

3. Country reports

3.1 BANGLADESH

STATUS OF PESTICIDE MANAGEMENT IN BANGLADESH

APPPC Regional Workshop on Enhancement of Regional
Collaboration in Pesticides Regulatory Management
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Chiang Mai, Thailand

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In Bangladesh all Pesticide activities going on under the pesticide rules and ordinance. In 2010 in case of new registration has changed the registration fee, No of trial and location. Currently is need two field trial

for two season and two location but earlier it was one trial product incase of mitoo product and two trial for a new product.

Registration committee consist of 22 member which is headed by executive Chairman BARC and all of the head department of Agriculture are member of the committee. Technical committee consist of 26 member. Headed by NPPO/Director Plant Protection wing, Department of Agriculture

Set up of Registration Authority

Pesticide administration and quality control
Director/NPPO
Deputy Director
Pesticide Regulation officer
Chemist(3)

Pesticide Registration flow chart

- > Receive application
- > Chemical Test (Done by Chemist)
- > Sub PTAC (Technical committee)
- > Field trial 2 seasons 2 location
- > Done by different Researcher
- > Sub PTAC
- > PTAC (Registration Authority)
- > Registration
- > Total 2-2½ years

Bangladesh obey all treaties and convention. In the 2010 Bangladesh introduced Biochemical and Microbial Pesticide rules

Regulation for Pesticide import all Pesticide registration holders require the following documents Import licence, repack licence wholesale licence, repacking factory, Environment licence, etc.

All pesticide Products label must be approved by the registration Authority. All label contain trade name of pesticide, Genetic Name, doses, Pest, Crop, first Aid, Toxic label, Name of Principle, waiting period, Manufacture. expiry date, MRP



Packaging containing pesticide may be transport by rail, trolley as according to the condition of railway or trolley authority in Red Tariff. No pesticide shall be transported if it has the possibility of direct contact with food stuff. To be safe from pesticide risks and health hazard PPW arranged the training programme on safe use of pesticide.



Procedure and data requirements for the registration of chemical products have been done. Only PPW i.e. registration authority all indicated data is required to make registration. Toxicology testing done by PPW toxicological laboratory. Field trial needs two seasons and two locations for Bio-efficacy.



Review the dossier by nominated chemist of PPW – and highly hazardous product it will be rejected according to WHO classification of pesticide. Bio-efficacy, toxicological data, ecotoxicological data all reviewed by chemist of PPW. Formulation analysis and quality control have been done by chemist of PPW. Bangladesh has 6 types of licence:

- 1) Formulation
- 2) Repack
- 3) Import
- 4) Wholesale
- 5) Retail
- 6) Pest Control



All licence renew after 2 years. Fumigation done in air tight chamber/room, waiting period is strictly maintained done by trained persons.

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Presented by:
Dr Dy Sam An
Mr Uch Sothy

- ## Type of License of Agriculture Materials
-
- 
1. Permit of Agriculture Materials (AMs) Trade
 2. Registration Certificate of AMs
 3. Import and Export Permit License
 4. Retail Permit License

- Sub-degree No. 69 on Standard and the Management of Agriculture Materials issued by Government
- Circular No. 345 on implementing guidelines of Sub-degree No. 69 issued by Government
- Proclamation No. 589 on the list of pesticides permitted, restricted and banned for use in Cambodia

- ## 1. Permit of Agriculture Materials Trade
-
- Purpose:** To grant the right to individual or company in access to the activities related to the trade, manufacture, storage, re-packing, export and import of AMs
- Trade permit is granted permanently without specific duration
 - Is processed within 15 working days from the date of application

