Overview of Pesticide Registration Regulations in Several Southeast Asia countries

Piyatida (Tung) Pukclai, Ph.D.
knoell companies / locations
Outline

➢ Introduction
➢ Pesticide registration regulations in:
   1. Thailand
   2. Malaysia
   3. Philippines
   4. Indonesia
   5. Vietnam
➢ Regulatory Hurdles
➢ Take home message
## Summary of pesticide registration regulations

<table>
<thead>
<tr>
<th>Country</th>
<th>Main Regulation</th>
<th>Registration Regulations</th>
</tr>
</thead>
</table>
| Thailand  | Hazardous Substance Act                | • Pesticides are regulated under the Hazardous Substance Act.  
• The requirements adopted from FAO Guidelines for Pesticide Registration.  
• Information relating to toxicity of technical grade material and finished product must be generated by the GLP Certified Laboratory according to OECD standard. |
| Indonesia | No. 39/Permentan/SR.33 0/7/2015         | • Different types of usage of pesticides include crop protection, household, forestry, fisheries, etc.  
• Permentan 39/2015 is currently in effect as from January 14th, 2016.                                                                              |
| Malaysia  | Pesticide act 1974                     | • For commodity products, the efficacy data can be obtained from the published paper or generated by the company if the trials are conducted under the similar climate as Malaysia and according to the quality and standards acceptable by the Pesticides Board.  
• (PB) published the new circular on adding 302 new active ingredients to Malaysia First Schedule under Pesticide Act 1974 |
| Philippines| Presidential Decree No. 1144          | • The FPA issues full (3 years) and conditional (1 year) registrations.  
• Requirements are quite complicated and demanding, but waivers are possible.                                                                            |
| Vietnam   | Circular No 21/2015/TT-BNNPTNT         | • The requirements applied from the FAO Guidance for Pesticide Regulatory Management.  
• The toxicity of the formulation by standard laboratory GLP or ISO 17025: 2005 implementation, test reports accompanying implementation confirmation.  
• If product is not registered in VN, additional registration certificates and use that product in foreign countries are required. |
## Summary of pesticide registration regulations

<table>
<thead>
<tr>
<th>Country</th>
<th>Main Regulation</th>
<th>Registration Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singapore</td>
<td>The Control of Plants Act (Registration of Pesticides) Rules.</td>
<td>• The Agri-Food and Veterinary Authority of Singapore (AVA) regulates agricultural pesticides used in the commercial cultivation of plants in Singapore under the Control of Plants Act and the Control of Plants (Registration of Pesticides) Rules.</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Pesticides Law</td>
<td>• Law on pesticide registration was enacted in May 1990 (and there is no BCA-specific regulation).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Currently there is only import of pesticides.</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>Regulation on Control of Pesticides in Lao PDR No. 2860/MAF</td>
<td>• Registration of products is done through the DOA in Vientiane.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No characterization and testing is done locally; if necessary, this is conducted abroad following FAO standards.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Chemical substances or pesticides chemicals which are classified should refer to The WHO Recommended Classification of Pesticides by Hazard and Guideline to Classification.</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Law on the Management of Pesticides and Fertilizers 2012</td>
<td>• The Law on the management of pesticides and fertilizers was promulgated in early February 2012.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Efficacy test of pesticides shall be conducted at the agricultural experiment station of the Ministry of Agriculture.</td>
</tr>
<tr>
<td>Brunei</td>
<td></td>
<td>• Application would be handled case by case; a MSDS is required.</td>
</tr>
</tbody>
</table>
The pesticide legislation & regulations in the ASEAN countries share the following basic concepts:

- Submission of application to register for pesticide use, with **required data** and other information, and a **draft of a label**
- Formation of a Technical Advisory Committee to assist in the **evaluation of scientific data** submitted for registration
- Appointment of inspectors or officers to monitor and enforce the law
- Control of imports and restrictions on availability
General data requirements for pesticide registration

- Impacts on human and animal
- Impacts on the environment
- Effects on non-target organisms
- Bio-efficacy data: registration systems start with requirements for local efficacy trials and expand to other locally generated data, such as residues in local crops
- Physical and chemical properties
- Product specifications
- MSDS
- Manufacturing process
- Stability test
- Method of Analysis
- Sample of the product
- Classification and labeling
- Registration status in other countries
- Letter of authorization from manufacturer/ sponsor giving permission to use data for registration
Typical registration steps for pesticides

