



Biocontrol Legislation in some selected Asia countries



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Regulatory diversity across Southeast Asia

Country	Biopesticides	Biofertilizers	Biostimulants	Soil Amendments
China	Regulations on the Management of Pesticides (State Council Decree 677)	MOA Order 32 [2000] (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	Law No. 41/2013/QH13 Decree No. 108/2017/ND-CP Decision 16/2004/BNN-BVTV Decision No. 73/2005/QD-BNN	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

- ✓ 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

- In Asia, biopesticides are still regulated by the same systems designed originally for conventional pesticides
- 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



- **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 for biopesticides:** Available in Thai and English
- **Local efficacy trials:** required
- **Overall registration timeframe:** 2 – 2.5 years
- **Evaluation process:** same as conventional pesticides but for specific biological pesticides, some tox data can be waived
- **Registration validity:** 6 years

- **Biopesticides:**

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

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

- This is significantly reduced process on the registration approval of these products
- Local bio-efficacy trials are required for biopesticides manufactured overseas

- **Biostimulants & soil amendments:**

- Registration is not required for biostimulants & soil amendments
- These products are label-controlled products
- Producing, importing, and selling the products in Thailand shall comply with the Consumer Protection Act B.E. 2522 and the amendment (No.2) B.E. 2541. The basic elements as well as information on labels required are to be consistent with the said Notification.

- **Authority:** the Pesticide Board (**PB**), Department of Agriculture (DOA)
- **Website:** <http://www.doa.gov.my/>
- **Online submission:** Yes
- **Regulation:** Pesticide Act 1974 (under GP 7/2016)
- **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.)
- **Data requirements for biopesticides:** Available in Malay and English
- **Local efficacy trials:**
 - Required for product use on local major crops (rice, oil palm, cocoa, black pepper, and rubber).
 - For other crops, results obtained from trials conducted in other countries under similar climatic regimes and cultural practices may be considered. ← shall be discussed with the PB in all cases.
- **Overall registration timeframe:** 2 – 3 years
- **Evaluation process:** same as conventional pesticides but for biological pesticides, some tox data can be waived
- **Registration validity:** 5 years

- **Biopesticides:**

- **Microbials:**

- Toxicity data can be exempted
- Residue data shall be submitted if microbes are suspected to produce any residue or metabolites of concern on food or feed items. Substances used for formulation must not produce residues of concern on food or feed items. Reports from any reliable and reputable publication journal is accepted.

- **Plant extract:**

- Toxicity data on acute oral and acute dermal are required for formulated product,
- Residue studies are not required for plant extract unless if the evaluation found any significant issue on toxicology, environment or non-target species.

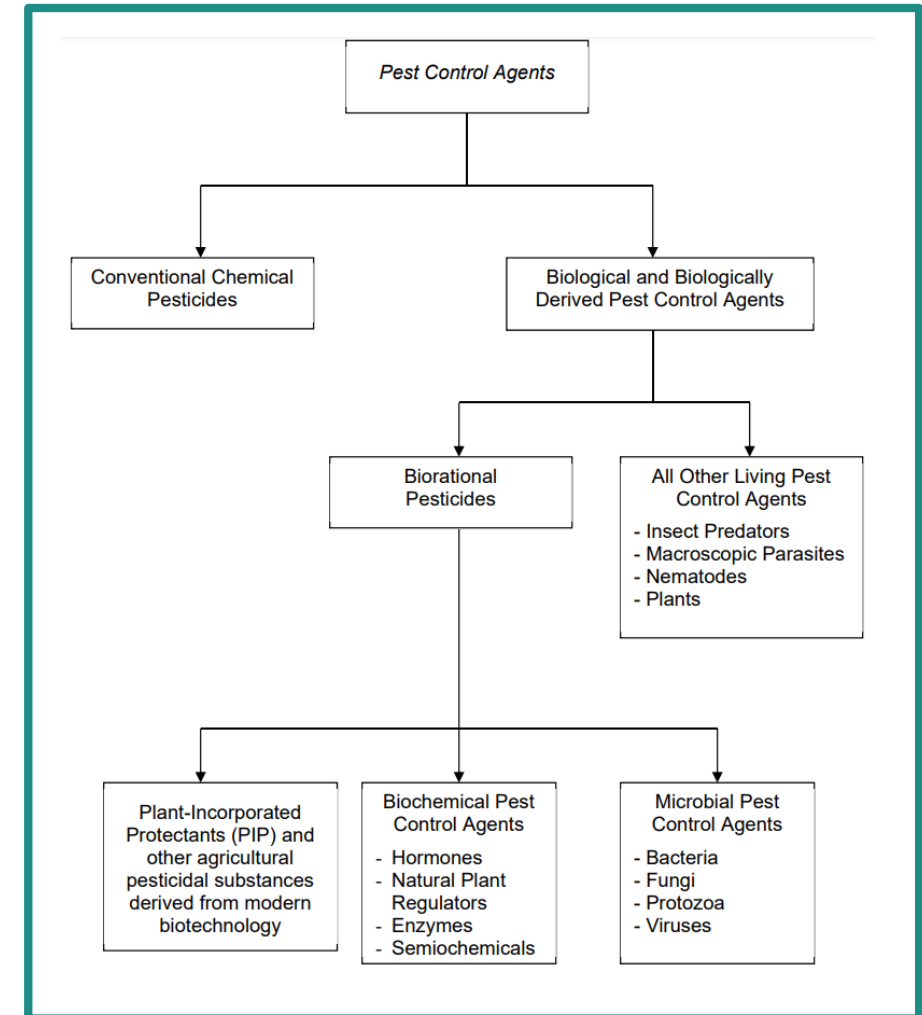
- **Authority:** the Plant Protection Department (**PPD**), Ministry of Agriculture and Rural Development (MARD)
- **Website:** <https://www.mard.gov.vn/en/Pages/default.aspx>
- **Online submission:** Yes
- **Regulation:** Circular No 21/2015/TT-BNNPTNT
- **Registration holder:** **Local entity only** (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 for biopesticides:** Available in Vietnamese language
- **Local efficacy trials:** required
- **Overall registration timeframe:** 2 – 3 years
- **Evaluation process:** same as conventional pesticides but reduce the number of bio-efficacy trails, evaluation process is shorter (**Fast-tracking**)
- **Registration validity:** 5 years