- ## 2. Pesticide Registration Process
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- The diagram illustrates the Pesticide Registration Process. It features a central box divided into two sections: 'Agricultural Legislation Department (DAL)' on the left and 'National Agriculture Laboratory (NAL) and Research Stations under GDA' on the right. A red arrow points from the DAL section to the NAL section, and another red arrow points from the NAL section back to the DAL section, indicating a cyclical process. To the left of the box, text states 'responsible for all procedures of Registration'. To the right, text states 'responsible for Formulation Analysis and Field Trial of registered products respectively'. Below the box, a blue banner states 'Final approval on product registration is made by Minister'.
- responsible for all procedures of Registration
- Agricultural Legislation Department (DAL)
- National Agriculture Laboratory (NAL) and Research Stations under GDA
- responsible for Formulation Analysis and Field Trial of registered products respectively
- Final approval on product registration is made by Minister**



2. Pesticide Registration (con't)

There are 2 type of Pesticides Registration in Cambodia:

- Full registration: The certificate is valid for 3 years from released date
- Provisional Registration or Conditional Registration: The certificate is valid for 1 year unless the conditions and requirements are fulfilled

2. Pesticide Registration (con't)

Registration Procedures and data requirements highlights:

- Application for pesticide registration
- Copy of Agriculture Materials Trade Permit
- Certificate of Trade Registration at Ministry of Commerce
- ID or Passport of Applicant

2. Pesticide Registration (con't)

- Documents from supplier:
 - Guaranteed Analysis Certification
 - Material Safety Data Sheet and Technical Document
 - Certificate of Pesticide Registration from country of origin

2. Pesticide Registration (con't)

- Product Labels in Cambodian Language
- Result of Formulation Analysis and Experiment field test conducted by General Directorate of Agriculture (GDA)

3. Pesticide Import/Export License

- The license can be issued for individual or company whose AMs were already officially registered with MAFF.
- The license is valid for 1 year after issuance date

3. Pesticide Import/Export License (con't)

After obtaining the license the individual or company shall:

- Comply with the standard for container, label or leaflet approved during registration
- Code the products by system of custom codes
- Comply with safety measurement under the law

3. Pesticide Import/Export License (con't)

- Record all information related to import/export operation
- Inform MAFF to undertake primary inspection during import/export operation or prior to distribution
- Provide company branches or dealers list who will distribute the imported products locally

4. Retailer License

All individual who wish to retail AMs need to be granted Retail License from Provincial Department of Agriculture located in their respective province

II. Status of Pesticide Registration from 2012

Current Status for Pesticide Registration in Cambodia

In 2012:

- Law on the Management of Pesticide and Fertilizer was endorsed on 14th January, 2012
- Proclamation of Procedures and Standard Requirements for Pesticides Registration

Some Key Highlights of New Pesticides Legislation

Type of License under new law:



Some Key Highlights of New Pesticides Legislation

- New law is more comprehensive
- Registration process is clearer for all traders to comply
- Sample analysis and field trial are technically completed
- Certain measurements are clearly stated and strictly applied for illegal pesticide trading operation. The measurement are including fine/punishment and imprison
- Decreasing illegal trade cases

Some Key Highlights of New Pesticides Legislation (con't)

Advertisement:

- The company has to seek for prior approval from the Ministry first before advertise AMs
- Advertisement shall contain enough technical information and appropriate application
- Advertisement should not promote the usage or over does usage by providing reward or gift for users or exaggerating on efficacy or safety

DAL Other activities...

- Provincial Agricultural Legislation Office (PALO) in 24 provinces are responsible for regular inspection on pesticide trade in all dealers
- Conduct regular direct inspection on quality control from DAL on imported pesticides by all companies in collaboration with PALO

DAL Other activities...(con't)

- Conduct dissemination workshop on pesticide legislation and professional training to all PALO staff at provincial levels

DAL Other activities...(con't)

- Conduct dissemination workshop on pesticide legislation to provincial staff, companies and stakeholders



DAL Other activities...(con't)

- Conduct Inspection to all Pesticide shop in hold Country



International Treaties and Conventions



Cambodia is a signatory of:

- Basel and Stockholm Conventions (Ministry of Environment is a focal point)
- Montreal Protocol
- Rotterdam Convention

Constraints



- Limited competent technical staff
- Limited financial resource to improve laboratory operation
- Flow of Illegal products in provinces neighbouring to borders
- Law extension activities are still limited to wholesale and retailer as well as farmers

Recommendations and Suggestions



- Capacity Building Trainings for involved staff are greatly needed
- Financial resource to implement law extension and pesticide trading inspection activities
- Financial resource to support awareness raising activities on proper pesticides usage application to wholesalers and retailers
- Collaboration with other related project on pesticide management are needed

Thank You!



