

Agrochemical Compliance in Southeast Asia countries



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Auxilife was incorporated in India November 2011 and became operational in June 2012. Auxilife is a subsidiary of Global Product Compliance (GPC) Europe AB, Sweden. Auxilife help agrochemical companies for regulatory compliance globally and help companies for product registration, understanding market, field trials, CRO collaboration for studies and holistic overview of agrochemical regulatory compliance.

Auxilife Elements



Experience



Quality Support

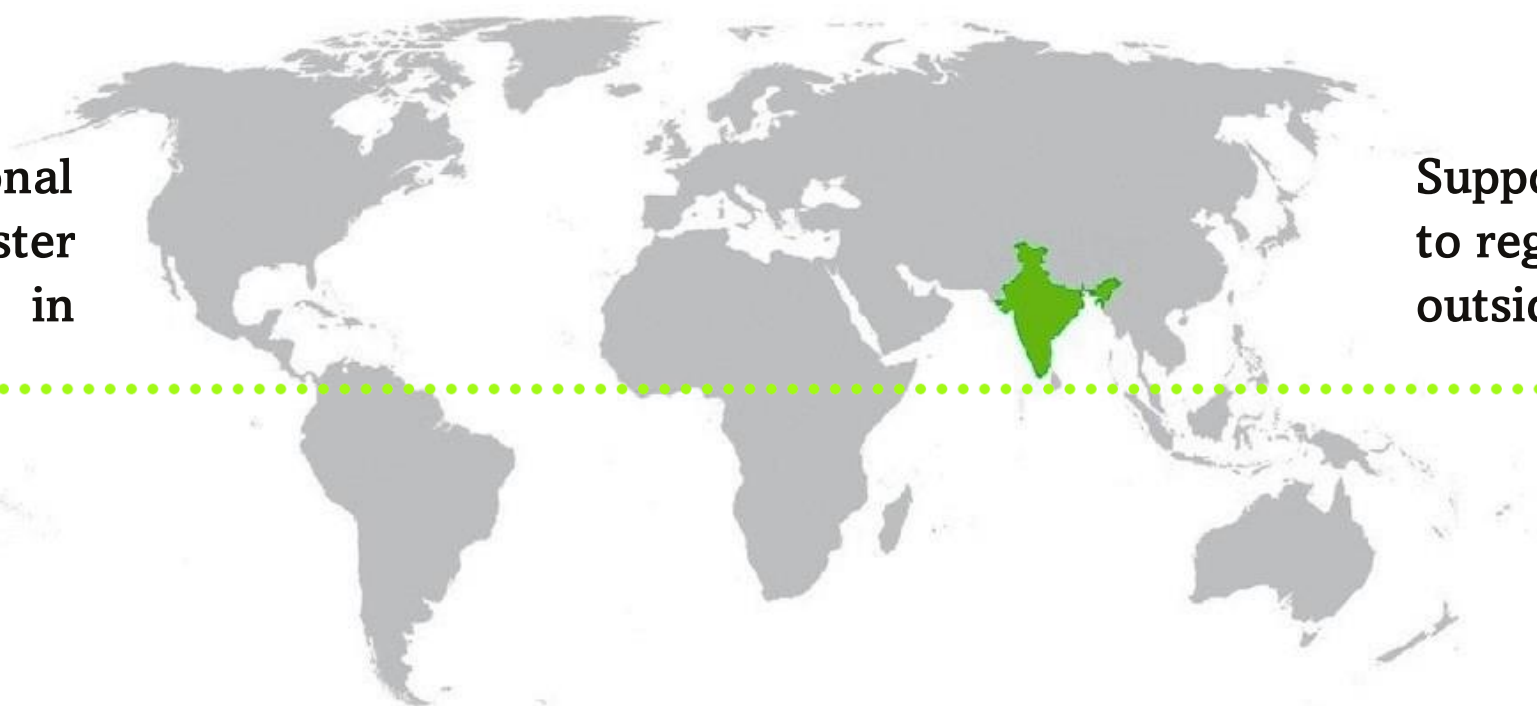


Confidentiality

Auxilife Business Model

Support International companies to register their products in India

Support Indian companies to register their products outside India.



