ▶ **General required information:**
 - Evidence of registration of biopesticide abroad or in the process of being registered (Experimental use permit)
 - Safety data sheet (SDS)
 - Product label and use instructions
 - Analytical method of active substance
 - Acute oral and acute dermal toxicity information
 - Information on residues in plants, animals (e.g., birds, fish, bees) and the environment (e.g., soil, water)
 - Specification
 - For plant protection products that are not yet registered in Thailand, long-term toxicity information is required
 - Documents must be in English or Thai language only
 - Efficacy results from other countries
 - Product registration/license certificate in other country
 - Other (if any)

Biopesticide Regulations - THAILAND

- ▶ 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!

Biopesticide Regulations - THAILAND



4. Sample Submission and Bio-Efficacy Trials:

- ✓ Submit the sample for analysis to the Department of Agriculture (DOA) and initiate local bio-efficacy trials (1 location in 2 seasons or 2 locations in 1 season).

5. DOA Inspection and Approval:

- ✓ The DOA inspector will visit trial sites for inspection and approval.

6. Phase III Registration Process:

- ✓ The applicant must submit the registration dossier, analysis results, and approved bio-efficacy data to the NSW.
- ✓ The authority will review the data (approximately 1 year).

7. Artwork Preparation and Submission:

- ✓ Once the review is complete, applicants can prepare label artwork and submit it to the authority.

8. Sub-Committee Evaluation and Certificate Issuance:

- ✓ A sub-committee will evaluate the submission and issue the registration certificate.

Biopesticide Regulations - THAILAND



- Thailand published a regulation regarding specific biopesticides (microbials & plant extracts) that the toxicity data can be exempted.

- | | |
|--------------------------------------|---|
| 1) <i>Bacillus subtilis</i> | 10) <i>Trichoderma viride</i> |
| 2) <i>Bacillus amyloliquefaciens</i> | 11) <i>Trichoderma virens</i> |
| 3) <i>Bacillus licheniformis</i> | 12) <i>Trichoderma atroviride</i> |
| 4) <i>Bacillus pumilus</i> | 13) <i>Bacillus thuringiensis</i> cv. aizawai |
| 5) <i>Beauveria bassiana</i> | 14) <i>Bacillus thuringiensis</i> |
| 6) <i>Metarhizium anisopliae</i> | 15) Nucleopolyhedrovirus (NPV) |
| 7) <i>Trichoderma asperellum</i> | 16) Entomopathogenic nematode |
| 8) <i>Trichoderma harzianum</i> | 17) Protozoa " <i>Sarcocystis singaporensis</i> " |
| 9) <i>Trichoderma gamsii</i> | 18) Plant extract (neem, saponin, galangal, citronella, <i>Acorus calamus</i> L.) |

- Local bio-efficacy trials are required for biopesticides manufactured overseas

Biopesticide Regulations - THAILAND



Data Requirements for Microbial Pesticides Registration:

- ▶ Identity of the Microbial Pest Control Product (MPCP):
 - Applicant and Manufacturer Information
 - Trade Name
 - Physical State (GIFAP Formulation Type)
 - Use Category
 - Scientific Name and Strain/Serotype
 - Composition, Chemical Name, Structure
 - CAS Numbers of Components/Additives (if applicable)
 - Microbial Impurities
- ▶ Physical and Chemical Properties of the MPCP
- ▶ Application Instructions and Precautions
- ▶ Proposed Instructions for Use (Specimen Label)
- ▶ Methods of Analysis
- ▶ Toxicological Studies and Exposure Data: Acute Oral, Dermal, Inhalation, Skin Irritation, Eye Irritation Studies
- ▶ Residue Data or Rationale for Waiving Residue Studies
- ▶ Effects on Non-Target Organisms
- ▶ Efficacy Data
- ▶ Product Registration/License Certificate (if applicable)
- ▶ Artwork for Thai Label
- ▶ Experimental Plan for Efficacy and/or Residue
- ▶ English Label (Translated label content for English usage)
- ▶ Safety Data Sheet (SDS) of the product and each additive

Biopesticide Regulations - THAILAND



Data requirements for botanicals (plant, plant extracts) registration – water extract:

- ▶ Plant Nomenclature (scientific name, common name, Genus, species, sub-species, variety or chemotype, geographic origin)
- ▶ Natural state (cultivated or wild), Growth stage, Organ or part of the plant sampled
- ▶ Name and address of grower (where relevant) and/or region of origin.
- ▶ Growing conditions, Place, time and conditions of harvest
- ▶ Length of storage and storage conditions
- ▶ Identity of the plant protection product
- ▶ Information on active substances (provide a concentration range for the active substances, chemical name, CAS No, structural formula, ISO name)
- ▶ Physico-chemical properties
- ▶ Information on product content and a full list of ingredients
- ▶ For any toxic substances that are relevant for human, animal health and the environment, provide a maximum content limit.
- ▶ If the active substance is not identified, define a representative marker i.e. a chemical naturally present in a known proportion in the plant in order to identify the plant protection product.
- ▶ Analysis report of 5 batches of different manufacturers, collected over several periods.
- ▶ Manufacture of the extract
- ▶ Product specifications
- ▶ Manufacturing process
- ▶ Detection and identification of possible contaminants such as heavy metals, toxins, and pesticides.
- ▶ Assessment of microbiological quality
- ▶ Application data
- ▶ Packaging data
- ▶ Analytical methods
- ▶ Toxicological studies i.e. acute oral, dermal, inhalation toxicity, cutaneous and eye irritation and skin sensitization
- ▶ Residue data
- ▶ Fate and behavior in the environment
- ▶ Ecotoxicology
- ▶ Classification and labelling
- ▶ Product registration/license certificate in other country

	(Quantity)
Plant (whole or part)	[] g/kg or g/l (express as fresh weight and dry weight or as a weight interval)
Other ingredient (Include CAS No.)	[] g/kg or g/l
Water	[] g/l

Biopesticide Regulations - THAILAND



Data requirements for botanicals (plant, plant extracts) registration – one or several ethanol/water-based extracts:

- ▶ Plant Nomenclature (scientific name, common name, Genus, species, sub-species, variety or chemotype, geographic origin)
- ▶ Natural state (cultivated or wild), Growth stage, Organ or part of the plant sampled
- ▶ Name and address of grower (where relevant) and/or region of origin.
- ▶ Growing conditions, Place, time and conditions of harvest
- ▶ Length of storage and storage conditions
- ▶ Identity of the plant protection product
- ▶ Information on active substances (provide a concentration range for the active substances, chemical name, CAS No, structural formula, ISO name)
- ▶ Physico-chemical properties
- ▶ Information on product content and a full list of ingredients
- ▶ For any toxic substances that are relevant for human, animal health and the environment, provide a maximum content limit.
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- ▶ Manufacture of the extract
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- ▶ Application data
- ▶ Packaging data
- ▶ Analytical methods
- ▶ Toxicological studies i.e. acute oral, dermal, inhalation toxicity, cutaneous and eye irritation and skin sensitization
- ▶ Residue data
- ▶ Fate and behavior in the environment
- ▶ Ecotoxicology
- ▶ Classification and labelling
- ▶ Product registration/license certificate in other country

	Quantity
Extract of [] prepared from	[] g/kg or g/l of extract corresponding to
<ul style="list-style-type: none">● Plant(s) [] g/kg● solvent (specified solvent composition) Indicating content in g/l or g/kg (Include CAS No.)	[] g/kg or g/l of active substance
Other ingredients	[] g/kg or g/l

Biopesticide Regulations - THAILAND



Data requirements for pheromone (semiochemicals):

- ▶ Information on finished/formulated product (Common name, Trade name, Content (%) and nature of components included in the formulation and appearance, formulator information);
- ▶ Analytical method for active ingredient;
- ▶ Product registration/license certificate in other country

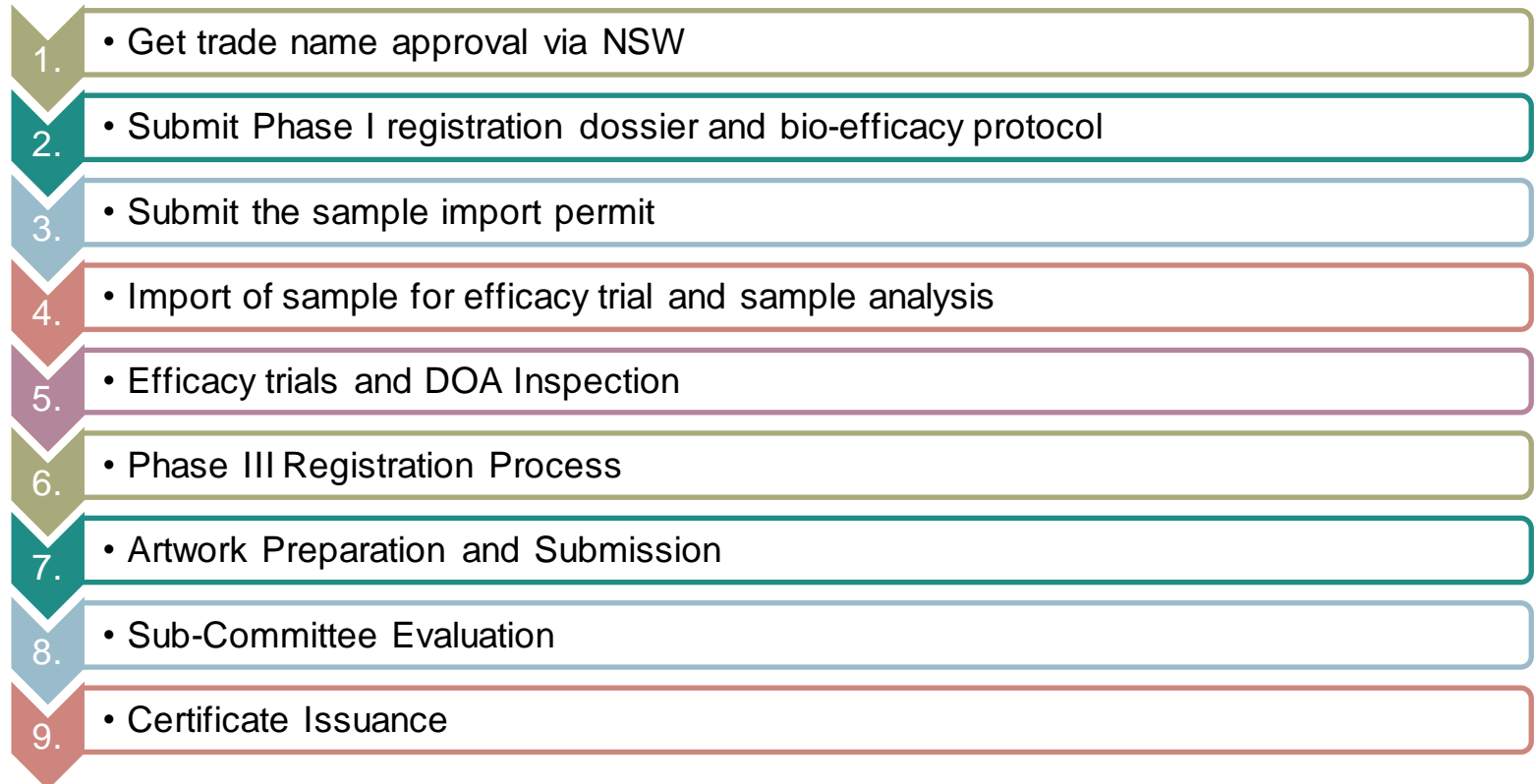
Biopesticide Regulations - THAILAND



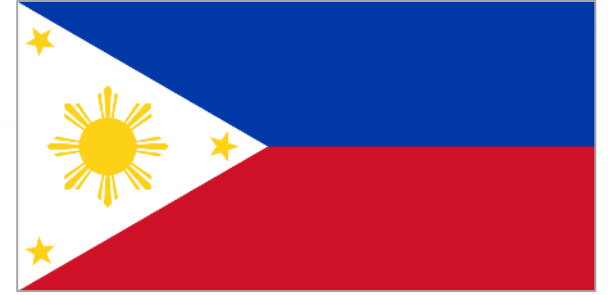
Summary

- Only local entity can be a registrant and registration license holder
- Registration process starts with:

Overall timeframe:
2 – 2.5 years



Biopesticide Regulations – THE PHILIPPINES



- **Main Regulation:** Presidential Decree No. 1144 (PD.1144)
- **Authority:** the Fertilizer and Pesticide Authority (**FPA**), Department of Agriculture (DOA)
- **Website:** <https://fpa.da.gov.ph/NW/index.php>
- **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.)
- **Data requirements for biopesticides:** Available in English
- **Local efficacy trials:** required
- **Overall registration timeframe:** 2 – 3 years
- **Evaluation process:** Same as conventional pesticides but evaluation process is shorter (**Fast-tracking**)
- **Registration validity:** 3 years

Biopesticide Regulations – THE PHILIPPINES

- ▶ 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 (e.g., auxin), Enzyme
 - 2) **Microbial pest control agents**: Bacteria, Fungi, Protozoa, Virus
 - 3) **Plant-incorporated protectants (PIP)**: Single, Combined/ Stacked such as *Bacillus thuringiensis* (Bt)

Biopesticide Regulations – THE PHILIPPINES



- 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.