- The pre-registration meeting
- Application form with instructions (Tiered approach to data requirements)
- Issue of acknowledgement
- Check list for completeness of documents
- Technical and scientific evaluation
- Risk assessment and risk management evaluation
- Preparation of summaries and conclusions
- Registration decision
- Publication and dissemination of registration decision
THAILAND

- **Authority:** Department of Agriculture, Pesticide registration division
- **Website:** [http://www.doa.go.th/ard/](http://www.doa.go.th/ard/)
- **Online submission:** [Link](http://www.doa.go.th/ard/)
- **Regulation:** Hazardous Substance Act B.E. 2535 (revised No. 3, B.E. 2551)

There are 2 types of registration;

- **Import registration:** registration to import finished product from overseas for sell or import the technical grade to Thailand for further formulate as finished product
- **Production registration:** registration of
  1. The pesticide which manufactured in Thailand
  2. Formulates the Technical grade to make the finished product
  3. Repack

Data requirements for pesticide registration (synthetic pesticide) are adopted from [FAO Guidelines](http://www.fao.org) for Pesticide Registration, information relating to toxicity of technical grade material and finished product must be generated by the GLP Certified Laboratory according to [OECD](https://www.oecd.org) standard

Data protection period: 10 years
There are 3 phases of registration:

**Phase 1**
Trials clearance – the step to review the efficacy protocol and assess acute toxicity.
Sample is allowed to be imported for efficacy test and quality analysis.

**Phase 2**
Provisional or Demonstration clearance – the step to demonstrate efficacy test in farmers' field and assess subchronic toxicity and effects to the ecosystem.

**Phase 3**
Full Registration – the step to make decision whether the pesticide is accepted for use or not.

The overall timeframe will be 2 – 3 years.
Data requirements

According to the announcement from DOA about the concentration of hazard substance formulation, **only the formulations and concentrations published on the royal gazette are accepted for the registration** under DOA.

To check the concentration lists in each formula of hazardous substances, applicant shall check from following link;


One formulation, one concentration!

However, if the substance or formulation is **not** published on the gazette, “manufacturer” needs to submit letter to request to add the substance/formulation to the list (1 – 2 years for this process)

Exemption: PGR, botanicals, Microbial
ค่าของมูลค่าผลิตหรือน้ำมันอ้อยวัตถุดิบ

วันที่ 21 ต.ค. 2561

นางสาว บุณี แซ่สินธุ์

นางสาว บุณี แซ่สินธุ์

เลขประจวบคีรีขันธง

0105560080372

นักวิจัยที่มีคุณสมบัติเป็นชุมชน

0105560080372

25 ว. 25 วัน ลิขสิทธิ์ ต้น/สาหร่าย คัดลงในแผนที่

รายละเอียด

และที่อยู่ของผู้ผลิต

0105560080372

0105560080372

โทรศัพท์ 022581763 โทรสาร 022581763 E-mail address

ขอให้ระบุเกี่ยวกับเรื่อง

KAGAWA K.K., 10 Roppongi, Minato-ku, Tokyo, 106-0032 Japan

1. วัตถุประสงค์ โดยรวม

2. สูตรปริมาณของวัตถุดิบในสกุลต้องมีสูตร

15% W/V SL

3. แหล่งวัตถุดิบที่ใช้ในการผลิตหลัก

Tung glufosinate

4. ข้อมูลเกี่ยวกับผลิตภัณฑ์

KAGAWA K.K., 10 Roppongi, Minato-ku, Tokyo, 106-0032 Japan

5. ข้อมูลผู้ผลิต บริษัท แซ่สินธุ์

6. ข้อมูลผู้ผลิต/ผู้ผลิตอื่น ๆ บริษัท สกุลแซ่สินธุ์

7. ข้อมูลของทำการผลิตไม่เกินจำนวน

10,000 ตัน

8. ข้อมูลผู้ผลิตและแหล่งผลิต

KAGAWA K.K., 10 Roppongi, Minato-ku, Tokyo, 106-0032 Japan

เลขทะเบียนเลขที่ 1 19 มิถุนายน 2561

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Registration certificate from FAMIC, Japan
Pesticide Registration Process in Thailand

**Applicant**
- Registration form
- Toxicological data
- Efficacy and residues data
- Experimental plan
- Sample for analysis

(10 Days)

Signed by DOA

(5 Days)

Process to get the Reg. No.