Worldwide office presence



Auxilife Expertise



● Pesticides & Bio-stimulants



● Biocides/disinfectants



● Medical Devices



● Others



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Introduction

- The agrochemicals' industry is growing
- Needs for agrochemical regulations to reduce pesticides' hazards
- In this webinar, the aim is to address registration requirements and procedures for agrochemicals in Indonesia, Cambodia, Philippines, and Vietnam
- Key points to be covered:
 - General reference to countries, and
 - Agriculture, pesticides used
 - Registration procedure including glimpses on household pesticides



Indonesia

Indonesia—Agriculture Overview

- The largest archipelago and island country and the fourth largest populated country
- One of the largest bio diversified areas
- Agriculture is one of the key sectors, contributing approx. 15 % to national GDP
- Main Agricultural Produces are Rice, corn, cassava, soybeans, peanuts, Palm oil, tea, coffee, cacao, medicinal plants, spices, and rubber
 - The major food crops by area of cultivation: rice
 - Main Fruits grown: banana and mango
 - Main Vegetables grown: potato, tomato, cassava and onion.

Indonesia—Agrochemical Overview

- Pesticide consumption is one of the lowest in Indonesia (0.04 kg/ha). A lot of spurious /substandard pesticides are present in the market
- A growth of ~ 9 % is predicted for agro chemicals annually.
- Herbicides dominate the market followed by fungicides & insecticides Demand for insecticides are increasing with prolonged dry seasons in the country.
- Liquid , granules and powder formulations are the major type of formulations used with consumption of granule and powder formulations dominating than of liquid products. Liquid formulations which are cheap and easy to use are preferred.
- US, China, France, UK, Malaysia, Thailand and Philippines are the major exporters of pesticides to Indonesia.
- India's export to Indonesia is only 3% of its total pesticide's exports.

REGISTRATION OF PESTICIDES

- **Ministry of Agriculture** is the responsible ministry.
- Pesticide Regulation No. 7. of 1973 is the original Decree. Ministry of Agriculture Decree No. 434.1/Kpts/TP.270/7/2001:Pesticide Registration is the current version.
- There are two types of pesticides with reference to registration. Pesticides which can be registered and pesticides which cannot be registered.
- Pesticides which cannot be registered are pesticides which are highly toxic by oral, dermal or inhalation route and/or corrosive to skin and mucous membrane and prohibited pesticides.
- Pesticides which can be registered are of two types- general pesticides and restricted use pesticides.

- General pesticides are pesticides which can be handled without any special training.
- Restricted pesticides are those pesticides which require special skill and training to handle.
- Application for registration shall be submitted to Director General of Agriculture under the Ministry of Agriculture accompanied by the required data prescribed in the guidelines. Pesticide Sub Committee will review the applications and submit its recommendation to Director General of Agriculture.
- There are three types of registrations
 - Trial use permission
 - Provisional registration
 - Full registration
- Trial use registration/permission
It is for establishing/verifying the efficacy of the product as claimed. Director General will grant trial permission, within 14 days after receiving recommendation from the pesticide sub committee.

- It is valid for 1 year and can be extended to 1 more year. No commercial manufacturing or distribution is allowed during this period.




- Provisional registration
- It is for completing the submission of the pending data/fulfilling additional data and is also valid for 1 year but can be extended to a maximum period of 3 years.