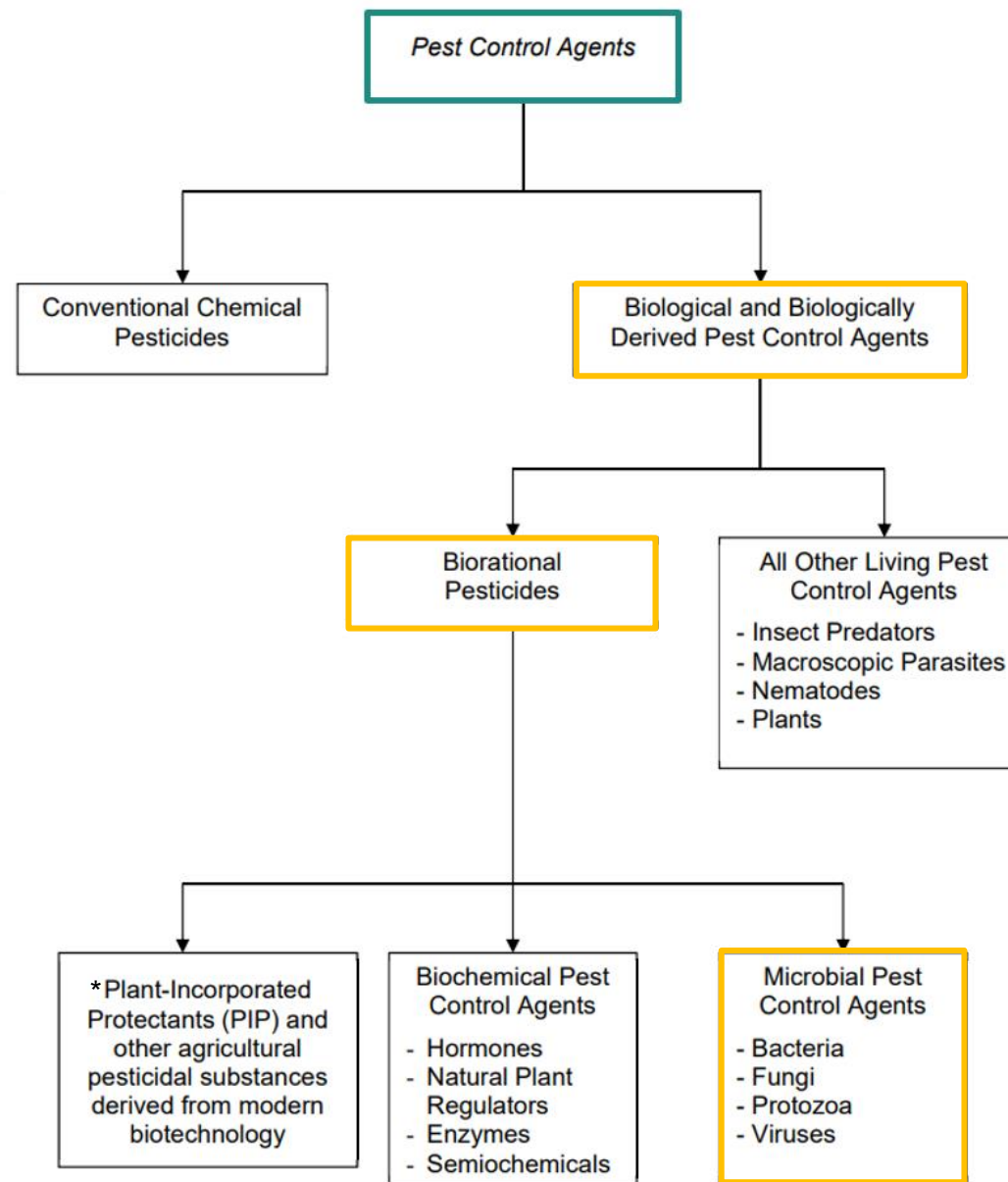
2. Full Registration

- 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 and biopesticide 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.



*Plant-incorporated protectant (PIP) refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance.

Biopesticide Regulations – Microbial Pest Control Agents (MPCA)

- ▶ For MPCA group, due to the unique nature, composition, and mode of action of microbial agents, data requirements differ in some respects.
- ▶ For example, bacteria (B), fungi (F), protozoa (P), and viruses (V) shall be identified to the extent possible by taxonomic position, serotype, composition, and strain, or by any other appropriate specific means.
- ▶ The methods used and the data submitted are capable of demonstrating that the biorational pesticide used in the field is the same as that which was tested for safety.
- ▶ [Here](#) is the checklist of data requirements

Microbial Pest Control Agents (MPCA) – EUP Registration Requirements

Types of Data	Food Crop Use		Non-Food Crop Use	
	Biochemical	Microbial	Biochemical	Microbial
1.0 GENERAL		↓		↓
1.1 Name/Address of Applicant	R	R	R	R
1.2 Product Trade Name	X	X	R	R
1.3 Source of Technical Grade Material	R	R	R	R
1.4 Material Safety Data Sheet	X	X	R	R
2.0 SPECIFICATIONS				
Full Specifications required as in the Registration of Biorationals (see Table 5)	R	R	R	R
3.0 BIOEFFICACY				
3.1 Pests Controlled and Names of Crops Materials as Premises to be Protected	R	R	R	R
3.2 Application Rate (Kg ai/Ha or % ai dilution rate)	R	R	R	R
3.3 Frequency and Timing of Application for each site/pest listed	R	R	R	R
3.4 Method of Application	R	R	R	R
3.5 Phytotoxicity	R	R	X	X
3.6 Laboratory Studies if any	X	R	X	R
3.7 Effects on Beneficial Organisms	X	R	X	X
4.0 TOXICOLOGY				
4.1 Acute Oral Toxicity	R	X	R	X
4.2 Acute Dermal Toxicity	R	R	R	R
4.3 Primary Eye Irritation	R	R	R	R
4.4 Primary Dermal Irritation	R	R	R	R
4.5 Studies to Detect Gene Mutation	R	X	R	X
4.6 Cellular Immune Response Studies	R	R	X	X
4.7 Intravenous, Intracerebral, Interperitoneal Infectivity	X	R	X	R
4.8 Tissue Culture with Viral Agents	X	R	X	X
5.0 RESIDUE DATA				
If rate of application exceeds 120 g ai/Ha and if Tier I toxicological studies indicate potential human hazard	R	X R	X X	X X

Types of Data	Food Crop Use		Non-Food Crop Use	
	Biochemical	Microbial	Biochemical	Microbial
6.0 NON-TARGET ORGANISM TOXICOLOGY		↓		↓
Test developed in Tier I studies	R	R	R	R
7.0 ENVIRONMENTAL FATE AND EXPRESSION DATA				
Tier I studies only	R	R	X	X
8.0 LABELLING				
8.1 Proposed Toxicity Category	R	R	R	R
8.2 Draft Label (3 copies)	R	R	R	R

- For EUP II, please use the [FPA form No. P-002](#) (application for EUP)

Biopesticide Regulations – 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.

Microbial Pest Control Agents (MPCA) Registration Requirements



DATA REQUIRED	Technical/ Purer Grade of Active Ingredient	Manufacturing- Use Product	End-Use Product
1.0 GENERAL INFORMATION			
1.1 Name/Address of Applicant	R	R	R
1.2 Product Trade/Brand Name	R	R	R
1.3 Company Code Number	R	R	R
1.4 Manufacturer Source of Microbial Material	R	R	R
1.5 Confidential Statement of Formula (includes nature and quantity of diluents and other ingredients)	R	R	R
1.6 Description of manufacturing process includes starting and intermediate materials, steps taken both chemical and biological, in unformulated microbial agent, procedures used in establishing identity and purity of product, quality control methods and presence of toxic sensitizing substances	R	R	R
1.7 Methods of Analysis If not standard, provide detailed description	R	R	R
2.0 SPECIFICATIONS			
2.1 Identification of Organism (bacteria, protozoa, viruses or fungi in the product) <ul style="list-style-type: none"> Taxonomic position, stereotype and strain Test procedure used for identification Common alternative or superseded names Natural occurrence and history of organism Description of any unusual morphological and biochemical characteristics 	R	R	R
2.2 List of Ingredients – Percent composition, whatever active, intentionally added or impurity <ul style="list-style-type: none"> Chemical name and CAS number Empirical and/or structural formula and Molecular Wt. or Mol. Wt. Range Composition limits for each ingredient Amount of microbial agent in the product in recognized units of potency, weight percent, etc. 	R	R	R

DATA REQUIRED	Technical/ Purer Grade of Active Ingredient	Manufacturing- Use Product	End-Use Product
2.3 Physical State, Color, Odor	R	R	R
2.4 Density or Specific Gravity	R	R	X
2.5 Stability	R	X	X
2.6 Storage Stability	R	R	R
2.7 Viscosity	X	R (for liquids)	R
2.8 Corrosion Characteristics	X	R (when packed in metal, paper or plastic)	R
3.0 BIOEFFICACY			
3.1 Description of mode of action of active agent on pest for which control is claimed	X	X	R
3.2 Pest controlled and names of crops, materials or premises to be protected, and life cycle	X	X	R
3.3 Application rate (Kg ai/Ha or % ai spray dilution for each site/pest tested)	X	X	R
3.4 Frequency and timing of application	X	X	R
3.5 Method of application	X	X	R
3.6 Phytotoxicity	X	X	R
3.7 Results of laboratory study, if any	X	X	R
3.8 Effects on beneficial organisms or non-target organisms	X	X	R
3.9 Complete description and data from local field trials or relevant tests performed abroad on request	X	X	R
4.0 TOXICOLOGY (Tier Tests on Microbial Pest Control Agents)*			
TIER I			
4.1 <u>LD₅₀ Determination</u> Oral (rat) Dermal (rat or mouse) Inhalation (mouse, rabbit or guinea pig)	BFVP BFVP BFVP	BFVP BFVP BFVP	BFVP BFVP BFVP
4.2 <u>Infectivity</u> Intravenous (newly weaned mouse and hamster) Intracerebral (newborn mouse and hamster) Intracerebral (mouse and rabbit) Intraperitoneal (mouse and rabbit) Intraperitoneal (mouse and one other species)	B, V V P P F	B	B

* B – Bacteria, F – Fungi, V – Virus, P – Protozoa

Microbial Pest Control Agents (MPCA) Registration Requirements

DATA REQUIRED	Technical/ Purer Grade of Active Ingredient	Manufacturing- Use Product	End-Use Product
4.3 <u>Irritation</u> Ocular, primary (rabbit) Dermal, primary (rabbit or guinea pig)	B	BFVP BFVP	BFVP BFVP
4.4 <u>Hypersensitivity</u> Immediate (human experience during product development) Non-immediate (honesty or albino guinea pig)	FVP B	BFVP BFVP	BFVP BFVP
4.5 <u>Cellular Immune Response</u> (mouse)	FVP		
4.6 <u>Tissue Culture</u> (various cell lines, see section on viral agents)	V		
TIER II*			
4.7 Acute oral (puppies administered large doses)		P	P
4.8 Acute oral (newly weaned mouse and/or hamster)		V	V
4.9 Acute inhalation (a different species than used in Tier I)		P	P
4.10 Acute inhalation (newly weaned mouse and/or hamster)		V	V
4.11 Acute interperitoneal or intracerebral (two species other than those used in Tier I; half the group are immunodepressed)	BF		
4.12 Subchronic oral (mice, rat or dog; 90 day test)	P		
4.13 Primary dermal (guinea pig, use dilution doses)	P		
4.14 Primary ocular (rabbit, use dilution doses)			BFVP
4.15 Cellular Immune Response (antibody formation cell mediated response)			BFVP
4.16 Teratogenicity tests (two species from rat, mouse, hamster, rabbit)	BFVP		
4.17 Mutagenicity tests (mammalian cell, see text)	BFV		
4.18 Virulence enhancement (mice or hamster, serial passage)	BFVP		
TIER III*			
4.19 Chronic oral (rat)	BFVP		
4.20 Oncogenicity test (newly weaned mouse and/or rat)	BFVP		
4.21 Mutagenicity test (mammals using the expected route of exposure)	BFVP		
4.22 Teratogenicity test (two species from rat, mouse, hamster or rabbit)	BFVP		

Toxicology Data Guidelines for Microbial Agents:

Microbial agent testing for human and animal effects follows a tiered sequence, including acute toxicity/infectivity, cellular immune response, irritation, hypersensitivity, virulence enhancement, tissue culture, teratogenicity, mutagenicity, sub-chronic, and chronic studies. Each organism may not undergo every study at each tier.

- Tier I Testing (Ref. Sub-series* 152A, Sections 152-30 to 152-39, pp. 142-173)
- Tier II Testing (Ref. Sub-series* 152A, Sections 152-40 to 152-49, pp. 174-189)
- Tier III Testing (Ref. Sub-series* 152A, Sections 152-50 to 152-53, pp. 190-192)

* EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides

** Not all tests may be indicated for each microbial pest control agent, the appropriate tests will depend on the results of Tier I and/or Tier II tests.