(3 Days)

Review/ Approval of the drafts by Subcommittee for pesticide registration

(1 month)

Preparation of the drafts

Agricultural Toxic Substances Division, DOA
Evaluation on;

<table>
<thead>
<tr>
<th>Tox. data</th>
<th>Efficacy</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan</td>
<td>Results</td>
<td></td>
</tr>
</tbody>
</table>

(10 Days)

(10 Days)

Data evaluation (By competent authorities)

<table>
<thead>
<tr>
<th>Tox. data</th>
<th>Efficacy</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan</td>
<td>Results</td>
<td></td>
</tr>
</tbody>
</table>

(1 Year + 3 months)

(3 months)
<table>
<thead>
<tr>
<th>ลำดับ</th>
<th>เลขทะเบียน</th>
<th>ชื่อสารเคมี</th>
<th>ชื่อสามัญ</th>
<th>สูตร</th>
<th>แหล่งผลิต</th>
<th>ผู้ผลิต (ประเทศไทย)</th>
<th>ผู้ผลิต (ประเทศจีน)</th>
<th>ประเภท</th>
<th>วันที่ออก</th>
<th>หมดอายุ</th>
<th>วันที่สกัด</th>
</tr>
</thead>
<tbody>
<tr>
<td>12733</td>
<td>69 - 2562</td>
<td>ไ_Instance</td>
<td>อะเมทริน (ametryn)</td>
<td>50 % W/V SC</td>
<td>Shandong Weifang Rainbow Chemical Co., Ltd. PRC</td>
<td>อะเมทริน (ประเทศไทย) บจก.</td>
<td>อะเมทริน (ประเทศไทย) บจก.</td>
<td>น้าเข้า</td>
<td>31 ม.ค. 62</td>
<td>30 ม.ค. 68</td>
<td></td>
</tr>
<tr>
<td>12734</td>
<td>70 - 2562</td>
<td>ไ_Instance</td>
<td>อะทริน (atrazine)</td>
<td>50 % W/V SC</td>
<td>Shandong Weifang Rainbow Chemical Co., Ltd. The Republic of China</td>
<td>อะทริน (ประเทศไทย) บจก.</td>
<td>อะทริน (ประเทศไทย) บจก.</td>
<td>น้าเข้า</td>
<td>31 ม.ค. 62</td>
<td>30 ม.ค. 68</td>
<td></td>
</tr>
<tr>
<td>12735</td>
<td>71 - 2562</td>
<td>เกรอกซี 48</td>
<td>ไกลโฟเซต ไกลโฟเซต ไกลโฟเซต และไนมีนิแมม (glyphosate-isopropylammonium)</td>
<td>48 % W/V SL</td>
<td>Zhejiang Xinan Chemical Industrial Group Co., Ltd. PRC</td>
<td>เจาะบัมบี ค้อมัมเมอร์ เชิลท์ ข้าวพาสติส์ บจก.</td>
<td>เจาะบัมบี ค้อมัมเมอร์ เชิลท์ ข้าวพาสติส์ บจก.</td>
<td>ผลิต</td>
<td>31 ม.ค. 62</td>
<td>30 ม.ค. 68</td>
<td></td>
</tr>
<tr>
<td>12736</td>
<td>72 - 2562</td>
<td>สิหกี 35</td>
<td>โมเทกซี (metalaxyl)</td>
<td>35 % DS</td>
<td>Jiangsu Baoling Chemical Co., Ltd. PRC</td>
<td>ฟอร์ม ไพรเทกซี บจก.</td>
<td>ฟอร์ม ไพรเทกซี บจก.</td>
<td>น้าเข้า</td>
<td>31 ม.ค. 62</td>
<td>30 ม.ค. 68</td>
<td></td>
</tr>
<tr>
<td>12737</td>
<td>73 - 2562</td>
<td>เฟดิทาซี</td>
<td>เฟนิเมทิลามิโน (pendimethalin)</td>
<td>33 % W/V EC</td>
<td>Shandong Binnong Technology Co., Ltd. PRC</td>
<td>เฟนิมิเซอร์ ฮิลล์ บจก.</td>
<td>เฟนิมิเซอร์ ฮิลล์ บจก.</td>
<td>ผลิต</td>
<td>31 ม.ค. 62</td>
<td>30 ม.ค. 68</td>
<td></td>
</tr>
<tr>
<td>12738</td>
<td>74 - 2562</td>
<td>ควินโทลาก</td>
<td>ควินโคคลาซ (quinclorac)</td>
<td>50 % WP</td>
<td>Xinyi Zhongkal Agrochemical Industry Co., Ltd. PRC</td>
<td>สิ่งพิษดาร์ ทีเค บจก.</td>
<td>สิ่งพิษดาร์ ทีเค บจก.</td>
<td>ผลิต</td>
<td>31 ม.ค. 62</td>
<td>30 ม.ค. 68</td>
<td></td>
</tr>
</tbody>
</table>
Thailand announced the new rules on:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria for measurement methods and condition of production, import,</td>
<td>The responsible person for controlling the sale of glyphosate, chlorpyrifos, and paraquat must be qualified and passed the DOA training and must attend the training every 3 years, and for the possession, the specialized person should be there, locally. Furthermore, selling of these 3 pesticides shall have the sign with the statement mentioned “restricted use pesticide” and shall be separated from other pesticides.</td>
</tr>
<tr>
<td>export, having in the possession and requiring the specialized person</td>
<td></td>
</tr>
<tr>
<td>responsible for controlling the sale of glyphosate, chlorpyrifos, and</td>
<td></td>
</tr>
<tr>
<td>paraquat</td>
<td></td>
</tr>
<tr>
<td>Restricted use, labeling and packaging of glyphosate, chlorpyrifos,</td>
<td>Limit the use of hazardous substances related to glyphosate and paraquat by prohibit the use in the area of growing vegetables or medicinal plants, Upstream area and public areas. In case of other areas, it is allowed to be used for controlling the weeds in sugar cane planting, oil palm, cassava, corn, and fruit crops. Chlorpyrifos is allowed to be used in fruit crops against the stem borer only</td>
</tr>
<tr>
<td>and paraquat</td>
<td></td>
</tr>
</tbody>
</table>
MALAYSIA:

- **Authority:** Pesticides Board
- **Website:** [http://www.doa.gov.my/](http://www.doa.gov.my/)
- **Online submission:** Link
- **Pesticides Act 1974**, implemented by the Pesticides Board
- **Objective:** Pesticides imported, manufactured and sold in the country are of good quality and will not cause adverse effects to man, food crops nor the environment
For the purpose of registration, pesticides are divided into 2 categories

- **Commodity pesticides** are pesticides containing active ingredients that have been registered in Malaysia > 10 years.

- **Proprietary pesticides** are pesticides that are not commodity pesticides as defined above and are classified as proprietary pesticides.

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Guidelines

- Guidelines For Implementation Of Development Projects Department Of Agriculture - MALAY VERSION
- Guidelines On Pesticide Methods (Pesticide Control Handler) - MALAY VERSION
- Guidelines On Registration For Course Organizer Preparation Of Pesticide Applicators And Assistant Pesticide Applicators Examination - MALAY VERSION
- Guidelines On Importation Of Logs, Pieces Of Wood/Lumber/Sawn Timber And Other Unmanufactured Wood Articles - MALAY VERSION
- First Guidelines For Preparations Of The Tenth Malaysia Plan, 2011-2015: Economic Prospects and Strategic Directions - MALAY VERSION
  - Appendix 1 - MALAY VERSION
  - Appendix 2 - MALAY VERSION
  - Appendix 3 - MALAY VERSION
  - Appendix 4 - MALAY VERSION
- Second Guidelines For The Tenth Malaysia Plan, 2011 – 2012: Preparation Of Public Sector Investment Plan - MALAY VERSION
  - Appendix 1 - MALAY VERSION
  - Appendix 2 - MALAY VERSION
  - Appendix 3 - MALAY VERSION
  - Appendix 4 - MALAY VERSION
  - Guidelines For Public-Private Partnership JPM - MALAY VERSION
  - EPU Circular, No 2 Year 2009 - MALAY VERSION
  - EPU Circular, No 3 Year 2009 - MALAY VERSION
MALAYSIA: Registration

- Application to register and re-register a pesticide must be made using application form and only locally registered companies may apply.

- Applicants are required to refer to the First Schedule of the Pesticides Act 1974, in order to ascertain whether their product contains any of the listed active ingredients, thus requiring registration. As the First Schedule is updated from time to time to include new active ingredients, it is necessary for the applicant to refer to the Pesticides Board for the updated listing.

- The period of registration of a pesticide is 5 years, effective from the date of registration unless it is terminated by the registrant or cancelled by the Pesticides Board.

- For re-registration, the registrant must submitted an application not earlier than 1 year but not later than 6 months before expiry.

- Timeline for registration: typically 1.5-2 years (including the efficacy trials generated locally).