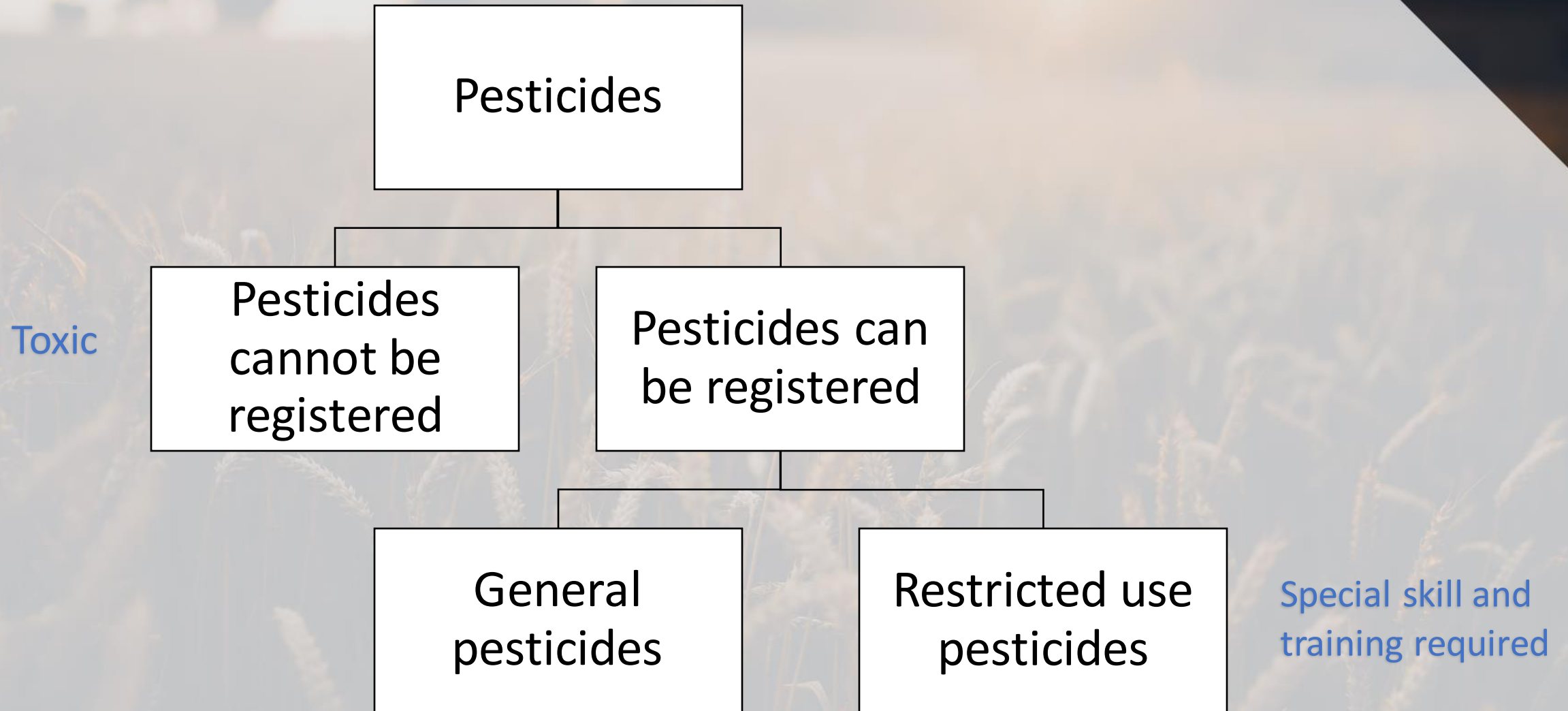
- Trial results shall be submitted to the pesticides sub committee, and it will review the results and submit its recommendation to the DG Agriculture. DG will send its recommendation to the ministry within 90 days
- The Ministry of Agriculture will grant registration with such terms and conditions which it may deem fit with regard to safety to the environment and human health.