3.3 CHINA

Brief introduction of China's Pesticide Management

1. Pesticide Industry in China

Number of registered product: more than 25 000
Number of registered active ingredient: more than 620
Production: 2 648 700 Tonnes (Year 2011)
Import: 52 890 Tonnes (Year 2011)
Export: 796 368 Tonnes (Year 2011)
Manufacture: 2 300

2. Legislation and Regulation, Responsible Departments

2.1 Legislation and Regulation

Regulation on Pesticide Management was established on May 1997, amended in 2001, second amendment is undergoing, and the new version is expected to come into force during 2013. Detailed guidelines was set up for better implementation of pesticide management measures according to the Regulations, such as Guidelines on pesticide registration and data requirement published by December 2007 and Measures on Pesticide Production Management etc.

Further more, Law on Food Safety and Law of Quality Security for Agricultural Products and Regulation on Hazardous Chemicals Management are also related to pesticide management due to food safety reasons.

2.2 International treaties

China has signed Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Stockholm Convention on Persistent Organic Pollutants and Basel Convention on the Control of Trans-boundary Movements of Hazardous Wastes and their Disposal, and willing to work together with the other member countries to take control of the hazardous chemicals, for sustainable development and human health.

2.3 Responsible departments

Ministry of Agriculture (MOA), together with other Ministries, are responsible for registration, production and commercial management of pesticide in China.

Ministry of Agriculture, is responsible for pesticide registration and marketing supervision

Ministry of Industry and Information Technology, is responsible for manufacture approval.

Ministry of Industry and Information Technology, together with

General Administration of Quality Supervision,

Inspection and Quarantine are responsible for production licensing.

State Administration for Industry and Commerce, is responsible for manufacture and sale registration.

State Administration of Work Safety is responsible for high hazardous pesticides.

Ministry of Environment is responsible for pollution supervision.

Ministry of Health is responsible for setting up Maximum Residual Levels of pesticide in food.

3. Pesticide management system

3.1 Pesticide registration

- 3.1.1 Applicant: Organizations producing or importing pesticide
- 3.1.2 Registration types: Field efficacy trail, Temporary registration, full registration
- 3.1.3 MOA set up Technical Data Review Committee and National Pesticide Registration and Examination Committee (temporary and full) to conduct the registration procedures.
- Members of Technical Data Review Committee are from the Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA)
 - Members of National Pesticide Registration and Examination Committee are from different professional field including Agriculture, Forestry, Industry Production Licensing, Health, Environment, etc.
- 3.1.4 Data Requirement: Same with most countries, Identity and properties, Toxicology data, Bio-efficacy data, Residue data, Environmental fate and effect data, Labelling data

Folder	Field Trail	Temporary Registration	Full Registration	Renewal of Registration ^b
Identity and properties	✓	✓	✓	
Toxicology data	✓	✓	✓	
Bio-efficacy data	✓	✓	✓	
Residue data ^a	✓	✓	✓	
Environmental fate and effect data	✓	✓	✓	
Labelling data		✓	✓	✓
Other				Original Registration Paper

^a Residue data can be exempt for some kind of biochemistry and biological pesticides according depending on the decision of the Registration Committee.