- Data protection period: 10 years.
MALAYSIA: Registration requirements

Applicant are required to submit the technical data and information on the pesticide product (technical active ingredient or/and formulation) which are adapted from the Food and Agricultural Organization (FAO) of the United Nations and also the Malaysian Standards

- Identity
- Physical and chemical Properties
- The method of analysis
- The impact on human and animal (mammalian toxicological data)
- Residue
- Environment fate and behavior
- The effects on non-target species
- Efficacy data (must be conducted in Malaysia)
Government fee:

The fee for registration or re-registration of a pesticide are as follows:

<table>
<thead>
<tr>
<th>Type of pesticide</th>
<th>Fees in Malaysia Ringgit (MYR)</th>
<th>Euro (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1a and 1b</td>
<td>3,500</td>
<td>800 approx.</td>
</tr>
<tr>
<td>Class II</td>
<td>2,000</td>
<td>460 approx.</td>
</tr>
<tr>
<td>Class III</td>
<td>1,000</td>
<td>230 approx.</td>
</tr>
<tr>
<td>Class IV</td>
<td>500</td>
<td>115 approx.</td>
</tr>
</tbody>
</table>
What you need to know?

- Check the active ingredient from the First Schedule
- If registration is necessary, contact the PB
- If product is commodity, and plan to be registered as technical, contact the efficacy team of PB to check if the efficacy trial is required or not (if yes, how many of trials they need)
- In general, local efficacy is required. Must submit bio-efficacy trial data for each crop
- For a major crop (oil palm, cocoa, paddy and black pepper), local bio-efficacy trial is required
- For non major crop, bio-efficacy trial from overseas with similar climate “may” acceptable. Need to discuss with authority
Updates: New Pesticides Registration Acceptance Procedure

- New procedure for the process of receipt of pesticide registration in Malaysia (2019 onward)
- Each company is only allowed to submit 1 registration application only on each month
- The bureau will only accept a maximum 5 products for each type of a.i. to be registered on a monthly basis
- The new application will be open on 5 working days at the beginning of each month. Only the new registration will be accepted during the period such as the table below:

<table>
<thead>
<tr>
<th>Month (2019)</th>
<th>New registration (5 working days at the beginning)</th>
<th>Other affair except new registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>1/10/2019 – 7/9/2019</td>
<td>8/10/2019 – 31/10/2019</td>
</tr>
</tbody>
</table>
INDONESIA

- Authority: Ministry of Agriculture (MOA)
- Regulation Number 39/Permentan/SR.330/7/2015* (Link)
- Type of pesticides registration

1. **Provisional Permission (Experimental use permission)**; The applicant holding a provisional permission is required to run a number of trials in collaboration with appointed research institutes. While holding provisional permission, the applicant is NOT allowed to work on trading or promoting activity or distribution for commercial purposes. Valid for one-year period and might be extended up to (two) period of times.

2. **Temporary Permission**; granted to those who have submitted part of data and/or information derived from efficacy trial. While expecting more data and information, temporary permission can be granted for a 1 year period and subject to extension 3 times.

3. **Permanent Permission**; granted to those who have thoroughly submitted all data and information required derived from the official trials on efficacy and toxicity. Pesticides holding full registration can be used and distributed on a commercial basis. **Permanent permission is granted for a 5 years period.** *The license can be transferred to a third-party after 3 years.*

*This regulation is based on the Regulation of the Minister of Agriculture No. 24 / Permentan / SR.140 / 4/2011 predetermined Pesticide Registration Requirements and Procedures.*
INDONESIA: Core Data Requirement for Products Registration

- Company document of registrant
- Six-Pack Toxicology Data
- Registration certificate (copy) from other countries
- Certificate of Origin, Appointment Letter, Guarantee supply, Manufacturing certificate
- Bio-efficacy report (local study): for full registration
- Certificate of analysis: For Experimental use permit (EUP), Export & Technical Grade Registration

Additional requirement for rice crop:
  - Resurgence against Brown Plant Hopper (BPH)
  - Fish toxicity study (Lab & Field): Insecticide, Fungicide, Herbicide
  - Bio-efficacy for target pest.
  - Beneficial insect/organism (Rice & Vegetable).
  - Natural Enemies
INDONESIA: Technical Requirement

1. Quality of Pesticide: Pesticide must meet purity level of active ingredients that meet the specification of Indonesia National Standard, FAO, WHO or other international bodies.

2. Bio-Efficacy: Local bio-efficacy trial is mandatory (1 unit, 1 season, 1 location). Trial protocol must follow the official guidance.

3. Premix formulation (>1 active ingredient in a pesticide formulation) must be proved there is no antagonism effect among the active ingredient. Local test is mandatory.

4. Mammalian Toxicity: Acute Toxicity for formulation; chronic toxicity for active ingredient.

5. Environment Toxicity; Fish Toxicity Test for pesticide registration in irrigated Rice or irrigated field → Local test is mandatory against 2 local species of freshwater fish.