Microbial Pest Control Agents (MPCA) Registration Requirements



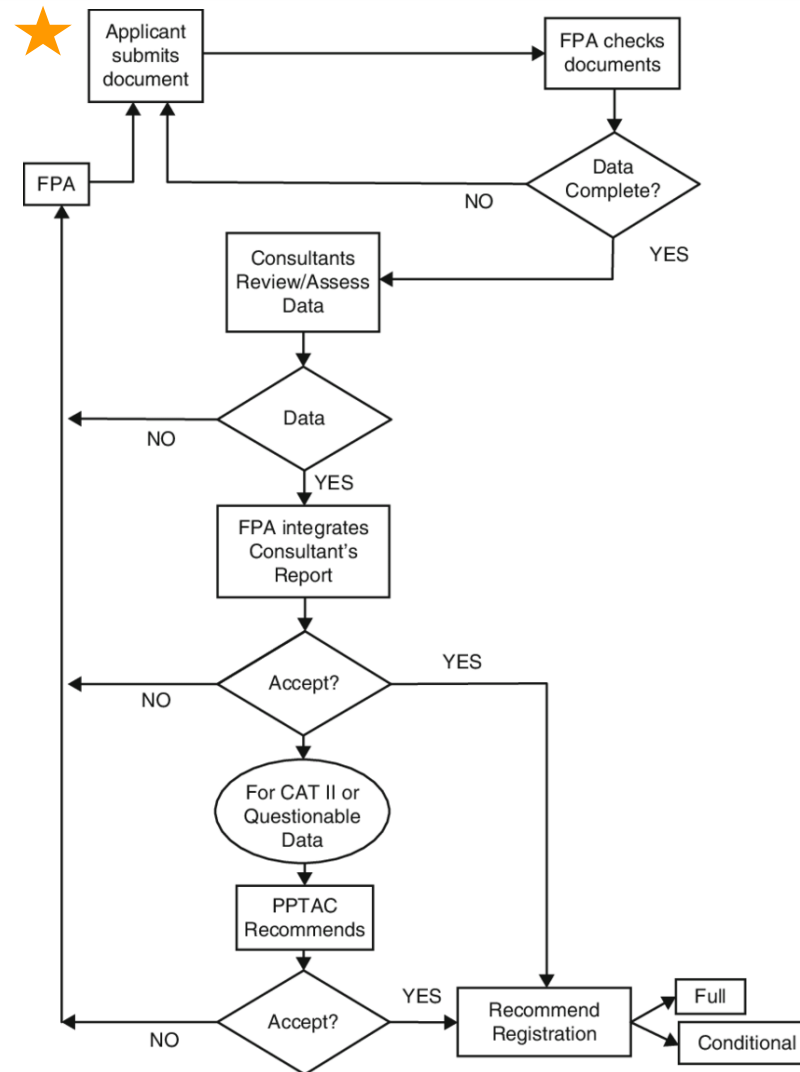
DATA REQUIRED	Technical/ Purer Grade of Active Ingredient	Manufacturing- Use Product	End-Use Product
5.0 ENVIRONMENTAL EFFECTS			
5.1 Avian Acute Oral Toxicity	R	X	R
5.2 Avian Dietary Acute Toxicity If need is indicated by Acute Oral	R	X	R
5.3 Fish Acute Toxicity (one species)	R	X	R
5.4 Sub Acute Fish Toxicity When prolonged exposure is likely; test period up to 30 days	R	X	R
5.5 Aquatic Acute Toxicity	R	X	R
5.6 Fish Accumulation When need is indicated by use pattern	R	X	R
5.7 Avian reproduction If need is indicated by feeding study results	R	X	R
5.8 Fish Reproduction If there is persistent exposure indicated by use pattern and persistence	R	X	R
5.9 Acute Toxicity to Honeybees If use involves crops where bees are present during and just after spraying	R	X	R
5.10 Contact Toxicity to Honeybees If exposure and acute test show high bee toxicity	R	X	R
5.11 Soil non-target microorganisms If high soil concentration is expected from use	R	X	R
6.0 ENVIRONMENTAL FATE AND EXPRESSION*			
6.1 Volatility	R	R	R
6.2 Adsorption/Desorption If pesticide is likely to reach soil or water	R	R	R
6.3 Leaching	R	R	R
6.4 Degradation in soil If pesticide is likely to reach soil	R	R	R
6.5 Biodegradation	R	R	R
6.6 Hydrolyses	R	R	R

DATA REQUIRED	Technical/ Purer Grade of Active Ingredient	Manufacturing- Use Product	End-Use Product
6.7 Aqueous photolysis	R	R	R
6.8 Ultra Violet Absorption Spectra	R	R	R
6.9 Biomonitoring for Degradation Products	R	R	R
6.10 Biomonitoring for Disappearance of Biochemicals	R	R	R
6.11 Analytical Method for Residues in Soil	R	R	R
6.12 Analytical Method for Residues in Water	R	R	R
7.0 LABELLING			
7.1 Proposed Toxicity Category	R	R	R
7.2 Draft/Final Label		R	R

Residue Data:

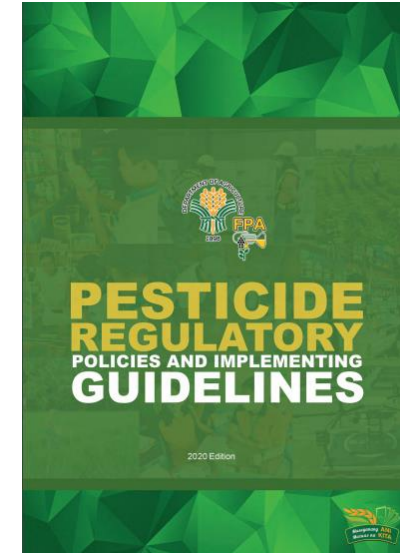
Residue data for microbial pest control agents in food, feed, or raw agricultural commodities is necessary only if Tier I toxicology tests reveal toxic or harmful properties. If Tier I tests show no such properties, no residue data is required, allowing for a potential exemption from tolerance requirements.

Biopesticide Regulations – Registration Process



Biorational Pesticides Registration Requirements

- ▶ Microbial pest control agents ✓
- ▶ Biochemical Pest Control Agents:
 - ▶ Semiochemicals
 - ▶ Hormones
 - ▶ Natural Plant Regulators
 - ▶ Enzymes



DATA REQUIRED	Technical/ Purer Grade of Active Ingredient	Manufacturing- Use Product	End-Use Product
1.0 GENERAL INFORMATION			
1.1 Name/Address of Applicant	R	R	R
1.2 Product Trade/Brand Name	R	R	R
1.3 Manufacturer Source of Technical Material	R	R	R
1.4 Description of Manufacturing Process includes starting material, steps taken, both chemical and biological, procedures in establishing identity and purity of feedstock quality control methods and presence of toxic or sensitizing substances.	R	R	R
1.5 Method of Analysis	R	R	R
2.0 SPECIFICATIONS			
2.1 Common Name	R	R	R
2.2 Chemical Name	R	R	R
2.3 Chemical Abstract Registry Number	R	R	R
2.4 Formula (Empirical and Structural)	R	R	R
2.5 Scientific Name of Associated Organism	R	R	R
2.6 List of Ingredients, Percent Composition and Molecular Wt. of each ingredient, include impurities (Certification of Composition Limits for each ingredient must be submitted)	R	R	R
2.7 Physical State, Colour, Odor	R	R	R
2.8 Melting Point	R (solid)	X	X
2.9 Boiling Point	R (liquid)	X	X
2.10 Vapor Pressure	R (pure form)	X	X
2.11 Density or Specific Gravity	R	R	R
2.12 Octanol/Water Partition Coefficient	R (non-polar, pure organic)	X	X
2.13 Solubility	R	X	X
2.14 Stability / Storage Stability	R	X	X
2.15 Flash Point / Flammability	X	R	R
2.16 Flame Extension	X	X	R
2.17 Viscosity	X	R (only emulsifiable liquids)	R (only emulsifiable liquids)
2.18 pH	R	R	R
2.19 Corrosion Characteristics	X	R (when packed in metal, plastic or paper)	R (when packed in metal, plastic or paper)

- ▶ **Plant-Incorporated Protectants (PIP):** pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance.
- ▶ **Pest Control Organisms** e.g., insect predators, nematodes, and macroscopic parasites → not considered biorational pesticides, and are exempt from the requirements of these guidelines.

Biopesticide Regulations – VIETNAM



- ▶ **Main Regulation:** Circular No 21/2015/TT-BNNPTNT
- ▶ **Authority:** the Plant Protection Department (**PPD**), Ministry of Agriculture and Rural Development (MARD)
- ▶ **Website:** <https://www.mard.gov.vn/en/Pages/default.aspx>
- ▶ **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.), **or representative offices** or branches of foreign companies with business licenses to carry out pesticide product business operations in Vietnam.
- ▶ **Key point:** Foreign organizations **without** a representative office, subsidiaries, or branches in Vietnam authorized for pesticide product business operations **are ineligible** to apply for registration.
- ▶ **Local efficacy trials:** required
- ▶ **Overall registration timeframe:** 2 – 3 years

Biopesticide Regulations – VIETNAM



- ▶ **Data requirements for biopesticides:** Available in Vietnamese language
- ▶ **Evaluation process:** same as conventional pesticides but reduce the number of bio-efficacy trails, evaluation process is shorter (**Fast-tracking**)
- ▶ **Registration validity:** 5 years
- ▶ **Key points:** Companies are permitted to apply for registration exclusively for formulations and concentrations *listed on the approved plant protection products allowed in the country.*
- ▶ The latest list of pesticides permitted for use in Vietnam and the List of pesticides banned from use in Vietnam (issued in 2023) is Circular No. 09/2023/TT-BNNPTNT

Biopesticide Regulations – VIETNAM



Pesticide Registration Types

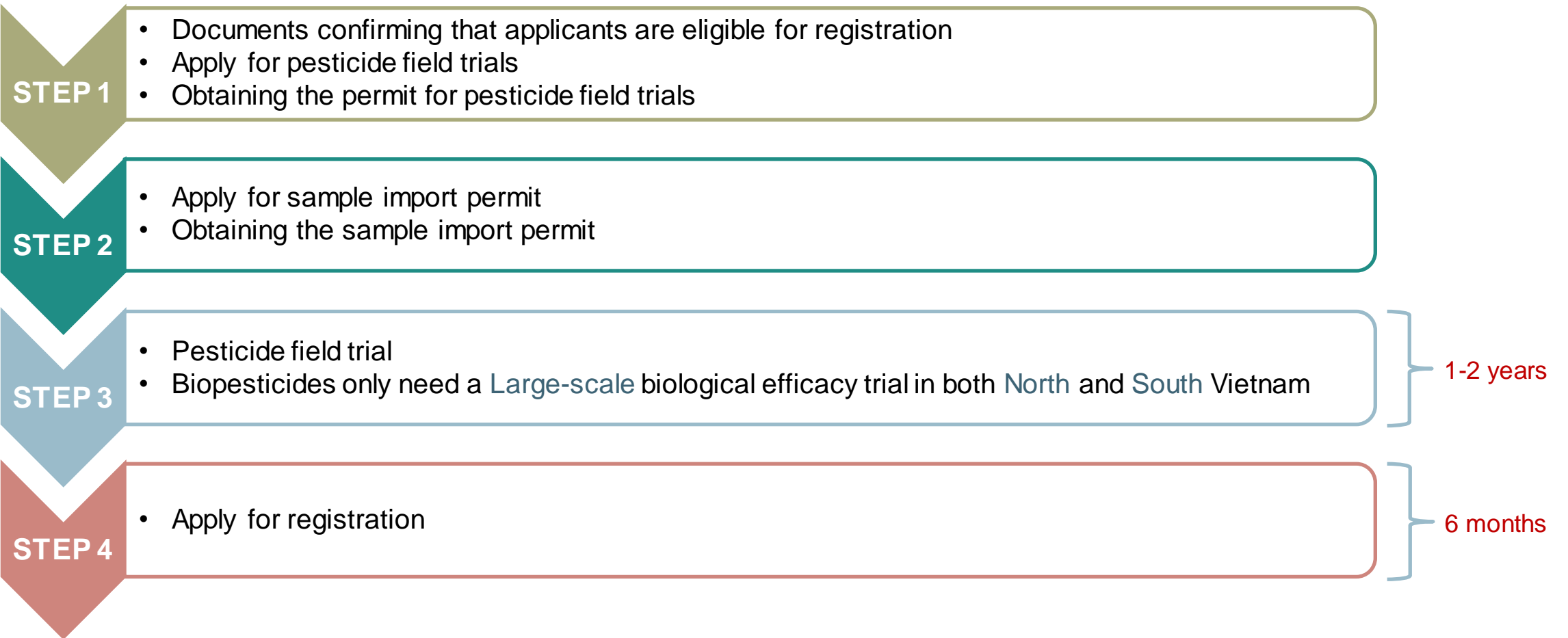
1. Full Registration:

- ▶ 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.

2. 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.

Biopesticide registration process



Biopesticide Regulations – Summary of data requirements microorganisms

- A. Administrative documents
 - i. An application for a biopesticides trial permit using the provided form
 - ii. Document proving the applicant's eligibility to register biopesticides in Vietnam
 - iii. Information of trade name, formulation type, active ingredient (a.i.), manufacturer
- B. Biological data
 - Identity of microorganisms
 - Identification characteristics of microorganisms
 - Biological properties of microorganisms
 - Specifications
 - Shelf life
 - Source or origin
 - Manufacturing process
 - Impurities and contaminants (other microorganisms, not more than 10^4)
- C. Infectivity and pathogenicity or toxicity to non-target organisms
 - Oral toxicity/ infectivity and pathogenicity
 - Dermal toxicity/ infectivity and pathogenicity
 - Inhalation toxicity/ infectivity and pathogenicity
 - Primary skin irritation
 - Mucous membrane irritation
 - Allergy/ sensitization/ immunosuppression
- D. Human health exposure/ environmental fate and effects data (Only if any results from [section C](#) suggest further risk assessment)
 - i. Human health exposure effects
 - Operators exposure data (dermal exposure/ inhalation exposure, biological monitoring) – field application
 - Bystander exposure data (dermal exposure/ inhalation exposure, biological monitoring) – field application
 - ii. Environmental fate & effects
 - Primary data on potential hazards (infectivity) to mammals (including humans)
 - Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)
 - Experimental data on infectivity to crop plant species (e.g. microbial agents used for control of weed species)

Rights and obligations on registration and import



Who Shall Register?

- Local importers, local distributors, local manufacturers, or foreign organizations involved in pesticide manufacturing may apply if they possess representative offices, subsidiaries, or branches authorized for pesticide product business operations in Vietnam.