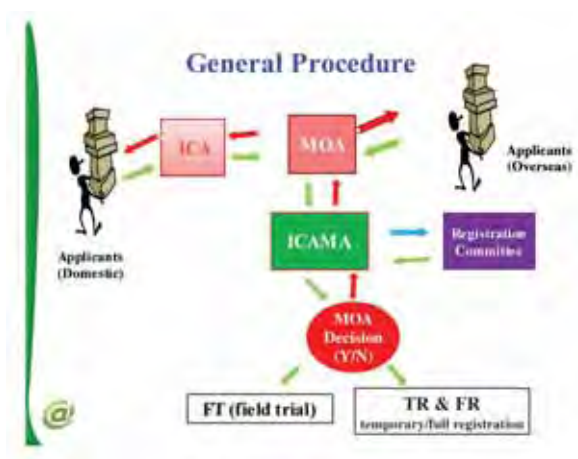
^b New data is needed when available.

- The tests for pesticide registration should be conducted by qualified pesticide registration testing institutes or labs that are accredited by MOA, mainly according to the relevant requirements of ISO17025.
 - 126 labs: for efficacy
 - 73 labs: for residue
 - 35 labs: for toxicology
 - 13 labs: for environmental effects
 - 42 Labs: for quality control

3.1.5 General procedure for pesticide registration

Data submission — Technical Review — Registration Committee — Decision Making — Licensing.

3.1.6 Data protection: compliance with WTO rules, the period of data protection is 6 years



3.2 Pesticide Production Management

- 3.2.1 Applicant: Pesticide Manufacture in China
- 3.2.2 General Procedure: manufacture approval — Manufacture Registration — Production Licensing

- 3.2.3 Requirements for Manufacture Approval: Technical Professionals, Producing Facilities, System for Safety and Health Control, System for Quality Control, Qualified Pollution Control Measures
- 3.2.4 Requirements for Production Licensing: Product Quality control compliance with Standards.

3.3 Pesticide Distribution and Sale

- 3.3.1 Distribution and Sale
Requirements: Technical Professionals, Place for Safe Storage, System for Safety and Health Control, System for Quality Control
- 3.3.2 Import and Export
Responsible Department: China Customs
Control Measures: Certificate for Registration in China issued by ICAMA is needed for customs clearance, except materials same to requested for common goods.
- 3.3.3 Advertisement Examination
Responsible Department: Provincial Administration of Agriculture
Standards to Follow: Guidelines for Advertisement Examination

3.4 Pesticide Application

- Good Application Practices are contained in the label of every single package; Guidelines for field application are available for public.
- Administration of Agriculture on county level is responsible for the guidance of field application for farmers.
- Pesticide suppliers are also responsible for guidance of field application for buyers.
- Chinese government has adopted a set of measures to reduce pesticide application, such as promoting professional pest control strategy.

4. Information Sharing

All information about pesticide registration, banned or restricted pesticides, pesticide management related matters, policy for pesticide management, etc. are all available on this official website: www.chinapesticide.gov.cn

The image shows the front cover of a book titled 'PESTISIDA PERTANIAN' (Agricultural Pesticides) by Yulia Purwanti. The cover has a green header with the logo of the Indonesian Ministry of Agriculture on the left and the Indonesian flag on the right. Below the header, the title 'PESTISIDA PERTANIAN' is written in large, bold, red capital letters, and 'Pesticide Regulatory in Indonesia' is written in smaller, blue capital letters. The author's name 'Yulia Purwanti' and her title 'Deputy Director for Pesticide' are centered in black text. The bottom section of the cover features a collage of six small images related to agriculture: a farmer spraying a field, a person in a white shirt, a green plant, a cow, a person in a yellow shirt, and a close-up of a plant.

1. GOVERNMENT LAW NO. 12/1992 ON CROP CULTIVATION SYSTEM
2. GOVERNMENT REGULATION NO. 7/1973, STATED THAT ALL PESTICIDES WHICH DISTRIBUTED, STORED AND COMMERCIALIZED IN INDONESIA SHALL BE REGISTERED AND HAVE PERMIT FROM MINISTER OF AGRICULTURE.
3. MINISTER OF AGRICULTURE DECREE NO. 24/2011, GUIDELINES AND REQUIREMENTS FOR PESTICIDE REGISTRATION.
4. MINISTER OF AGRICULTURE DECREE NO. 42/2007, PESTICIDE INSPECTION.
5. MINISTER OF AGRICULTURE DECREE NO. 642/2012, PESTICIDE COMMITTEE