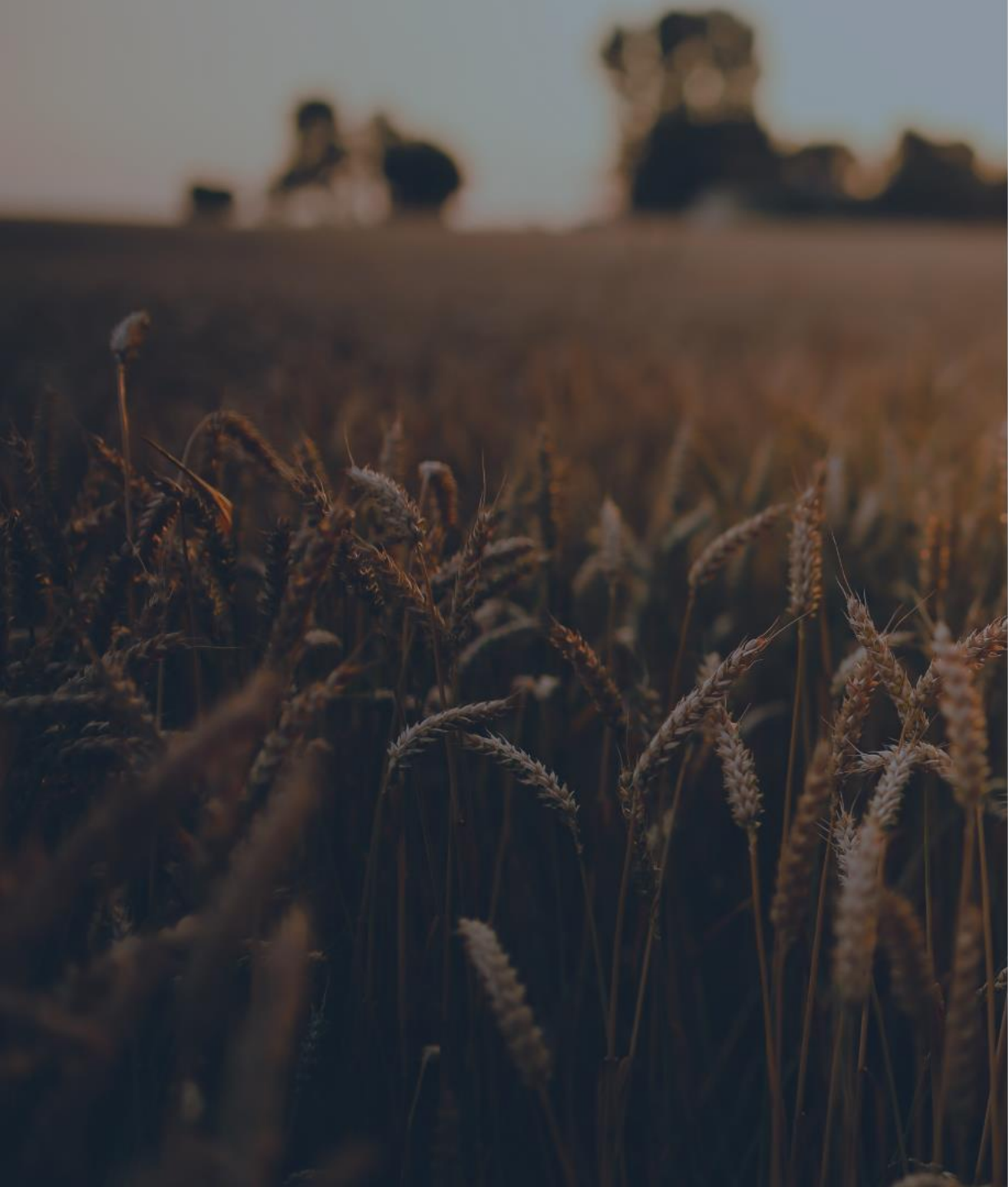


- As per the Decree No. 01 of 2019 of the Minister of Agriculture organic fertilizers, biofertilizers and soil enhancers produced locally or imported, are also to be registered

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- Requirement for registrations are
 - Quality testing based on the relevant Indonesian Standard (SNIs) as applicable. Minimum Technical Requirements as prescribed by FAO, information on composition, impurities present, physico-chemical properties, efficacy residue, toxicity to human and environment, disposal, safety precautions etc.
 - Household pesticides and Public health pesticides
 - Are also registered by the ministry of Agriculture.
 - Quality testing and efficacy testing are to be mandatorily done in Indonesia.
 - Registration will take around 18 months to complete.
 - Registration is valid for 5 years and can be renewed further if not banned.