	Representative office	Subsidiary company
Rights	<ul style="list-style-type: none">Serve as the applicant and can communicate with the relevant state agency throughout the registration process.Hire Vietnamese and expatriate employees for the Regional Office (RO).Engage in commercial promotion activities such as advertisements, product displays, exhibitions, trade fairs, and promotional events.	<ul style="list-style-type: none">Serve as the applicant and the sole importer/distributor of the pesticide product in Vietnam. Authorization from the applicant owner is mandatory for other local importers.Have the authority to engage in all commercial activities, including direct import and distribution of pesticide.Operate as a legal entity with complete eligibility to participate in activities sanctioned by Vietnamese regulations.
Obligations	<ul style="list-style-type: none">Abstain from engaging in direct profit-generating activities in Vietnam, which includes import activities.Ensure the payment of personal income tax for employees working in the RO.Submit an annual written report detailing the activities of the RO to the relevant authority.	<ul style="list-style-type: none">Ensure timely capital contributions.Adhere to tax regulations, including invoicing, VAT, income tax, and import-export tax, as well as social insurance obligations for employees and other activities related to the project.Submit an annual written report of the investment project to the relevant authority.

Rights and obligations on registration and import



Who Shall Register?

Conclusion

Items	Representative office	Subsidiary company
Timeframe	Shorter (20 – 25 working days)	Longer (2 – 3 months or maybe prolonged)
Cost	Lower	Higher
Process	Simple	Complicated
Rights and obligations	<ul style="list-style-type: none">• Be the applicant• Because RO is not authorized to conduct the import activity, it is necessary to authorize the local company to import.• Vietnamese regulations do not limit the number of companies authorized.	<ul style="list-style-type: none">• Be the applicant, registration license holder, and exclusive importer in Vietnam.• Establishing a subsidiary offers better control over registration, import, and sales. However, the process is time-consuming, involving extensive preparations for personnel and facilities, leading to a prolonged registration period.

Biopesticide Regulations – INDONESIA



- ▶ **Main Regulation:** Regulation Number 43/2019
- ▶ **Authority:** The Centre of Plant Variety Protection and Agricultural Permit- PPVTPP
- ▶ **Website:** <https://simpel1.pertanian.go.id/perizinan/pestisida>
- ▶ **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.)
- ▶ **Data requirements for biopesticides:** Available in Indonesian language
- ▶ **Local efficacy trials:** required
- ▶ **Overall registration timeframe:** 2 – 3 years
- ▶ **Evaluation process:** same as conventional pesticides
- ▶ **Registration validity:** 5 years

Biopesticide Regulations – INDONESIA



Pesticide Registration Types

1. Provisional Permission (Experimental Use Permission: EUP)

- ▶ Granted for a 1-year period and might be extended for 2 times for a period of 1 year each.
- ▶ The applicant holding provisional permission is required to run a number of trials in collaboration with accredited research institutes.
- ▶ The applicant is required to obtain technical data and information on efficacy and toxicity tests for registration purposes.
- ▶ While holding provisional permission, no applicant is allowed to work on trading or promoting activity or distribution for commercial purposes.

2. Permanent Permission

- ▶ Granted to those who have thoroughly submitted all data required derived from the official trials on efficacy and toxicity.
- ▶ Pesticides holding full registration can be used and distributed on a commercial basis.

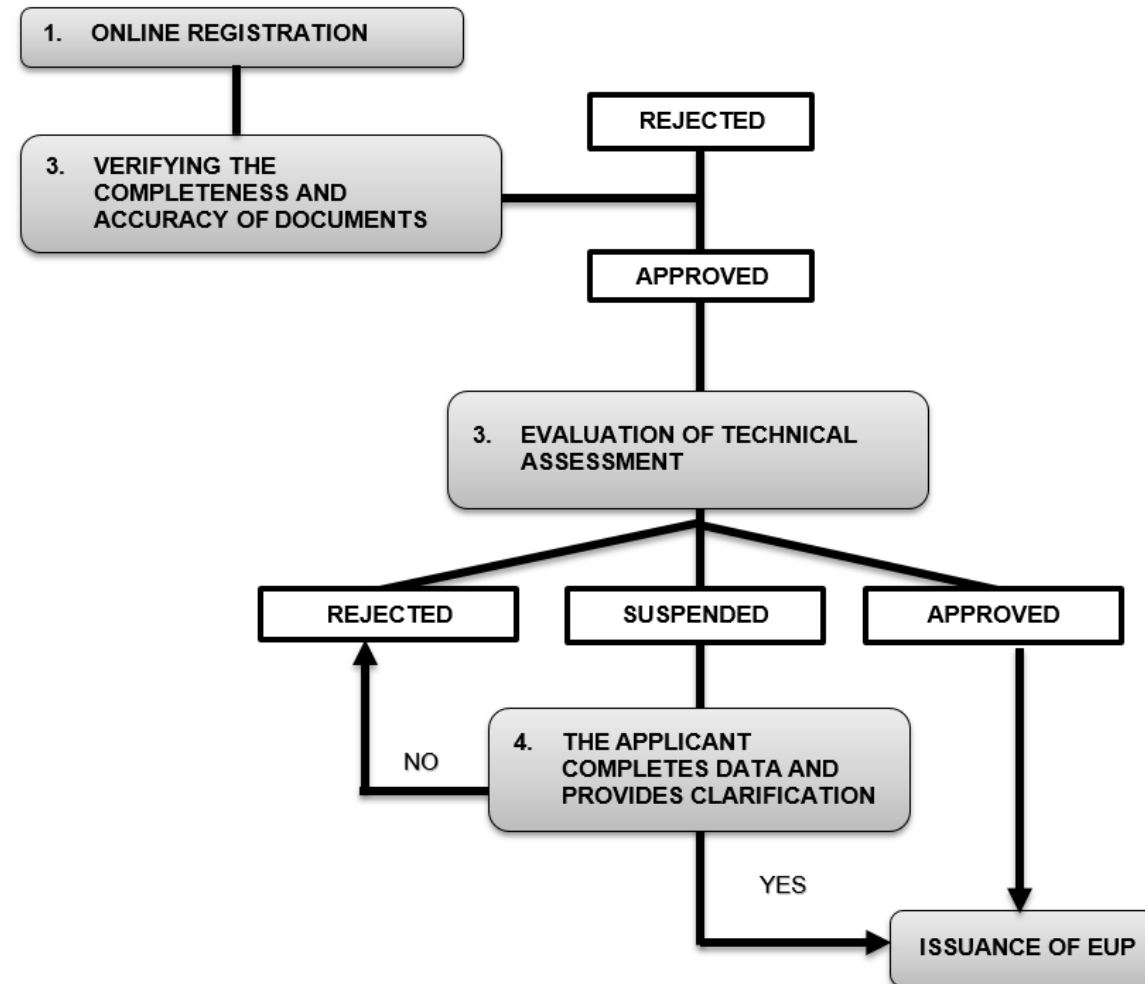
Experimental Use Permits (EUP) – Data requirements



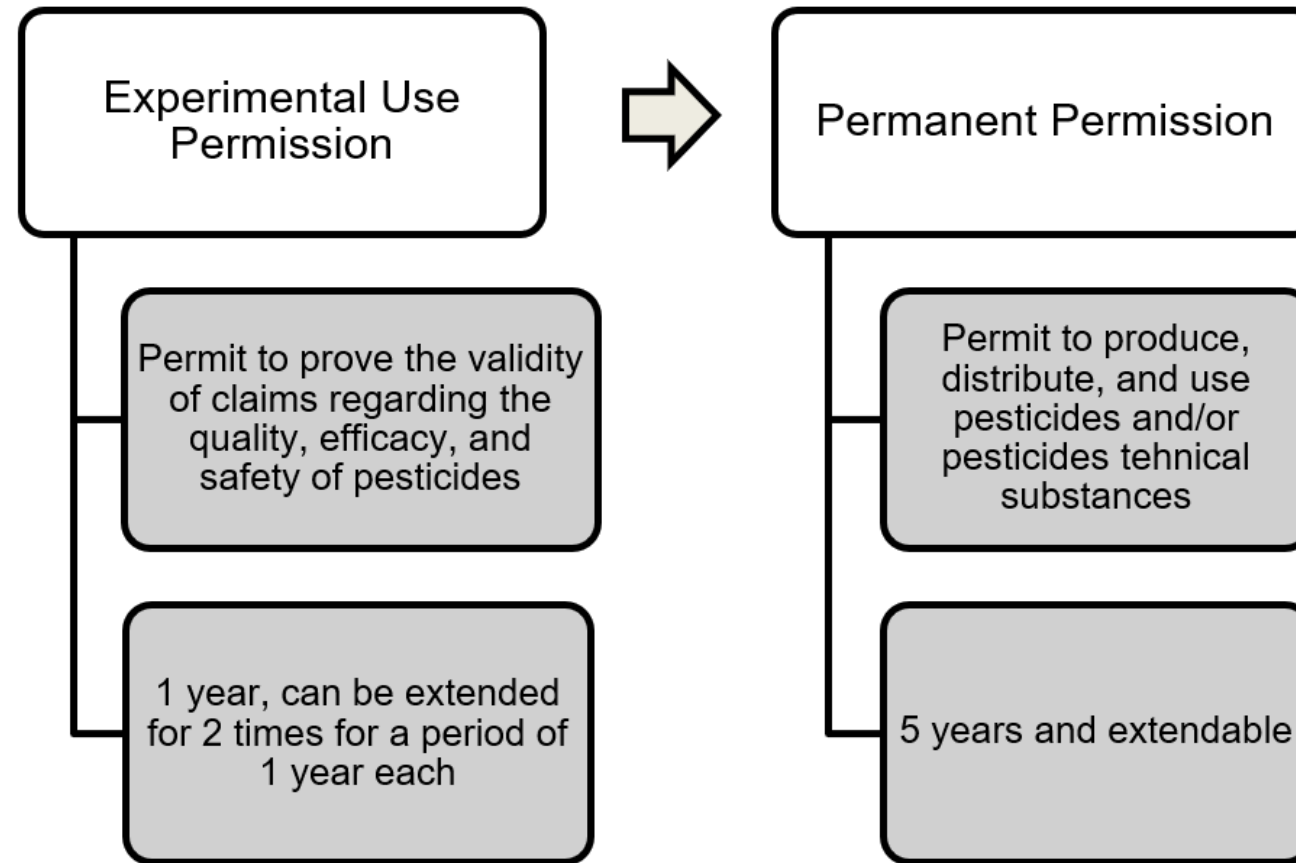
► The Administration Requirements are as follows:

- a) Business Identification Number/ Nomor Induk Berusaha (NIB) from the appointed legal entity;
- b) Pesticides registration form that has been filled;
- c) Statement letter regarding the entitlement of registration and licensing;
- d) Trademark certificate or proof of trademark registration;
- e) Letter of authorization as a guarantee to supply the active ingredients or the technical substances from its supplier and/or access to registration data from the active ingredients or technical substances supplier for self-production;
- f) Letter of access for the active ingredients / technical material from its, for those who do not produce by their own;
- g) Manufacturing license issued by the authorized institution in the origin country, for those who produce by their own;
- h) Proof of mastery of domestic production facilities (manufacturing for Active Ingredient / Technical Material, manufacturing for formulation or packing) in the form of a Pesticides Industry Permit;
- i) Letter of statement regarding the authenticity of documents in the provided format;
- j) Certificates of analysis (CoA) from an accredited quality testing laboratory;
- k) Production permit from the competent body regarding the manufacture of Active Materials / Technical Materials (Manufacturing licenses) issued by the competent body in the country of origin;
- l) Formulation certificate (Certificate of Composition/ CoC) from formulator / original manufacturer;
- m) Chromatograms from the analysis of Technical Materials from accredited quality testing laboratories Having production facilities (active materials / technical materials, formulation, or packaging in Indonesia) proven by industrial licenses; or cooperation with a local formulation manufacturer or packaging factory as evidenced by a production cooperation certificate.

Pesticides Registration Process for Experimental Use Permission (EUP)



Biopesticide Regulations – INDONESIA



The Permanent Permission – Data requirements



► The Administration Requirements are as follows:

- a) Business Identification Number (NIB) from the appointed legal entity;
- b) Completed Pesticide Registration form;
- c) Declaration of Authority (a statement confirming the right to sign a letter for registration and licensing purposes);
- d) Brand certificate or proof of trademark registration;
- e) Guarantee letter for the supply of Active Material/Technical Material from the supplier, including registration data access (Letter of Authorization) for self-production;
- f) Guarantee letter for the supply of Active Material/Technical Material from the supplier (Letter of Access) for those not engaged in self-production;
- g) Production permit from the competent authority for manufacturing Active Materials/Technical Materials (manufacturing license) issued by the authorized body in the country of origin;
- h) Evidence of domestic mastery of production facilities (Active Material/Technical Material factory, Formulation factory, or packaging factory) through a Pesticide industry permit; and
- i) Declaration of document accuracy as per Format-1 in Appendix VI, an integral part of this Ministerial Regulation.