[illegible]

Regulatory Process

I. PVP crop donors, Promoters & Agribased, Lower Cost / Cheap for smallholder farmers

II. PVP agribased facilities and technologies available to smallholder farmers

III. Technical Project (TTP)

IV. Pesticide Committee

MOA, MOF, MOE, MOT, MOI, MONPT, TE, AACC

PESTICIDE COMMITTEE
Under Ministry of Agriculture

Inter Ministries (±30 persons):

1. Ministry of Agriculture (MOA)
2. Ministry of Marine and Fishery (MOMF)
3. Ministry of Forestry (MOF)
4. Ministry of Health (MOH)
5. Agency for Food and Drugs Controlling (AFDC)
6. Ministry of Environment (MOE)
7. Ministry of Trade (MOT)
8. Ministry of Industry (MOI)
9. Ministry of Man Power & Transmigration (MOMPT)

❖ Technical Expert of Pesticide Committee (TE) → 11 people
detail in next slide

1. Expert on Insecticide evaluation from Bogor Agriculture University
2. Expert on Insecticide Toxicology from Gadjah Mada University
3. Expert on Vector Control from Research Institute for Vector Control – Ministry of Health
4. Expert on Fungicide Efficacy from Bogor Agriculture University
5. Expert on Herbicide Efficacy from SEAMEO BIOTROP
6. Expert on Chemistry from Indonesia Institute for Sciences
7. Expert on Public Hygiene from Indonesia University
8. Expert on Environment Toxicology from Bandung Institute of Technology
9. Expert on Public Hygiene from Bandung Institute of Technology
10. Representative from Agricultural Research Center (Ministry of Agriculture)
11. Deputy Director of Pesticide (Ministry of Agriculture)

The flowchart illustrates the New Drug Approval Process in India, starting with 'Application submission (documents)' and leading to the 'MOA Decree'. The process involves several steps, including administrative and technical checks, experimental use permit (EUP) issuance, chemical analysis, evaluation by PSP, sample sealing, efficacy/toxicity testing, expert team evaluation, and a pest committee meeting. Decision points for 'Reject/Pending' or 'Accepted' are shown at various stages. Timeframes for each step are indicated on the right, and a timeline of ±1.5-2 years is shown on the left. The final MOA Decree is noted as temporary (5 years) or permanent (renewed every 5 years). A note at the bottom states 'QUARTELY (every: Jan., April, July, Oct.)'.

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graph TD
    A[Application submission documents] --> B[Administrative aspect check by PVT&P]
    B --> C[Technical aspect check by PSP]
    C --> D[Experimental Use Permit EUP issued by PSP]
    C --> E[Reject/Pending -> letter issued]
    E --> A
    D --> F[Chemical analysis]
    F --> G[Evaluated by PSP]
    G --> H[Sample sealed & protocol approved by PSP]
    H --> I[Efficacy / toxicity test]
    I --> J[Evaluated by Expert Team of Pesticide Committee]
    J --> K[Approved]
    J --> L[Reject/Pending]
    K --> M[Pest Com-Plenary meeting]
    M --> N[MOA Decree]
    M --> O[Reject/Pending -> letter issued]
    N --> P[MOA Decree]
    P --> Q[QUARTELY every: Jan., April, July, Oct.]
  
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Application submission (documents)

Administrative aspect check by PVT&P

Technical aspect check by PSP

Experimental Use Permit (EUP), issued by PSP

Chemical analysis

By accredited laboratory

Evaluated by PSP

Sample sealed & protocol approved by PSP

Efficacy / toxicity test

By Independent Institution/University/ Government Research Institution

Evaluated by Expert Team of Pesticide Committee

Approved

Pest Com-Plenary meeting

MOA Decree

Reject/Pending → letter issued

Reject/Pending → letter issued

MOA Decree

QUARTELY (every: Jan., April, July, Oct.)