Indonesia—Pesticide Types





Philippines

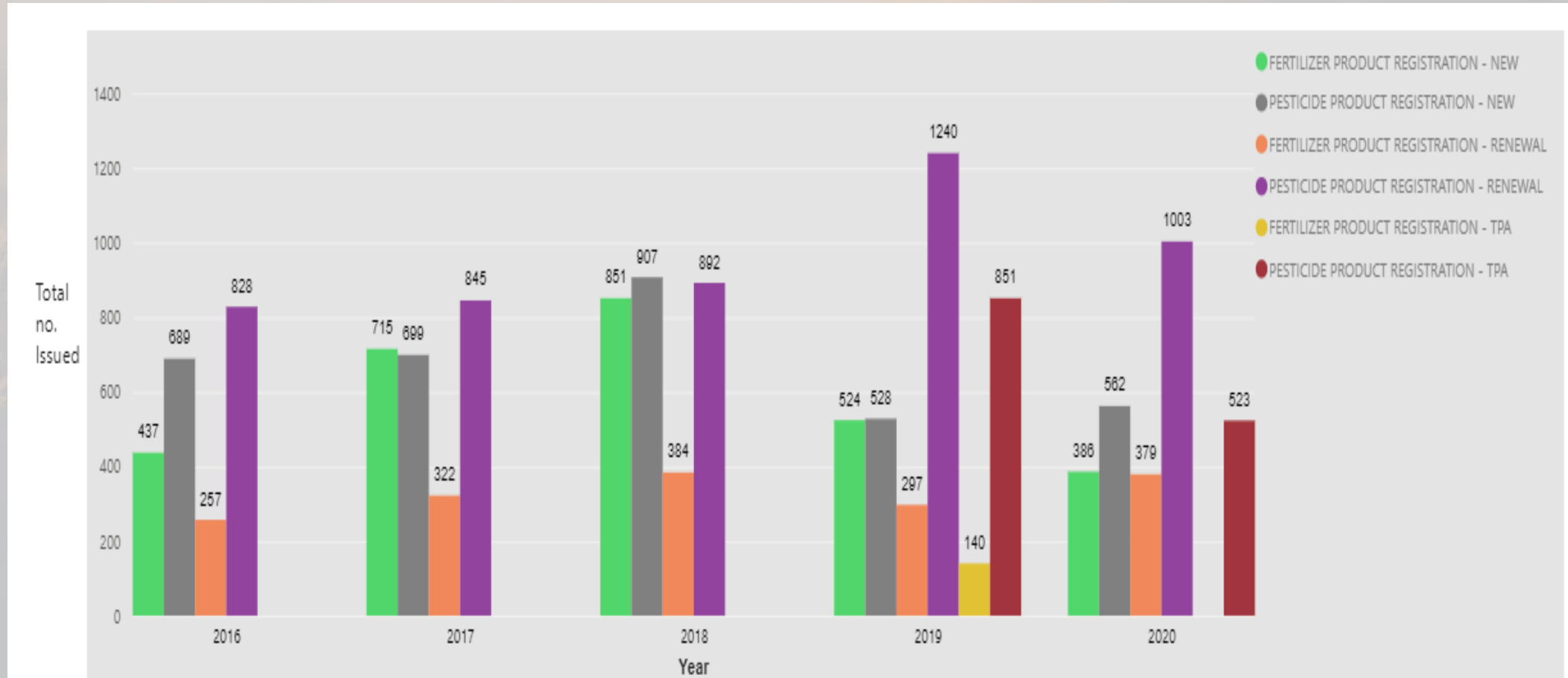
Philippines—Agriculture Overview

- An archipelagic country situated in the western Pacific Ocean and consists of about 7,640 islands, covering 300,000 km² area
- 3rd largest economy in the ASEAN. Economy is changing from agriculture based to services and manufacturing based
- Major trading partners: the US, Japan, China, Singapore, South Korea, the Netherlands, Hong Kong, Germany, Taiwan, and Thailand.
- Main agricultural crops: rice, corn, coconut, sugarcane, bananas, pineapple, coffee, mangoes, tobacco, and abaca
 - Other crops include peanut, cassava, camote, garlic, onion, cabbage, eggplant, calamansi, rubber, and cotton
 - Coconut oil & coconut products are the major export products along with Banana and pineapple.