- Biopesticides are encouraged to register on all crops
- Reduce the number of biological efficacy testing, registration technical documents
- Registration fee are much lower and implementation time duration is much shorter than chemical pesticides
- According to regulations on transporting dangerous goods, biopesticides are exempted from procedures for licensing to transport pesticides
- Biopesticide have been registered mainly in the following 3 main groups:
 - Microbiological pesticides
 - Plant extracts
 - Biochemicals
- Registration procedures for pesticides are easier and simpler than registration for chemical pesticides, there are still a few complicated registration approval procedures that hinder the rapid registration of biopesticides.

- **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 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:** 6 years

Philippines – What we should know

- Have a **Fast-track registration** for less hazardous, less persistent, environmentally- friendly, target and Integrated Pest Management (IPM) compatible pesticide products
- Products not having a direct impact on public health may have their efficacy data requirements waived (case-by-case).
- Toxicity: The testing for possible effects on humans & domestic animals is performed in a tier sequence.
- Testing are acute toxicity/ infectivity studies, cellular immune response studies, irritation, hypersensitivity, virulence enhancement, tissue culture, teratogenicity, mutagenicity, sub-chronic, and chronic studies.
- **Biostimulants & soil amendments:** Must be registered (guideline is available)



- **Authority:** the Centre of Plant Variety Protection and Agricultural Permit- PPVTPP
- **Website:** <https://perizinan.pertanian.go.id/portal-simpel/public/>
- **Online submission:** Yes
- **Regulation:** Regulation Number 43/2019 (Peraturan Menteri Pertanian Nomor 43 Tahun 2019)
- **Registration holder:** **Local entity only** (local manufacturer, local importer, etc.)
- **Data requirements for biopesticides:** Available in Bahasa Indonesia (Indonesia language)
- **Local efficacy trials:** required
- **Overall registration timeframe:** 2 – 3 years
- **Evaluation process:** same as conventional pesticides but for biological pesticides, some tox data can be waived

- Acute inhalation, chronic and sub-chronic toxicity are not required for biopesticides
- Environment toxicity is not required for biopesticides
- Less data requirements for biopesticides
- **Biostimulants and soil amendments:** Must be registered under the Minister of Agriculture Regulation No. 01 of 2019

- There is **no harmonization** for the pesticides or biopesticides registration in Asia
- The differences in regulatory landscapes across the region have made it challenging for companies to seek registration
- Biopesticides are regulated by the same systems designed originally for conventional pesticides
- In **April 2023**, there was a Regional Regulatory Workshop on Biopesticide and Pesticide Maximum Residue Levels in Bangkok, Thailand
- Regulatory officers from several South Asia and Southeast Asia countries discussed on the development and harmonization of biopesticide and pesticide regulations
- The status of biopesticide regulatory development in the participating countries has been assessed and presented in the workshop in line with the East Asia Biopesticide Guidelines
- Regulatory discussions were linked with their national Integrated Pest Management (IPM) programs to ensure alignment and synergies
- **Current status:**
 - This is a high-level discussion, **still no harmonization**
 - National regulatory officers shall follow the common regional regulatory standards that can increase approval rate of biopesticides

Global Regulatory Compliance in Crop Protection & Biocontrol

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