The Permanent Permission – Data requirements

► The Technical Requirements are as follows:

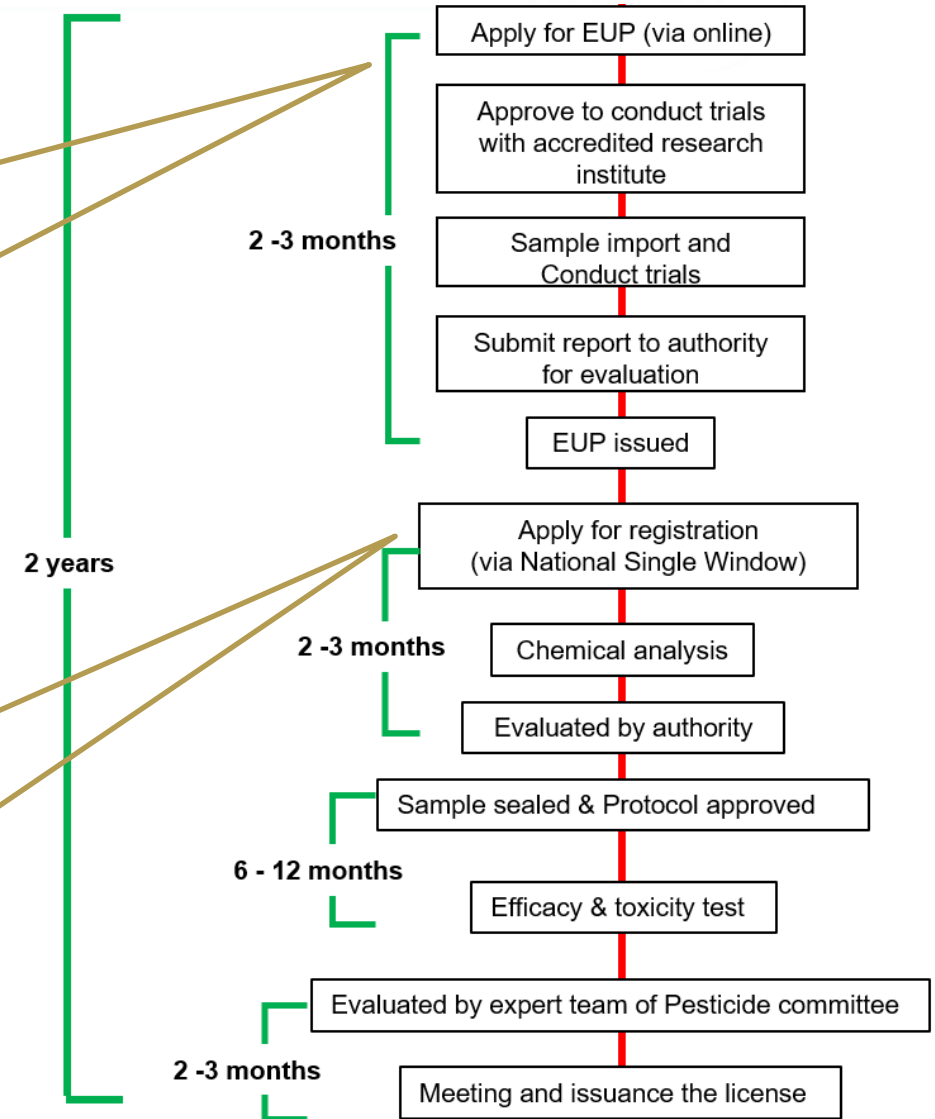
- a) Trade name:
- b) Certificates of analysis (CoA);
- c) Common name accepted by ISO or others (if any)
- d) Manufacturer Code Number (if any)
- e) Chemical name in IUPAC nomenclature or others
- f) Structural and Empirical formula
- g) Specification
- h) Formulation composition
- i) Acute inhalation, chronic and sub-chronic toxicity are not required for biopesticides
- j) Report on the results of environmental toxicity tests for lowland rice commodities
- k) Antagonistic test results for registration of Pesticide Formulations with active ingredients in the fields of use of plant management
- l) Physical and Chemical Properties
- m) Composition of technical including impurities
- n) Compatibility
- o) Stability
- p) Method of analysis
- q) Mode of action
- r) Quality of Pesticide
- s) Local bio-efficacy trials
- t) Precaution
- u) First-aid measures
- v) Type of packaging, containers
- w) Proposed label
- x) Information on registration and permit in other countries

Biopesticide registration process

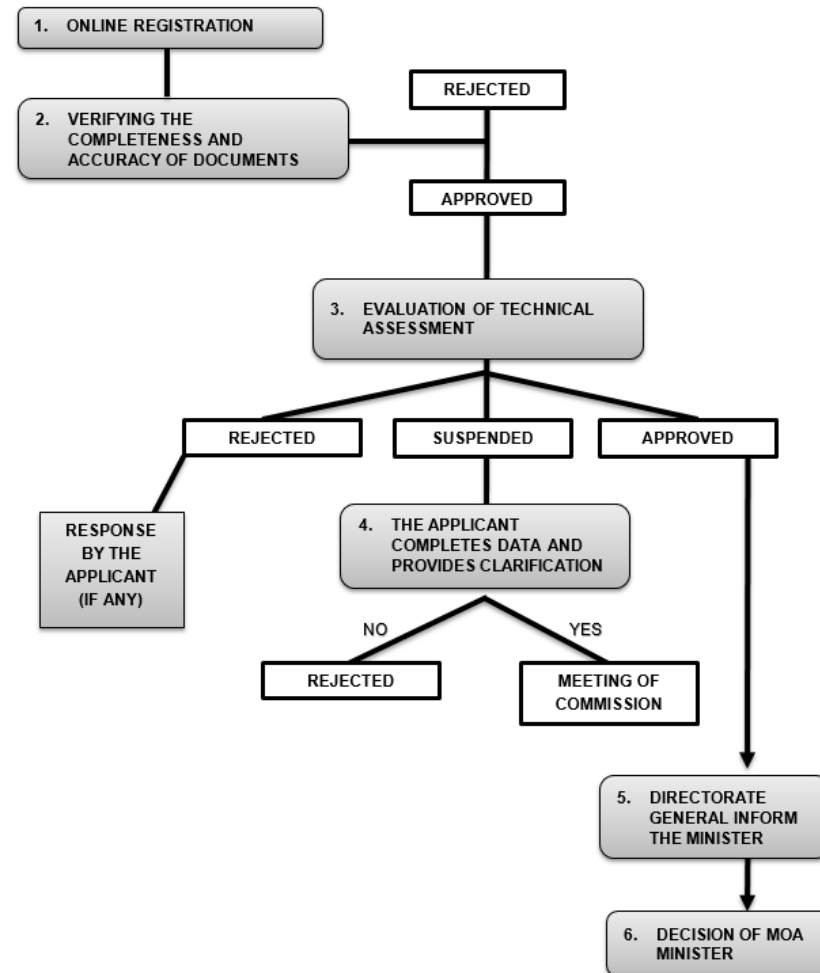
1. The applicant needs to create the account and access code for online registration by submitting a scanned copy of administrative required documents via <http://simpler.pertanian.go.id/>.
2. The original copy of the documents is required to be submitted to the authority for verification before the access code is issued.
3. The applicant submits the application form for the trial permit and the required documents via the online system.

The Permanent Permit shall fulfil the following requirements:

- a) Obtained EUP;
- b) Quality testing analysis result certificate;
- c) Technical data for registration;
- d) For biopesticides, the result of testing the efficacy of target organisms following applicable provisions and carried out at 1 location of commodity centres for each target organism and commodity;
- e) 1 efficacy testing unit for only 1 commodity and 1 target organism



Pesticides Registration Process for Permanent Permission



Biopesticides: Regulations



Country	Main Regulations	Guidelines for biopesticides	Registration holder
Thailand	Hazardous Substance Act	Available	Local entity
Philippines	Presidential Decree No. 1144	Available	Local entity
Vietnam	Circular No. 21/2015/TT-BNNPTNT	Available	Local entity, Foreign company with RO, subsidiary, branch with pesticide operation business license
Indonesia	Regulation No. 43 of 2019	Available (Indonesian language)	Local entity



Navigating Regulations for Biofertilizers in Selected Southeast Asian Countries

Biofertilizer Regulations - THAILAND



- ▶ Main regulation: The Fertilizer Act
- ▶ Authority: the Fertilizer Control Division, Department of Agriculture (DOA)
- ▶ Website: <https://www.doa.go.th/ard/>
- ▶ Registration holder: Local entity only (local manufacturer, local importer, etc.)
- ▶ Registration submission: Online
- ▶ Data requirements : Available in Thai
- ▶ Local efficacy trials: Not required
- ▶ Overall registration timeframe: 6 - 8 months excluding the trademark registration
- ▶ Registration validity: 5 years

Biofertilizer Regulations



- ▶ “**Biological fertilizer**” refers to a fertilizer derived from **living microorganisms** that facilitate the formation of plant nutrients or provide essential nutrients for plant growth. It contributes to soil enrichment, inducing biological, physical, chemical, and biochemical changes in the soil. This definition also encompasses microorganisms in concentrated form, often referred to as effective microorganisms.
- ▶ **Eligibility Criteria for Registered Biological Fertilizers:**
 1. **Nitrogen-Compounding Biological Fertilizers:**
 - Rhizobium Biological Fertilizer **with at least 10^6 cells per gram**
 - Plant Growth-Promoting Rhizobacteria (PGPR) Biological Fertilizer **with at least 10^6 colonies or cells per gram**
 - Blue-Green Algae Biological Fertilizer **with at least 10^5 colonies or cells per gram**
 2. **Arbuscular Mycorrhiza** as a Plant Nutrient-Absorbing Biological Fertilizers **with at least 25 spores per gram**
 3. **Phosphate Solubilizing Biological Fertilizer (PSB)** **with 10^8 colonies per gram (for bacterial types) or 10^9 colonies per gram (for mold types)**
 4. **Potassium Solubilizing Biological Fertilizer (KSB)** **with at least 10^8 colonies per gram**

Biofertilizer Regulations – Key Points



► Trademark Registration:

- The mark (brand or label) on the fertilizer must be registered as a trademark before registering the fertilizer itself.

► License for Import/ Manufacture:

- Obtain a license to import or manufacture fertilizers before applying for registration.

► Registration Application for Biological Fertilizers:

- Submission of the application and supporting documents (e.g., recent fertilizer analysis report, manufacturer's summary, usage instructions) via the DOA National Single Window (NSW)

► Submission of Supporting Documents and Samples:

- Submit labeled samples and supporting documents in person or by post after confirmation of application completeness by DOA.

Biofertilizer Regulations – Key Points



► Review by DOA Officer and Fertilizer Committee:

- The DOA officer and Fertilizer Committee review the application; approval granted if no further comments from the committee.

► Timeline for Approval:

- Estimated overall timeline from submission to approval is 6 months (may be longer with comments from the Fertilizer Committee).

► Validity and Renewal:

- Registration certificate valid for 5 years; renewable

► Legal Requirements in Thailand:

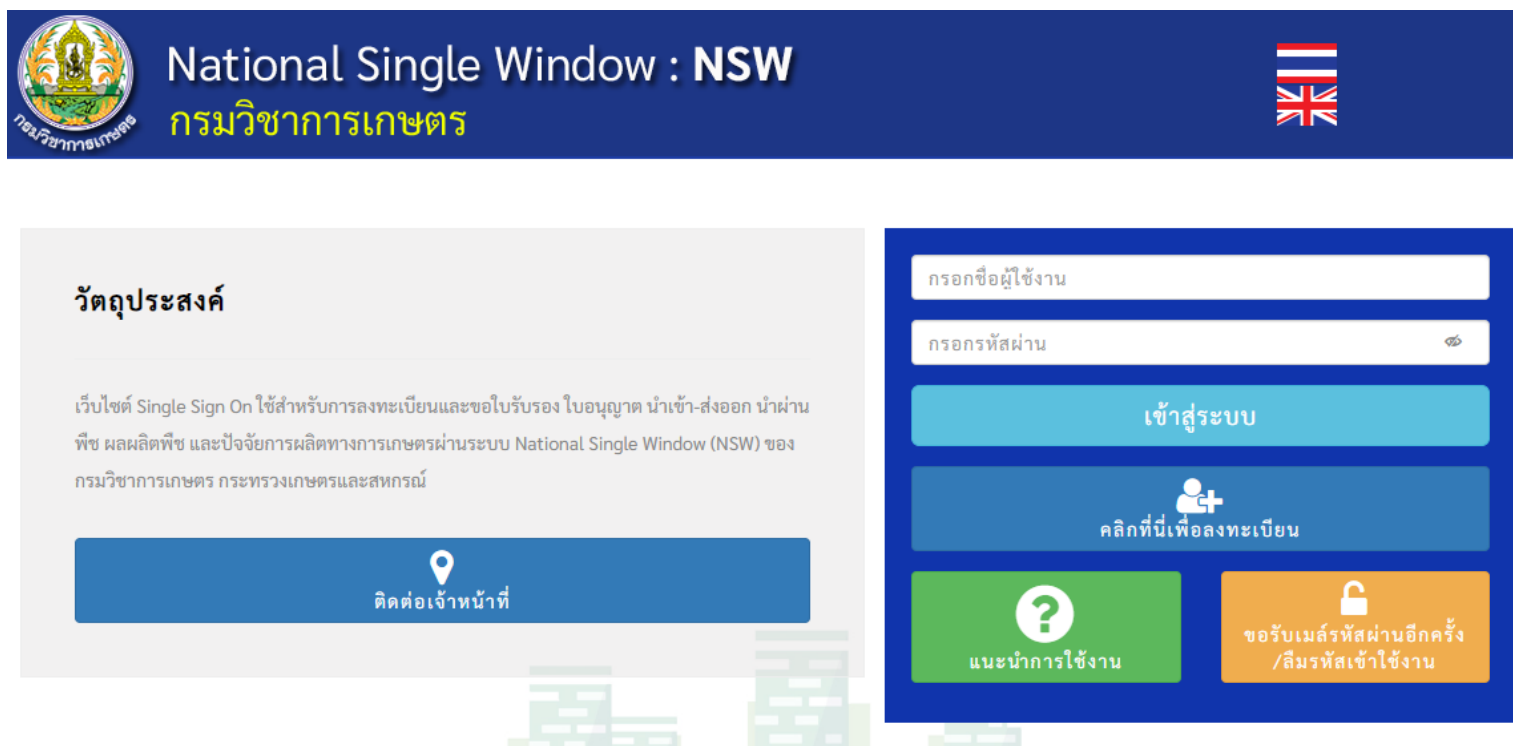
- Prohibition on manufacturing, selling, importing, exporting, or transporting fertilizer **without** permission or a license.