Philippines—Agrochemical Overview

- According to FAO statistics, Philippines pesticide market grew at a rate of 11.6 % between 2011&2017
- Pesticides imported mainly from USA, China, Indonesia, India, Malaysia, Thailand and Korea.
- Insecticides are the most imported category of pesticides

Registration Cases



<https://fpa.da.gov.ph/>

Philippines—Registration of pesticides

Registering authority

Fertilizer & Pesticide Authority of Ministry of Agriculture

Requirements for imported pesticides

Certificate Authorizing Importation of Pesticides (CAIPs) issued by Fertilizer & Pesticides Authority (FPA)*

Requirements for importers

Licence to Operate (LTO)

Philippines—Registration requirements

- Prior to the issuance of CAIP, importing companies shall also hold a Certificate of Product Registration (CPR)
- Companies or businesses registered as per the Philippine Law can only do business and apply for registration of pesticide product/active ingredients may to the FPA, Philippines.
- An application for registration of an active ingredient shall be submitted in P-012 and a formulated product in P022 (in duplicate) along with data required to support the registration as specified in the guidelines.
- Test reports shall comply with internationally accepted scientific practices, GLP's and test protocols.

Philippines—Registration requirements

- A summary of the data submitted and an applicant's assessment of how these data support registration for the purpose, uses and directions for use in the draft label
- Proof of registration in other countries
- Proposed label for Philippines
- An applicant shall submit 500 ml/g (as the case may be) of the sample of the product to be registered along with 1g analytical grade of the active ingredient(s) and 10g technical material to FPA
- Reviews of data done by other countries of international organizations, if available.
- Registration fee
See <https://fpa.da.gov.ph/index.php/information-resources/fees-and-charges/fertilizer-pesticide-fees-and-charges>
- Any authorization necessary to cite previously submitted data.

Philippines—Registration requirements for EUP

Experimental Use Permit (EUP)

If experimental samples are to be imported for the registration of a pesticide, a prior approved Experimental Use Permit (EUP) from FPA is required.

Documents required:

- 1) Completed application form
- 2) Technical data requirements
- 3) Application for a company license as Importer-National Distributor /End-user.

Philippines— Household Pesticides

- Registered by the Department of Health/FDA
- Both Household pesticides and their active ingredients are to be registered with FDA.
- If the active ingredient is already registered with FPA and is valid while applying for the registration of a formulation with FDA, then there is no need of registration of the active ingredient again. FDA shall accept FPA registration.
- If the formulation to be registered with FDA can also be used as an agrochemical then the product shall be registered with both FPA and FDA.
- Registration is valid for a period of maximum 5 years.



Vietnam

Vietnam—Agriculture Overview

- Vietnam is located at the Southeast Asia and is the world's 15th most populous country with a population over 96 million
- Agriculture and forestry accounted for around 20% of Vietnam's GDP, in which agriculture takes up about 14%
- Agriculture's share on economic output is declining in recent years
- Agricultural land in Vietnam is 27.3 million ha including forestry land. Land holdings are fragmented with 90 % having less than 0.5 ha. And 25 % having 0.5 to 2.0 ha
 - Major agriculture products: corn, sorghum, cassava, sweet potatoes, beans, sugarcane, groundnut, soybeans, Rubber, fruits, and vegetables
 - Industrial and export crops produced in Vietnam: coffee, tea, tobacco, pepper, cashew and jute

Vietnam—Agrochemical Overview

- Most of the pesticide applications are in crops like cereals & grains, fruits & vegetables, oilseeds & pulses, and others
- According to Ministry of Agriculture and Rural Development, Vietnam spent around USD 1000 million on imported pesticides.
- Paddy field rice cultivation accounts for about 50% of crop protection demand in Vietnam.
- Most imported items are herbicides followed by insecticides, fungicides and others including rodenticides, chemicals used for drainage, timber preservatives, storage chemicals etc.