±1.5-2 years

±2-3 months

±2-3 months

±6-12 months

Depend on kind of crop/ type of trials

±4 months

Temporary permit – Permanent permit: re-new every 5 years

Registration

- ❑ Company document of registrant
- ❑ Six-Packs Toxicology Data
- ❑ Registration certificate (copy) from other countries
- ❑ Certificate of Origin, Appointment Letter, Guarantee supply, Manufacturing certificate
- ❑ Bio-efficacy report (local study): For Full Approval.
- ❑ Certificate of analysis: For EUP, Export & Technical Grade Registration
- ❑ Additional requirement for rice crop:
 - BPH
 - Fish toxicity study (Lab & Field): Insecticide, Fungicide, Herbicide
 - Bio-efficacy for target pest.
 - Beneficial insect/organism (Rice & Vegetable).
 - Natural Enemies



Pesticide Type of Usage

- ☐ Crop Protection
- ☐ Animal Husbandry
- ☐ Fishery
- ☐ Forestry
- ☐ Agricultural Product Storage
- ☐ Residential Area & Household Pesticides
 - for free sale as OTC (Over the Counter), additional permit on distribution from Ministry of Health is needed. Permit valid for 4 years.
- ☐ Quarantine and Pre--Shipment



Pesticide Classification

Base on the level of hazard pesticide:

A. Pesticide can be registered

- should qualify the purity levels of active ingredients that meet the specifications of SNI (Indonesian National Standard), FAO, WHO or other international bodies.

B. Prohibited pesticide

Base on the scope of use:

A. Pesticide for general use

B. Restricted pesticide



Criteria of Prohibited Pesticide

1. Pesticide formulation within class IA (very dangerous) or IB (dangerous) of WHO classification.
2. Active ingredient or other additive indicates carcinogenic, teratogenic or mutagenic (category I and IIA based on the classification of IARC) FAO, WHO, US-EPA & other provisions).



Criteria of Restricted Pesticide

- ☐ Pesticide formulation corrosives to eyes, causing irreversible damage to the ocular tissue, causing cornea shrinkage or irritate up to 7 days or more.
- ☐ Pesticide formulation corrosives to skin or causing severe irritation up to 72 hours or more.
- ☐ When used in accordance with the label directions, the pesticide cause significant toxicity either sub-chronic, chronic or delay effect to human.
- ☐ LC50 inhalation of active ingredient <0.05 mg/l for 4 hours of exposure.
- ☐ Ozone depleting substance.



Type of Registration Permit, Fee & Validity

A. EXPERIMENTAL USE PERMIT (EUP)

- ☐ EUP is given to prove the truth of claims (quality, efficacy & safety).
- ☐ Registration fee for EUP : ±200 USD*
- ☐ Registration fee for trial : ±1 500-7 500 USD* (depend on crop)
- ☐ Not allowed to make business activity (trading, promotion, etc.).
- ☐ Valid for 1 year, can be extended for 1 more year.

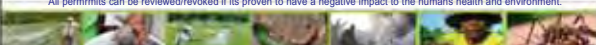
B. TEMPORARY PERMIT

- ☐ Permit is given if the pesticide has met some of requirements.
- ☐ Registration fee : ±600 USD*
- ☐ Allow to make business activity (production, distribution etc.) in limited quantity in accordance with crop registered, dose and application number.
- ☐ Valid for 1 year, can be extended for 1 more year.

C. PERMANENT PERMIT Note *: assumption 1 USD = 10.00 IDR

- ☐ Permit is given if meet the entire requirement for registration.
- ☐ Can be extended its use to other target/crop.
- ☐ Registration Fee : ±600 USD*
- ☐ Allow to sell, distribute & store the products (unlimited).
- ☐ Valid for 5 years, can be renewed every 5 years.

Note :
All permits can be reviewed/revoked if its proven to have a negative impact to the humans health and environment.