► Penalties for Violation:

- General penalties for violating the Fertilizer Act; specific penalties for biological fertilizer violations, including fines and imprisonment.

Biofertilizer Regulations: Registration Requirements

- Company shall have an account for the registration submission
- Registration submission can be done via the DOA's National Single Window (NSW): <https://nsw.doa.go.th/public/>



วัตถุประสงค์

เว็บไซต์ Single Sign On ใช้สำหรับการลงทะเบียนและขอใบรับรอง ใบอนุญาต นำเข้า-ส่งออก นำผ่านพืช ผลผลิตพืช และปัจจัยการผลิตทางการเกษตรผ่านระบบ National Single Window (NSW) ของกรมวิชาการเกษตร กระทรวงเกษตรและสหกรณ์

ติดต่อเจ้าหน้าที่

กรอกชื่อใช้งาน

กรอกรหัสผ่าน

เข้าสู่ระบบ

คลิกที่นี่เพื่อลงทะเบียน

แนะนำการใช้งาน

ขอรับเมล์รหัสผ่านอีกครั้ง / ลืมรหัสเข้าใช้งาน

Biofertilizer Regulations: Registration Requirements



National Single Window :
กรมวิสาหกิจ



Logout

Profile

Receive/grant authority

License/Registration

PLANT INSPECTED

Q-SHOP

MANAGE OPERATOR INFORMATION

ELECTRONIC SIGNATURE (OPERATOR)

1. List of biological fertilizers requested for registration

Types of biological fertilizers

Select

Trade name

Trademark (brand)

Trademark registration

Attached trademark registration file

SELECT FILE

Type and amount of microorganisms *

When specifying the name and quantity of 1 type of microorganism, press it with the symbol ,

Superscript key H ² ->

H²

Subscript key H ₂ ->

H₂

Italic key *Abc* ->

<i>Abc</i>

Characteristics of biological fertilizers

Select

Type and quantity of biological
fertilizer support material

SELECT ITEM

for filling out information Types of supporting materials for biological fertilizers that are not on the list

In case there is more than 1 item of information, separated by ", " (please enter 1 space)

Name and quantity of other substances
or ingredients in biological fertilizer
(percentage by weight)

SELECT ITEM

Biofertilizer Regulations: Registration Requirements

knoell

biofertilizer
regulations

Receive/grant authority License/Registration PLANT INSPECTED Q-SHOP MANAGE OPERATOR INFORMATION ELECTRONIC SIGNATURE (OPERATOR)

Names and quantities of toxic substances mixed in biological fertilizers

Packing size per unit (according to the metric system) and container type

Methods for analyzing biological fertilizers

Select ▼

Name of producer and place of production of biological fertilizer

country

Select ▼

Life of microorganisms from production date (days)

2. Evidence attached to the application for registration of biological fertilizer submitted for consideration of registration of biological fertilizer.

- ☐ Examples of biological fertilizer labels and text displayed on the label (if any)
- ☐ The original report of biological fertilizer analysis results must not exceed 6 months from the date of reporting the analysis results.
- ☐ Brief manufacturer's biofertilizer production process
- ☐ Biological fertilizer documentation (Instructions for using biological fertilizers, how to use, rate of use, precautions, etc.) (if any)
- ☐ Samples or photographs of bio-fertilizer containers (if any)
- ☐ Examples of biological fertilizers that request registration

Biofertilizer Regulations: Registration Requirements



I hereby certify that List of biological fertilizers requested for registration Attached evidence and samples of biological fertilizers sent as requested.
The above is absolutely true. and certify that you are the owner of the trademark or is actually a person authorized to use the above mentioned trademarks
If it is a violation or infringement of the rights in the name and/or trademarks of others, I accept sole responsibility.

Date of issue of analysis report *

laboratory

Lab No.

Analysis list

+Add information

list	Scientific name	Analysis results	Quantity of microorganisms			unit	note	
			amount	Number multiplied by base 10	exponent			
Microbial type	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	
Efficiency: dissolves phosphates	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	
pH	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	
moisture	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	
Efficacy: dissolves potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	
Efficiency: Fixes nitrogen	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	
sp.gr.	<input type="text"/>	<input type="text"/>	<input type="text"/>	10	<input type="text"/>	Select	<input type="text"/>	

SAVE DRAFT SEND REQUEST

Biofertilizer Regulations: Registration Requirements



Biological fertilizer analysis results, dated within 6 months from the reporting date.



Date of issue of analysis report *



List of accredited laboratory

laboratory



Select

Rajamangala University of Technology Suvarnabhumi

Agricultural Production Factors Research and Development Division

Office of Agricultural Research and Development, Area 1

Office of Agricultural Research and Development, Area 2

Office of Agricultural Research and Development, Region 3

Biofertilizer Regulations: Registration Requirements



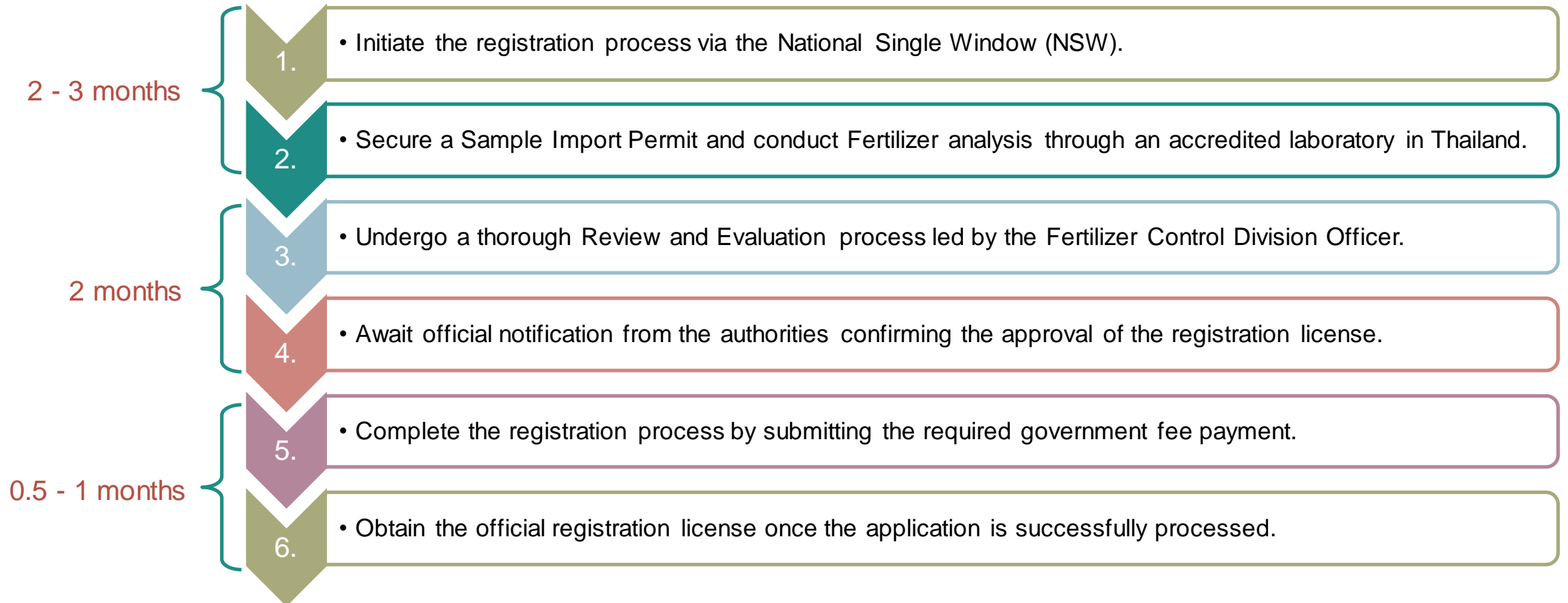
- ▶ Application for registration of biological fertilizer
- ▶ Power of attorney (if any)
- ▶ Certificate of trademark registration (in Thailand) or letter of consent to use a trademark (if the trademark belongs to someone other than the applicant)
- ▶ Fertilizer import license or fertilizer production license for trade
- ▶ Original report of biological fertilizer analysis results, dated within 6 months from the reporting date.
- ▶ Labeling Information:
 - ▶ Examples of labels and texts displayed on labels
 - ▶ Documentation providing instructions for using biological fertilizers, application methods, recommended rates, and precautions
 - ▶ Samples or photos of containers
 - ▶ Actual label format for printing on the container, based on the requested package size for registration
- ▶ Product Information:
 - ▶ Methods for analyzing biological fertilizers
 - ▶ Names and quantities of components or substances mixed in biological fertilizers
 - ▶ Names and amounts of toxic substances mixed in biological fertilizers
 - ▶ Brief manufacturer's biofertilizer production process
 - ▶ Sample of biological fertilizers

Biofertilizer Regulations: Label

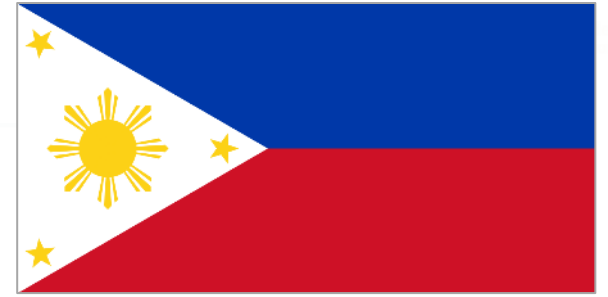


- ▶ Provide label in Thai attached to the container or package of the biological fertilizer
- ▶ The statement on the label shall consist of the following contents:
 - a) Trademark or any mark displayed on the container or package;
 - b) The word “biological fertilizer”;
 - c) Guaranteed quantity of microorganisms;
 - d) Method of storage;
 - e) Net weight or size of biological fertilizer package in metric measurement system;
 - f) Filler of biological fertilizer;
 - g) Name of manufacturer and location of the office and place of manufacturing biological fertilizer for trade;
 - h) Date of manufacturing and date of expiration;
 - i) Other statements stipulated by the Minister to be shown on the label

Biofertilizer Regulations: Registration Process



Biofertilizer Regulations – THE PHILIPPINES



- **Main Regulation:** Presidential Decree No. 1144 (PD.1144)
- **Authority:** the Fertilizer and Pesticide Authority (FPA), Department of Agriculture (DOA)
- **Website:** <https://fpa.da.gov.ph/NW/index.php>
- **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.)
- **Registration submission:** Online
- **Data requirements:** Available in English
- **Local efficacy trials:** required
- **Overall registration timeframe:** 12 - 18 months
- **Registration validity:** 3 years

Biofertilizer Regulations



- In the Philippines, fertilizer products and raw materials falling under specific grades, types, and classifications (as per the Philippine Standard) are required to undergo registration with the FPA:

1. Inorganic Fertilizer

1. Traditional
2. New Grades
3. Specialty Grades
4. Controlled Release

2. Biostimulants

1. Humic substances —
 - Humic acid
 - Fulvic acid
2. Protein hydrolysates
3. Seaweed extracts
4. Chitosan and other biopolymers
5. Inorganic compounds
6. Microbial Inoculants/ Biological fertilizer —
 - Beneficial bacteria
 - Beneficial fungi

Biofertilizer Regulations




- ▶ Microbial Inoculants/ Biological Fertilizers are biologically active products containing an optimal population of one or a combination of active strains of bacteria, actinomycetes, algae, and fungi.

These microorganisms play a crucial role in various biological activities, including nitrogen fixation, the decomposition of organic residues, and the solubilization of essential nutrients such as phosphorus from the soil.

- ▶ FPA mandates registrants to secure clearance from the committee before biofertilizer product registration.
- ▶ **Experimental Use Permit (EUP)** must be filed by the applicant and approved by FPA before any bio-efficacy field test is conducted to generate data required for registration.
- ▶ All experiments must be conducted by FPA-accredited researchers who will be chosen by the applicant within their financial capability.

Biofertilizers: Experimental Use Permit (EUP) for Bio-efficacy trial



	Document title	Form no.	FPA-FRD-F09
	APPLICATION FOR EXPERIMENTAL USE PERMIT FOR FERTILIZER EFFICACY TRIAL	Revision no.	04
		Date	01.19.2022
		Page	1 of 1

Reminder: Please fill out the form completely and legibly

Contact person :		(to be filled out by FRD)
Designation :		
Contact number :		
E-mail address :		

1. PRODUCT INFORMATION	
a. Brand/Trade Name :	
b. Purpose :	<input type="checkbox"/> Initial trial <input type="checkbox"/> Second trial <input type="checkbox"/> Label expansion
c. Guaranteed Composition :	
(Please indicate the proper units e.g. %w/w, %w/v)	
d. Product Classification	
<input type="checkbox"/> New Inorganic	<input type="checkbox"/> Specialty <input type="checkbox"/> Plant Growth Regulator <input type="checkbox"/> Controlled Release
<input type="checkbox"/> Biostimulant	<input type="checkbox"/> Soil Conditioner <input type="checkbox"/> Biofertilizer <input type="checkbox"/> Decomposer
e. Production Type :	<input type="checkbox"/> Local <input type="checkbox"/> Imported

2. COMPANY INFORMATION	
a. Company name :	
b. Company address :	
c. TIN :	
d. Contact no. :	

3. BIOEFFICACY TRIAL INFORMATION	
a. Test crop :	
b. Total amount of product needed :	
c. Inclusive dates for the duration of trial :	
d. Proposed treatment and method of application :	
e. Location of Trial (specify Sitio and attach vicinity map) :	
f. Name of Researcher/Accreditation No. :	
g. Address of Researcher/Research institute/ Affiliation :	

CONSENT TO PROCESS AND SHARE DATA	
In compliance with the Data Privacy Act, I hereby give my consent to the Fertilizer and Pesticide Authority to share my contact details to the public for whatever legal purpose it may serve.	
<div style="text-align: right;">_____ Signature over Printed Name of the Contact Person</div>	

- Conduct in 2 seasons or 2 locations
- One bio-efficacy data is required for provisional registration while 2 bio-efficacy data for the same crop conducted in 2 different locations or 2 seasons are required for full product registration.