Vietnam—Registration of pesticides

Registering authority

Plant Protection Department (PPD) Ministry of Agriculture and Rural Development

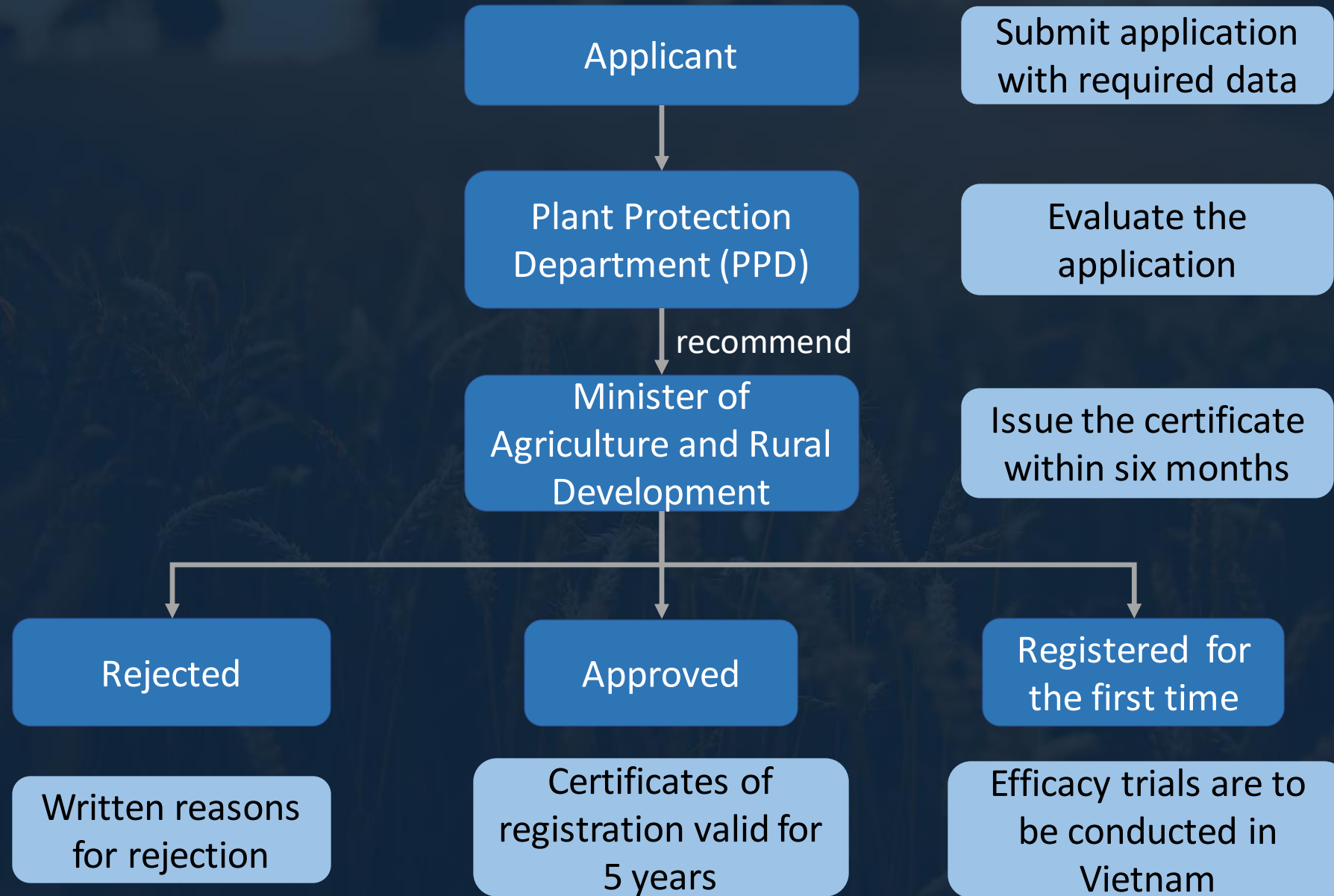
Eligible applicants

- Vietnam Citizens (legal/individuals) who manufacturing pesticides
- Permitted Foreign organizations and individual manufacturers

Required data

Including: data on Phys-chem, toxicity, environmental effects, efficacy and residue

Vietnam—Registration process



Vietnam—Household /Public Health

- Public Health products are to be registered with Health and Environmental Agency (HEMA), Ministry of Health.
- Process of registration is not time consuming. Limited data is required for registration.
- Testing of products in Vietnam is compulsory.
- Time required for approval is around 6 - 8 months for vector Control Products. Products used in Vector Control Program shall be evaluated and recommended by WHO.
- Chlorpyrifos ethyl, Hexythiazox, Fipronil, Beta-cyfluthrin and Cyfluthrin are banned for Household & Public health use.
- Novaluron, Diflubenzuron, Pyriproxyfen, Temephos, Spinosad and Emamectin benzoate are restricted for use.