6. Residues

7. Resurgence against Brown Plant Hopper (BPH); Local test (laboratory & field) is mandatory & required for registration in all rice pests.

8. Effect against stem borer’s egg parasitoid is required for insecticide registration against all rice pests.
Trial permission

- Application letter
- Filled in pesticide registration form
- Statement and Proof of Trademark Registration / Brand Certificate
- Supply guarantee formulation / a.i. / technical materials from suppliers and / or Letter of Access for those who do not produce themselves and / or Letter of Authorization for those who produce themselves
- Appointment letter from the owner of an overseas formulation / own formulation
- Proof of PNBP payment
- Formulation analysis methods, residual analysis, environmental resistance, work methods for target organisms, acute toxicity, acute dermal toxicity, documentation of inhalation, sources of eye and skin irritation data, seritation, long-term toxicity, medical registration in other countries
- Certificate of Analysis (COA) from quality testing laboratories
- Production permit from the competent body regarding the manufacture of Active Materials / Technical Materials (manufacturing licenses) issued by the authorized body in the country of origin
- Formulation certificate (certificate of composition / COC) from Formulation maker / original producer
- Having production facilities (factories of Active Materials / Technical Materials, Formulation factories, or packaging factories in the country) as evidenced by an industrial permit; if these requirements are not met, the applicant for registration must cooperate with a domestic formulation plant or packaging factory as evidenced by a production cooperation certificate.
What you need to know?

- Residue trial data must be submitted if ADI to human ≤ 0.015 mg/kg/day (equivalence to the estimation safe residue ≤1 ppm), for insecticide & fungicide on some crops i.e. rice, maize, soybean, vegetables, edible fruits (with skin), crop for drink, etc.

- For herbicide, the residue trial might not necessary.

- Bio-efficacy trial:
  - Insecticide: Minimum efficacy 70% (80 % control will be more acceptable)
  - Fungicide: Minimum efficacy 50% (80 % control will be more acceptable)
  - Herbicide: biomass of dry weeds must be significantly different with untreated one

- Acute oral & dermal toxicity on formulation is not required for registration of: attractant/pheromone, fumigant, rodenticide, PGR, household pesticide in form of tablet, circles solid, pieces solid, tissue paper, net.

- Acute inhalation, chronic and sub chronic toxicity are not required for biopesticide, PGR, rodenticide, attractant/pheromone.

- Environment toxicity is not required for: household pesticide, vector control, and veterinary/animal health, forestry, housing/wood preservative, transportation, quarantine/pre shipping, PGR, biopesticide, attractant / pheromone and rodenticide.
## Government fee & process of Pesticides Registration

<table>
<thead>
<tr>
<th>Type of Certificate/License</th>
<th>Indonesian currency (IDR)(^1,2)</th>
<th>Euros (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Experimental use permission: registration fee for experimental use permit</td>
<td>± 2,000 USD</td>
<td>1,448 (approx)</td>
</tr>
<tr>
<td>2. Temporary permission</td>
<td>±6,000 USD</td>
<td>4,350 (approx)</td>
</tr>
<tr>
<td>3. Full registration</td>
<td>±6,000 USD</td>
<td>4,350 (approx)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14,000 USD</td>
</tr>
</tbody>
</table>

- Prepare Registration Dossier
- Patent Brand Registration
- Company should have the warehouse/packaging facility
- Submit Efficacy Trial Permit
- Quality testing
- Acute Oral/ Dermal Toxicological Testing
- Efficacy Trial
- Submit Permanent Permit
- Propose Label
- Product ready to sell

INDONESIA: Registration Process

Application submission

- Check dossier by PVT&PP
- Technical aspect check by PSP
  - Reject/ Pending/ Accepted

- EUP issued by PSP*
- Chemical analysis
  - Evaluated by PSP
- Sample sealed & Protocol approved by PSP
- Efficacy & toxicity test
  - Evaluated by expert team of Pesticide committee
- Meeting and issuance of the license (quarterly)

PSP: Prasarana dan Sarana Pertanian (Agricultural Infrastructure and Facilities)

*EUP: Environmental Impact Statement
THE PHILIPPINES

The Fertilizer and Pesticide Authority (FPA) is the regulatory agency attached to the Department of Agriculture which was created under Presidential Decree (P.D.) No. 1144 and mandated to license and register fertilizer and pesticide products.

**Regulation:** Presidential Decree (P.D.) No. 1144


FPA’s Pesticide Regulatory Policies and Implementing Guidelines (*the Green book*); prescribe the procedure for the registration of chemical pesticides, policy guidelines on bio rational pesticides, licensing, certification and accreditation of pesticide handlers, product stewardship and responsible care, post-registration activities, and penalties for violations.