Biofertilizer Regulations: General Data Requirements



Administrative Requirements:

- ▶ Duly notarized application form with documentary stamp;
- ▶ Product Information
- ▶ Company Information
- ▶ List of raw materials used in the production of the product
- ▶ Target crops (refers to crops to which the fertilizers are to be applied)
- ▶ FPA-accredited researcher (the name of the FPA-accredited researcher who conducts the efficacy test)

Technical Requirements:

- ▶ Production Process
- ▶ Passed Confirmatory Analysis done by FPA-recognized laboratory.
*Test reports are valid as confirmatory analysis within 1 year.
- ▶ Sample of the Product
- ▶ Methods of analysis
- ▶ Test of guaranteed composition
- ▶ Test of total coliform (for liquid samples, fertilizers with naturally available raw materials and microbial inoculants)
- ▶ ~~Test of heavy metals (only for some inorganic fertilizers, fortified organic fertilizers and soil conditioners)~~
- ▶ Certificate of Analysis (COA) from the manufacturer (for imported fertilizers)
- ▶ Safety Data Sheet or MSDS (for imported fertilizers)
- ▶ Draft Label

*: In cases where no FPA-recognized laboratory can perform the analysis, this can be done by other independent laboratories in the country or from abroad.

Biofertilizer Regulations: General Data Requirements



- ▶ The list of requirements is the same as non-traditional inorganic fertilizer, but no test for heavy metals is required.
- ▶ For biological fertilizers, the guaranteed analysis of the inoculants must conform to the minimum count in the PNS/BAFS 183:2016 standard.
- ▶ A certificate of analysis of a population of one or a combination of active strains of bacteria, actinomycetes, algae and fungi by a recognized laboratory together with 2 samples of 200 g or 200 mL taken from the same batch should be submitted.
- ▶ One sample will be analyzed for confirmation at any FPA-recognized laboratory.
- ▶ The remaining sample will be retained at FPA for analysis a month before the expiry date claimed by the manufacturer.
- ▶ The expiry date should be indicated on the label. Test for pathogens will be done too.
- ▶ **Data requirements** for living organisms producing biofertilizers **will be determined case by case** through the National Committee on Biosafety of the Philippines (NCBP) and FPA consultation.

Biofertilizer Regulations: Label content



Front

BRAND NAME
(with logo)

Guaranteed Analysis:

Nitrogen (N) %: _____

Phosphorus (P₂O₅) %: _____

Potassium (K₂O) %: _____

Trace and secondary nutrients, if any:

FPA Registration No. _____

Target Crop/s:

Country of Origin: _____
(optional for locally manufactured products)

Name of Manufacturer (optional)

Name and address of Distributor

Back

BRAND NAME
(with logo *optional)

DIRECTION FOR USE

Batch number or Lot number (if applicable)

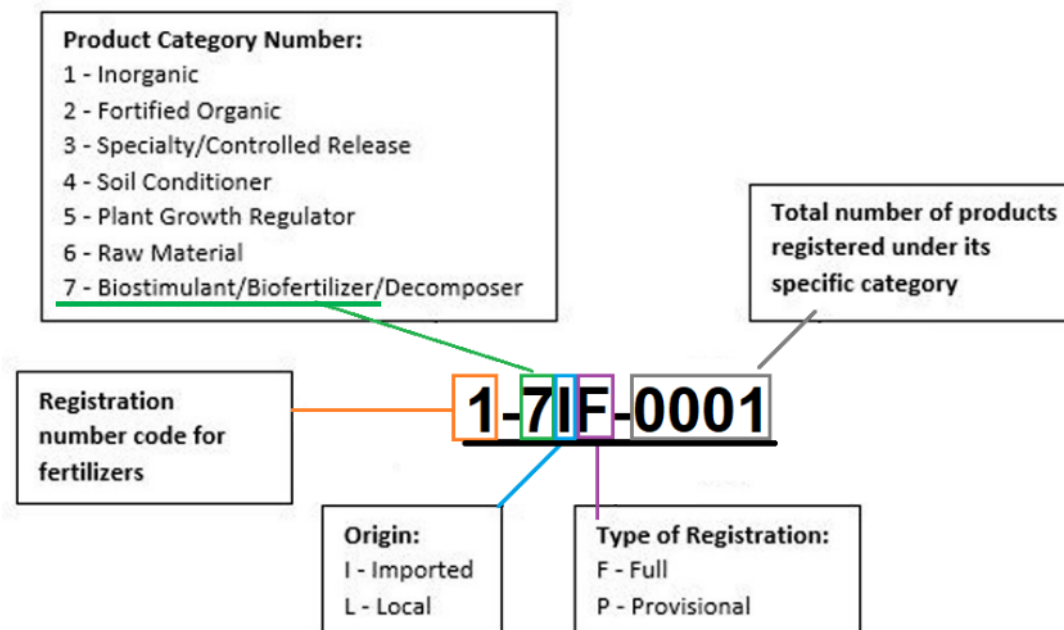
Date Manufactured:

Expiry Date:

Net Content: ____ kg


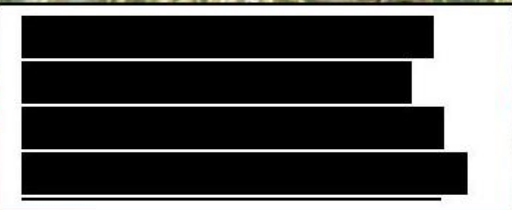
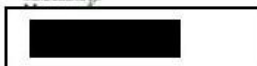


Biofertilizer Regulations: Label content

- Each registered product has its own unique alphanumeric registration number.
- Since it is unique to a product, then it is the most vital information that the public can use to identify and trace its registration in the FPA.
- The format for an **FPA fertilizer product registration** along with its meaning is given as follows:



Biofertilizer Regulations: Label Example



Product Name		
		
		
Guaranteed Analysis: Each gram contains 100 spores of Vesicular Arbuscular Mycorrhizae (VAM)		
<p>Registered with the Fertilizer & Pesticide Authority Pursuant to P.D. 1144 FPA Registration No: 1-71F-0004</p> <p>Manufactured by: </p> <p>Imported and Distributed by: </p> <p>Net Weight: 125 grams</p> <p></p>		
KEEP OUT OF REACH OF CHILDREN		
PRODUCT INFORMATION: MycoApply® EndoSmart™ contains 100 spores per gram of Vesicular Arbuscular Mycorrhizae (VAM). Beneficial endomycorrhizal fungi form symbiotic relationships with plants, it colonizes plant roots and expands into the surrounding soil. Application of this product reduces drought stress, water inputs, transplanting shock and nutrient loss. MycoApply® EndoSmart™ promotes rooting and nutrient uptake thereby increases yields.		
DIRECTIONS FOR FIELD USES: MycoApply® EndoSmart™ is best applied at the early development stages of the crop to enable the Mycorrhizal species spores to colonize the root system early on and maximize the product benefits.		
CROP / USE	APPLICATION RATE (g/Ha)	METHOD AND TIMING OF APPLICATION
DIRECT-SEEDED RICE (Pre-Germinated)	125-250	Prepare appropriate amount of water enough to wet pre-germinated rice seeds to be used and dissolve in it the required amount of MycoApply® EndoSmart™. Apply the MycoApply® EndoSmart™ solution to pre-germinated rice seeds before sowing. Ensure that all seeds have been coated with MycoApply® EndoSmart™ but not to the point of run-off.
TRANSPLANTED RICE		<ul style="list-style-type: none">• Wet bed Follow procedure above before seed sowing.• Dapog Dissolve the required amount of MycoApply® EndoSmart™ in water. Drench 2-3 days before transplanting.
FRUITING VEGETABLES (Eggplant, Tomato, Ampalaya, Pepper, Okra, Cucumber, Squash, Upo, Patola and other similar crops)	125-250	Nursery/Seedling Tray: Uniformly mix 125-250 grams of MycoApply® EndoSmart™ to the potting medium sufficient for the number of seedlings that will be planted in one (1) hectare of land. Fill the potting medium to the seedling trays and seed as practiced. Field Application: Dissolve 125-250 grams MycoApply® EndoSmart™ in 200 liters of water and apply directly to the root zone of the newly transplanted seedlings.
SUGARCANE (including pineapple, tobacco and other annual/biennial industrial crops)	125-250	Dissolve MycoApply® EndoSmart™ in minimum of 200L water. For sugarcane, drench directly to the cane line prior to covering with soil. For pineapple, use at least 250g/Ha. Dip the base of the panting materials to the MycoApply® EndoSmart™ solution and/or drench the solution along the plant line.
STORAGE & DISPOSAL: Keep containers tightly closed when not in use. Store in a dry area below 60 degrees Celcius. Do not reuse or refill empty container. Dispose of containers in accordance with local regulations.		
PRECAUTION: Avoid breathing dust. Use outdoors or in a well-ventilated area. If inhaled, remove person to fresh air and keep comfortable for breathing. In case of eye contact, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		
PROHIBITION / WARRANTY STATEMENT: "It is a violation of FPA rules and regulations to use this product in a manner inconsistent with its label. No warranty of any kind, expressed or implied, is made concerning the use of this product. User assumes all risks and liabilities from handling, use or application."		
Formulation date: Batch no:		

Biofertilizer Regulations – VIETNAM



► Main Regulations:

1. Decree **130/2022/ND-CP** amending Decree 84/2019/ND-CP on fertilizer management
2. Decree **94/2019/ND-CP** on guidelines for some Articles of the Law on Crop Production 31/2018/QH14 regarding plant varieties and crop cultivation.

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

► **Website:** <https://www.ppd.gov.vn/quan-ly-phan-bon.html>

► **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.), **or representative offices** or branches of foreign companies with business licenses to carry out fertilizer business operations in Vietnam.

► **Registration submission:** Submit dossiers in person, by post, or online

► **Data requirements:** Available in Vietnamese

► **Overall registration timeframe:** 6 - 18 months

► **Registration validity:** 5 years

Biofertilizer Regulations



- ▶ Fertilizers can be classified into the following 3 categories based on raw materials and production process;
 1. **Chemical fertilizers** (or inorganic fertilizers).
 2. **Organic fertilizers**, produced mainly from natural organic substances (excluding synthetic organic substances) treated through physical or biological processes.
 - ➡ 3. **Biological fertilizers**, produced through biological processes or natural fertilizers containing one or more biological substances, such as humic acids, fulvic acids, amino acids, vitamins, or other biological substances.

- ▶ Regarding the different uses, fertilizers can be classified into 2 types:
 1. **Foliar fertilizer** is a fertilizer belonging to one of the groups of organic, inorganic and biological fertilizers used to provide nutrients for plants through stems and leaves.
 2. **Root fertilizer** is a fertilizer belonging to one of the groups of organic, inorganic, biological fertilizers used to provide nutrients for plants through the root system or have the effect of soil improvement.

Biofertilizer Regulations



- ▶ Fertilizers must be tested (local trials) before being recognized for circulation (aka fertilizer registration) in Vietnam
- ▶ Local efficacy trials: required except the following types;
 1. Organic fertilizers (using for root), meeting quality indicators defined in national technical regulations.
 2. Single fertilizers and complex fertilizers (using for root), ingredients must comply with quality in national technical regulations as follows;
 - Single fertilizers are fertilizers containing only one macronutrient (N, P, or K);
 - Complex fertilizers are fertilizers which contain at least 2 macronutrients (N, P, or K) connected by chemical bonds
 3. Fertilizers that are recognized by the competent authority as technical progress
- ▶ These categories are **exempt** from the mandatory trial testing requirements.
- ▶ **All other types of fertilizers** will be tested on both large and small scales. Once the small-scale testing is completed, we can move on to the large-scale testing.
- ▶ The number of trials for both scales varies depending on the crop types, such as Perennial Plants and Annual Plants.

Biofertilizer Regulations - importing into Vietnam



- ▶ Before importing fertilizer, it is necessary to complete procedures for applying for **import permits for fertilizer testing**.
- ▶ Then obtain official approval through a "**Decision on recognition**" (fertilizer registration).
- ▶ This decision authorizes the circulation of the imported fertilizer within Vietnam.
- ▶ It indicates that the product complies with specific criteria or standards set by the authorities.
- ▶ Imported fertilizer must adhere to the National Technical Standard for fertilizer quality.
- ▶ Ensures that composition, properties, and overall quality meet the specified standards.

Biofertilizer Regulations - Import Process



► Step 1: Obtain Import permits for fertilizer testing (trials) ← exempt for some fertilizers

- Prepare technical declaration, manufacturer's letter, and certificate of free sale.
- Submit documents to the Plant Protection Department (PPD).
- If no additional requirements, an import license for fertilizer trial is granted in 7 working days.

► Step 2: Conduct Trial Process for Non-Exempt Fertilizers

- Sign a fertilizer trial contract with an eligible organization in Vietnam.
- Trial content based on product indications, instructions, and national technical standards.