Cambodia

Cambodia—Agriculture Overview

- Located in the southern portion of the Indochinese Peninsula in Mainland Southeast Asia
- Per capita income is low compared to most of the neighbouring countries
- One of the fastest-growing economies in Asia
- Agriculture remains dominant economic sector, most rural households depend on agriculture and its related subsectors
 - Major crop is Rice. The principal commercial crop is rubber and is second only to rice in cultivation.
 - Other Crops cultivated include maize, cassava, sweet potatoes, ground nuts, soybeans, sesame seeds, dry beans, groundnuts and coconuts

Cambodia—Agriculture Overview

- The principal fruit crops: bananas, oranges, and mangoes, and are supplemented by a variety of other tropical fruits like breadfruits, mangosteens, and papayas.
- Cambodian agriculture is undergoing transformation with use of new technologies, mechanization, productive use of labour etc.
- Cambodia's agricultural production in the past grew mainly due to higher paddy rice production, along with increase in production of maize cassava, sugarcane, and vegetables.
- On the basis of profitability Vegetables were at the number one position in Cambodia followed by cassava, maize, dry and wet season rice.

Cambodia—Agrochemical Overview

- No pesticides are manufactured in Cambodia and are imported from neighbouring countries through legal or illegal means.
- According to an FAO publication the widely used category of pesticide in Cambodia are insecticides
- Major pesticide used in Cambodia are paraquat, glyphosate, metolachlor, quizalafop, and etc.
- Tricyclazole and pesticides in Group I of GHS table are banned in Cambodia

Cambodia—Registration of pesticides

Registering authority

Ministry of Agriculture, Forestry and Fisheries

Eligible applicants

A natural or a legal citizen of Cambodia

Pesticides need Registration

Pesticides to be traded, formulated or imported in Cambodia

Cambodia—Registration requirements

- The standard requirements for pesticide registration shall include information and data on :
 - Identity of the applicant
 - Identity of the pesticide and its formulating process;
 - Data on product specification, compositions of active ingredients and finished product
 - Physical and chemical properties of active ingredients and other data of pesticide
 - Analytical method
 - Data on bio-efficacy from country of origin as well as the local reports.
 - Data on toxicity;
 - Data on residue;
 - Safety to human, animal, and environment;
 - Reports on quality, adverse effects if any.
 - Directions for use and safe disposal;
 - Package and label in Khmer.

Cambodia—Registration requirements

- A registration may be denied if
 - Information and data submitted with the application are false;
 - Pesticide is highly toxic to public and environment
 - Pesticide is found to be phytotoxic
 - Efficacy of pesticide is lower than what is claimed
 - Pesticide is persistent and remain in crops and the environment
- The certificate of registration is valid for 3 years after the date of issuance of the certificate, except for the revocation before expiration.
- household pesticides and public health pesticides registration shall be jointly decided by the Ministry of Agriculture, Forestry and Fisheries and the Ministry of Health.

Summary



In order to sell or distribute plant protection products(PPP) in Southeast Asian Countries knowing your registration obligation is crucial.

Prepare in advance to not to disrupt your trade with Southeast Asian Countries.

Auxilife can help you comply with those regulations. For more information please contact us



How can Auxilife help you?

- Development of regulatory strategy and technical assistance to overcome regulatory challenges including project strategy and scoping
- Identification of compliance requirements under various guidelines including all the data requirements
- Data gap analysis and pre-assessment support
- Technical documentation support
- Preparation of data waivers and bridging arguments
- Study placement, monitoring, and design
- Pre and Post submission support and technical liaison with authorities

Thank you for your attention!