Only local companies registered by the Securities and Exchange Commission to do business in the Philippines and duly licensed by the FPA may apply for registration of pesticide products. For pesticide registration, the applicant should be the distributor or the local subsidiary of a foreign-based pesticide company.
PESTICIDE REGULATIONS DIVISION

DATA

LIST OF REGISTERED PESTICIDE (as of December 2016)

LIST OF LICENSED DEALERS (Fertilizer, Pesticide, F/P) (as of July 2017)

LIST OF PESTICIDE DISTRIBUTORS

PESTICIDE IMPORTATION (2012-2014, 2016)

LIST OF REGISTERED PLANT-INCORPORATED PROTECTANTS DERIVED FROM MODERN BIOTECHNOLOGY (as of October 30, 2018)
Types of Registration Granted

- **Conditional registration**: this registration is granted upon satisfaction of the minimum requirements. A status report of conditional registration with the product registration number is issued to the applicant.

- **Full registration**: this registration 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. This registration is valid for 3 years.

- Data protection period: 8 years

- A conditional registration may be converted into a full registration within 1 year when conditions and requirements have been met satisfactorily.

No renewal/extension of conditional registration shall be granted except in cases of force majeure of fortuitous events and/or where the efficacy trials of other tests require a devotion of more than 1 year.
THE PHILIPPINES

Data requirements for the registration of pesticides are;

1. General Information
2. Specification
3. Biological Efficacy
4. Toxicology
5. Human Exposure and Safety
6. Environmental Effects
7. Environmental Fate and Transport
8. Residue on Foods
9. Labelling

Standards are set by FPA on quality and suitability of the active ingredients and of the formulated products, bio-efficacy, and safety to handlers, safety to consumers and users, safety to the environment, handling, packaging, labelling and disposal.
# Government fee

<table>
<thead>
<tr>
<th>Type</th>
<th>Philippine Peso (Currency of the Philippines)</th>
<th>Euros (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. New Application- Filing Fee</td>
<td>Active Ingredient Php 4,500</td>
<td>75 (approx.)</td>
</tr>
<tr>
<td>2. Conditional Registration Renewal (Annually)</td>
<td>Product Php 3,000</td>
<td>60 (approx.)</td>
</tr>
<tr>
<td><strong>Product</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1 &amp; 2</td>
<td>Php 5,000</td>
<td>84 (approx.)</td>
</tr>
<tr>
<td>Category 3 &amp; 4</td>
<td>Php 3,000</td>
<td>60 (approx.)</td>
</tr>
<tr>
<td><strong>Active Ingredient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1 &amp; 2</td>
<td>Php 7,000</td>
<td>118 (approx.)</td>
</tr>
<tr>
<td>Category 3 &amp; 4</td>
<td>Php 5,000</td>
<td>84 (approx.)</td>
</tr>
<tr>
<td>3. Full Registration / Renewal (3 yrs. Validity)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1 &amp; 2</td>
<td>Php 15,000</td>
<td>250 (approx.)</td>
</tr>
<tr>
<td>Category 3 &amp; 4</td>
<td>Php 7,000</td>
<td>118 (approx.)</td>
</tr>
<tr>
<td><strong>Active Ingredient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1 &amp; 2</td>
<td>Php 20,000</td>
<td>335 (approx.)</td>
</tr>
<tr>
<td>Category 3 &amp; 4</td>
<td>Php 15,000</td>
<td>250 (approx.)</td>
</tr>
<tr>
<td>4. Submission of Additional Data</td>
<td>Php 4,000</td>
<td>67 (approx.)</td>
</tr>
<tr>
<td>5. EUP Application / Protocol / Crop Season</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I - A &amp; B</td>
<td>Php 1,500</td>
<td>25 (approx.)</td>
</tr>
<tr>
<td>II - III</td>
<td>Php 3,000</td>
<td>60 (approx.)</td>
</tr>
<tr>
<td>6. Label / Expansion / Crop</td>
<td>Php 3,000</td>
<td>60 (approx.)</td>
</tr>
</tbody>
</table>
Pesticide Registration Process in the Philippines

1. Applicants Submit Documents
   - 1 Month

2. FPA Check Documents
   - 1-3 Months

3. Data Complete
   - 3 Months

4. Yes: Consultants Review/Assess Data
   - 12 Months

   a. FPA Integrates Consultant’s Reports
   - Accept

   b. Recommend Registration
      1. Full Registration
      2. Conditional Registration