Biofertilizer Regulations - Import Process



► Step 3: Apply for Decision on Recognition of Fertilizer Circulation

- Submit application to PPD with required documents.
- Include general information, certified manufacturer details, trial results, and certificate of free sale.
- Decision on recognition issued within 3 months if no amendments are needed, valid for 5 years.

► Step 4: Carry out Import Activities

- Conduct State Inspection on Imported Goods Quality, using designated testing organizations.
- Prepare customs clearance documents as per regulations, including State inspection results and Power of Attorney if applicable.

Biofertilizer Regulations - Import Process



► **Conclusion:** The process involves

1.

- Obtaining an import permits, 30 - 40 working days

2.

- Conducting fertilizer testing (trials) for non-exempt fertilizers (3 months on vegetables or 1 year on fruit trees)

3.

- Applying for recognition of circulation (fertilizer registration), 4 months approx.

4.

- Carrying out import process after decision on recognition (meeting quality standards and inspections).

Biofertilizer Regulations – Data Requirements for Recognition of Circulation (Step 3)

- ▶ An application form
- ▶ General information on fertilizers certified by the manufacturer
- ▶ Type of fertilizer
- ▶ Fertilizer name
- ▶ Fertilizer form
- ▶ User instruction
- ▶ Expiry date
- ▶ Safety warnings
- ▶ Quality criteria
- ▶ Content of restricted elements of the fertilizer enclosed with the test result sheet
- ▶ The original report on the results of the fertilizer trial
- ▶ Certificate of free sale issued by the origin country (for fertilizer falls into the exempt categories)
- ▶ Import contract

Biofertilizer Regulations – Import Process After Decision on Recognition (Step 4)

1.

State Inspection Registration:

- After obtaining the decision on recognition of circulation, initiate the **Registration of State Inspection on the Quality of Imported Goods**.
- Data requirements: Article 21 of Decree No. 84/2019/ND-CP

2.

Testing Organization Selection:

- Choose a **testing** organization designated by the PPD for fertilizer quality inspection.

3.

State Inspection Process:

- Complete the **state inspection** of the imported goods.

4.

Customs Clearance Documentation:

- **Prepare customs clearance documents**, including general import documents as per regulations.

5.

Notice of State Inspection Results:

- Include the **Notice of State inspection results** in the documentation.

6.

Power of Attorney (If Applicable):

- Provide a Power of Attorney if authorization is given to other organizations or individuals for the import process.

Biofertilizer Regulations – Labeling



► Fertilizers for sale must be labeled (in Vietnamese language) with the following:

1. Fertilizer name;
2. Name and address of the responsible entity;
3. Origin of the goods;
4. Fertilizer type and code;
5. Date of manufacture;
6. Expiration date;
7. Ingredients and quantities;
8. Warnings;
9. Instructions for use and storage.

- This must match the information in the decision on the recognition of fertilizer for circulation.
- If the label of an imported product insufficiently represents this information in Vietnamese, a secondary label meeting the requirements must be provided.

Biofertilizer Regulations – INDONESIA



- ▶ **Main Regulation:** Regulation Number 01/ 2019 concerning Registration of Organic Fertilizers, Biological Fertilizers, and Soil Improvement
- ▶ **Authority:** The Centre of Plant Variety Protection and Agricultural Permit- PPVTPP
- ▶ **Website:**
- ▶ **Registration holder:** Local entity only (local manufacturer, local importer, etc.)
- ▶ **Data requirements:** Available in the Indonesian language
- ▶ **Local efficacy trials:** required
- ▶ **Overall registration timeframe:** 1 year
- ▶ **Registration validity:** 5 years

Biofertilizer Regulations – Definitions



- ▶ **Biological Fertilizer** is an active biological product consisting of microbes that have been identified to at least genus level and function to facilitate the provision of nutrients directly or indirectly, break down organic matter, and increase fertilization efficiency, fertility and soil health.
- ▶ **Organic fertilizer** is fertilizer originating from dead plants, animal manure and/or animal parts and/or other organic wastes which have been through engineering processes, in the form of solid or liquid; enriched with mineral and/or microbial materials; and useful for increasing nutrient content and soil organic matter and improving physical, chemical and biological properties of the soil. The formula is the composition of organic materials and minerals.

Biofertilizer Regulations – Testing (before Registration Process)



► There are 2 types of testing that are mandatory before registration:

1. Quality testing:

- must adhere to minimum technical requirements outlined in the relevant MOA decree 01/2019
- Tests must be conducted by an approved testing agency

2. Efficacy testing: efficacy testing can be conducted simultaneously with or after quality testing.

► Online Application:

- Businesses can apply online using the MOA's dedicated submission system.

► Validity of Testing Certificates and Reports:

- Certificates and testing reports (quality or effectiveness) remain valid for 12 months from the date of issuance.

► Mandatory for Registration:

- Certificates and testing reports are essential requirements for the fertilizer registration process.

Biofertilizer Regulations – Registration Process



- ▶ After successful completion of testing, companies can apply for registration of organic fertilizers, biological fertilizers, and soil enhancers through the MOA's online business licensing submission system.
- ▶ Applications should include the following materials:
 1. Detailed fertilizer description;
 2. Proposed label (in Indonesian) disclosing required information;
 3. Certificate of mark registration or authorized mark certificate;
 4. Effectiveness test report;
 5. Quality certificate or testing report;
 6. Stamped statement that the required documents are complete and correct according to applicable regulations.
- ▶ For registration of organic and biological fertilizer **from abroad**, the application should also include **a power of attorney from the owner of the formula.**

Biofertilizer Regulations – Registration Process



- ▶ Approved applications are submitted to the Director General of the Agricultural Infrastructure and Facilities Department for technical verification and issuance of a registration number, which has a validity of 5 years.
- ▶ Applications for re-registration for an additional 5 years can be submitted no later than 30 working days before the 5-year registration period ends.
- ▶ Under MOA Regulation 1/2019, registration holders must do the following:
 1. Guarantee the continued quality of the registered organic or biological fertilizer or soil enhancer;
 2. Include all the required information on the packaging label;
 3. Report production or imports every 6 months; and
 4. Report any change of address during the registration period.

Biofertilizer Regulations – Transfer of Registration



- ▶ Transfers of registration can only take place after 3 years from the issuance of the registration number and must be proven by a notarized deed of transfer.
- ▶ Registration number holders must report transfers to the Director General of the Agricultural Infrastructure and Facilities Department through the head of the Center for Plant Variety Protection and Licensing (PVTTP).

Biofertilizer Regulations – Labeling



Label must be in Indonesia language and shall consist of the following information;

- ▶ Registration number
- ▶ Name of Registration holder
- ▶ Product name
- ▶ Registered trademark
- ▶ Type of fertilizer
- ▶ Composition
- ▶ Net weight
- ▶ Distribution permit period
- ▶ Production code
- ▶ Expiration date
- ▶ Name and address of manufacturer (for domestic production)
- ▶ Name and address of the overseas manufacturer and importer
- ▶ Country of manufacture
- ▶ Use instructions



BIOAG WORLD
ACADEMY



Biostimulants and Soil Amendment Regulations of Thailand

Biostimulants and Soil Amendment Regulations - THAILAND



- ▶ **Main regulations:** The Consumer Protection Act B.E. 2522 and the amendment (No.2) B.E. 2541
- ▶ **Authority:** the Office of the Consumer Protection Board (OCPB)
- ▶ **Definitions:**
 1. “**Biostimulants**” means a product that has properties, benefits, and usage purposes to enhance plant growth efficiency including chitosan, seaweed extracts, amino acids for plants and other substances similar to those mentioned above that are **not classified as fertilizers** according to the Fertilizer Act, **and hazardous substances** according to the Hazardous Substances Act of Thailand.

Biostimulants and Soil Amendment Regulations - THAILAND



► Definitions:

2. “**Soil amendment**” means a product with properties, benefits, and purposes of use for soil improvement and nourishment that are **not classified as fertilizers** according to the Fertilizer Act, **and hazardous substances** according to the Hazardous Substances Act of Thailand.

► Registration of Biostimulants/ Soil amendment: **Not** required

Biostimulants and Soil Amendment Regulations - THAILAND



Label Requirements:

1. Product Identification: Name or type of the product for clear understanding.
2. Manufacturer Information: Name or registered trademarks of the Thai manufacturer if producing for the local market.
3. Importer Information: Name or registered trademarks of the importer (if bringing the product into the country)
4. Chemical Identification: Chemical or common name (if applicable).
5. For biostimulants, specify properties, benefits, and usage purposes enhancing plant growth efficiency.
6. For soil amendments, specify properties, benefits, and purposes for soil improvement and nourishment.
7. Concentration (For Liquid Products): Specify the concentration of the active substance (w/v) for liquid products.
8. Application Details: Include application rate, usage method
9. Storage Instructions: Clearly state the recommended storage method.
10. Safety Information: Include poisoning symptoms, and preliminary antidote.

Biostimulants and Soil Amendment Regulations - THAILAND



Label Requirements:

11. Mandatory Thai Text
12. Manufacturing Details: Specify the manufacturing country.
13. Importer's Address: Include the address of the importer.
14. Product Size/Quantity: Specify the size, dimension, quantity, volume, or weight of the product.
15. Usage Instructions: Clearly outline use instructions.
16. Recommendations and Storage Instructions: Provide use and storage recommendations.
17. Safety Information (Warnings): Include warnings, contraindications, or cautions, ensuring visibility and legibility.
18. Manufacturing Date: Specify the manufacturing date or, if not feasible, the week and year of manufacture.
19. Expiration/Best Before Date: Specify the expiration date or best before date if applicable.
20. Selling Price: Display the selling price in Thai baht; alternatives include specifying prices in other currencies or indicating "price indicated at the point of sale" (in Thai language) if the specific price is not provided.

Biostimulants - THAILAND



Soil Amendment - THAILAND

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Biostimulants and Soil Amendment Regulations - THAILAND



Key points:

Must specify the following Thai text on the label:

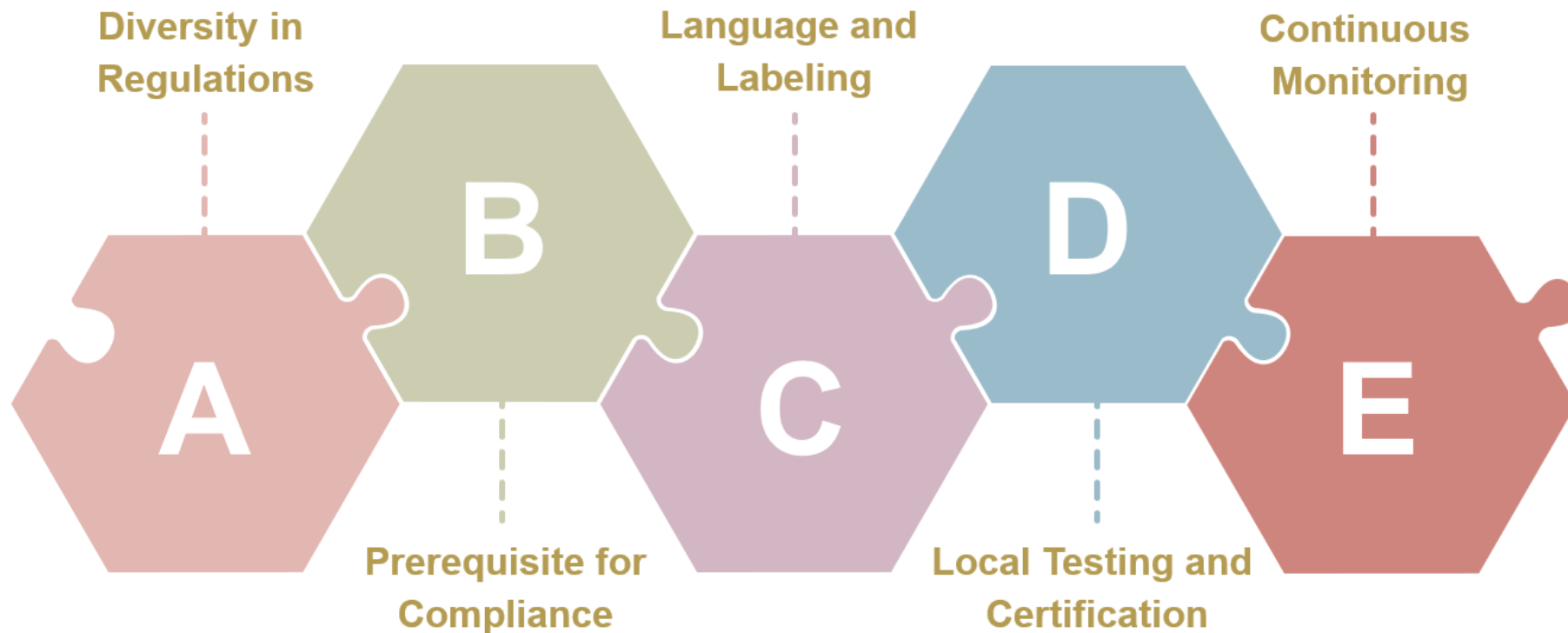
ผลิตภัณฑ์นี้ไม่จัดเป็นปุ๋ยตามกฎหมายว่าด้วยปุ๋ยและวัตถุอันตราย
ตามกฎหมายว่าด้วยวัตถุอันตรายทางการเกษตรหรือสารป้องกันกำจัดศัตรูพืช

(meaning, “This product is not classified as fertilizer under the Fertilizer Act, and hazardous substances according to the Hazardous Substances Act or pesticides”).

- ▶ The text height of this Thai sentence must **not be less than 5 millimeters**.
- ▶ The text color **must contrast** with the background color;

Take Home Messages

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Dr. Piyatida (Tung) Pukclai

Email: ppukclai@knoell.com

Tel: +66 52 080451, +66 88 2514601



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