*The overall registration process is 1.5 - 2 years if all completely data are submitted to authorities.
VIETNAM

Authority:

- The Ministry of Agricultural and Rural Development (MARD) by Plant Protection Department (PPD) conduct pesticide registration and residue control


Regulation: Circular No 21/2015/TT-BNNPTNT (Link)

Guidelines: National technical regulations (QCVN), national standards (TCVN), and standards (TC) established by the PPD

Application for the registration of pesticides shall be submitted to the Plant Protection Department (PPD), Pesticide Management Division. Local or foreign organizations and individuals who produce active substances can either directly register their own products, or authorize other accredited organizations or individuals to register their active substance using only 1 single trade mark

The Pesticide Control Centers are assigned to conduct pesticide quality assurance, residue control and field trials for bio-efficacy of pesticides to be registered in Vietnam

Data protection period: 5 years

Registration license can be transferred
VIETNAM: Types of registration

- **Supplementary registration**: Not applicable for current registration target.

- **Full registration**: it applies to pesticides which have already become commercialized (marketed) in foreign countries, but introduced for the first time in Vietnam;

  For full registration, a **biological efficacy trial shall be conducted** in the **North & the South** in 2 stages: small and large-scale efficacy trials. These trials should be carried out following the Vietnamese regulations on pesticides.

- **Renewal of the registration certificate**: for renewal registration process. It applies to pesticides listed as permitted or restricted in the country, when the registration certificate has expired.

  **Validity period time**: 5 years, 1 single trade name
VIETNAM: Documents for Pesticide Registration

- Application form for pesticide registration
- Copy of permit for pesticide field trial
- Label
- Phys-Chemical Data
- Toxicological Data: the toxicological data must be generated by a GLP Certified Laboratory according to OECD standard
- MSDS
- Environmental Fate and Effects
- The reports of bio-efficacy testing
- The reports of PHI* testing (chemical pesticide registry to use on vegetable, fruit or tea)
- Residue data

*PHI – post-harvest interval
Pesticide Registration Process in Vietnam

**Field trial test permit**
- Application form, label
- Trade name
- Manufacturing certificate for TC or Formulation (issued by concerned authorities)
- Technical data for TC & Finished product
- Letter of authorization (if any)

**Official trial**
- Sign test contracts with NPCC (North) & SPCC (South)
- Prepare trial test protocol
  - 5 bio-trial tests (4 small scales & 1 large scale) in North and another 5 tests in South for full registration and generic registration (10 in total)
  - 4 PHI (Pre-harvest interval), 2 in North & 2 in South in case of registration on Tea, Vegetable & Fruit tree

**Approval**
- Bio-efficacy evaluation (after finishing all trial tests)
- Council meeting will be held after product approved by Bio-efficacy evaluation meeting
- Decision issued by MARD for product registration
- Issue the registration certificate (by PPD)

--- 05 – 06 months ---  --- 02 years ---  --- 03 – 05 months ---

NPCC: Northern Pesticide Control Centre, SPCC: Southern Pesticide Control Centre
Registration Process

Dossier Preparation
(Label, tech. data, MSDS, etc.)

Pre-examination by Regulatory Agency

Application submission

License Issuance

Local Efficacy Test

Specification Test

Depend on national regulatory requirements

➢ General information
➢ Physical & chemical properties
➢ Identification method
➢ Toxicity data (OECD-GLP)
➢ Efficacy results

Allowed to be registered
The Regulatory Hurdles

Regulatory Hurdles

- Language barrier
- Insufficient information with regard to the updates on laws & regulations for registration of in Southeast Asia countries
- Regulatory process and data requirements are challenging
- Harmonization of laws and regulations in relation to pesticides in Southeast Asia — Can It Happen??
- Insufficient coordination among relevant ministries, unclear role & responsibility between authorities
- Insufficient of manpower and budget
- Weakness of inspection and enforcement
- Government/ political issue
- Changes in regulatory science are very slow compared to science developments
- Limited guideline for Industry stakeholders
Take home message

- Decision should be based on facts and reliable data. Need for regulatory science-based decisions, neither science-based decision nor political decision.

- Consistent application of guidance document and the agreed standards.

- Foster cooperation between regulatory agencies → trust building.

- Think about the public when your write/ evaluate dossiers!

- Analysis marketing of similar products abroad or in the target market e.g. Market approvals, manufacturer, marketing entry strategy, etc.

- Make use of available help to ensure a successful registration, work with reliable partners or engage the experienced consultant.
knoell group

Crop Protection Unit

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Contact us