Requirement for Registration

Administrative Requirements:

- ☐ Registration can be done only by a company who has Indonesia legal entity.
- ☐ Submitting the company documents & other supporting documents (i.e.: deed of company establishment, trading business permit/trading registration certificate, tax registration number, Letter of company domicile, power of attorney, reg. authorization letter, guarante supply letter, reg. certificate from other countries).
- ☐ Pesticide Naming:
 - Consist of 3 elements: 1) trade name/technical material name, 2) active ingredient content, 3) type of formulation or type of technical material.
 - Has a proof of registration/trade mark registration certificate from authorized institution/Intellectual Property Right.
 - Not agitating: horrifying, imposing & super.



Technical Requirement

1. Quality of Pesticide

- ☐ Pesticide must meet purity level of active ingredients that meet the specification of SNI (Indonesia National Standard), FAO, WHO or other international bodies.
- ☐ Tolerance limit of the test result:

Active ingredient content (%)	Active ingredient content (g/l)	Tolerance limit
≥ 50	≥ 500	± 2.5 unit (%), ± 25 unit (g/l)
25 - < 50	250 - < 500	± 5 %
10 - < 25	100 - < 250	± 6 %
2.5 - < 10	25 - < 100	± 10 %
0 - < 2.5	0 - < 25	± 15 %

- ☐ Impurities content of paraquat technical should meet the tolerance limit → terpiridine: max 1 ppm; bipiridil: max 1 000 ppm.
- ☐ Emetic content in the paraquat formulation should meet the tolerance limit → min 0.4 ppm



Technical Requirement

2. Bio-Efficacy

- ☐ **Local bio-efficacy trial is mandatory** (1 unit, 1 season, 1 location). Trial protocol must follow the official guidance
- ☐ Minimum efficacy 70% for insecticide & 50% for fungicide, biomass of dry weeds must be significantly different with untreated one fro herbicide.
- ☐ Premix formulation (>1 ai in a pesticide formulation) must be proved there is no antagonism effect among the a.i. **Local test is mandatory.**
- ☐ Product Re Registration: every 10 years (even years: 10, 20, 30 years), Previously: must re do the bio-efficacy trial against at least 1 target pest in 1 crop.



Technical Requirement

3. Mammalian Toxicity

- Acute Toxicity for formulation:
 - LD50 oral (rat) : solid >50 mg/kg ; liquid >200 mg/kg
 - LD50 dermal (rat) : solid >100 mg/kg ; liquid >400 mg/kg QR
 - LD50 dermal (rabbit) : solid >200 mg/kg
 - LC50 inhalation of active ingredient (4 hours) ≥0.05 mg/l
 - No severe eye & skin irritation, no severe skin sensitization.
 - if the test method & research institute has been established.
- Chronic toxicity of active ingredient:
 - No effect on carcinogenic, teratogenic & mutagenic (IARC, FAO, WHO, US-EPA & other international bodies)



Technical Requirement

4. Environment Toxicity

- DT50 of active ingredient in soil <120 days for pesticide registered in agriculture ecosystem (food crops, horticulture & plantation).
- Fish Toxicity Test for pesticide registration in irrigated RICE or irrigated field. **Local test is mandatory** against 2 local species of freshwater fish.

Criteria of the fish toxicity test:

 - Fish toxicity in laboratory – for liquid & powder formulation:
 - Toxic unit >3 (harmful): not allowed to be registered.
 - Toxic unit 0.3-3.0 (slightly harmful): should be completed with field test.
 - Toxic unit <0.3 (harmless): will be given permanent permit.
 - Fish toxicity in the field – for granule formulation:
 - T50 (half life) >7 days → harmful – not allowed to be registered.
 - T50 (half life) <7 days → harmless – allowed to be registered.

5. Residue

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 the following crops:

Rice, maize, soybean, vegetables, edible fruits (with skin), crop for drink, agriculture product storage, fish culture & its product, drinks treated pesticide.



Technical Requirement

6. Resurgence againsts Brown Plant Hopper (BPH)

Insecticide will be registered in RICE must not induce & produce resurgence effect against BPH (*Nilaparvata lugens*). **Local test (laboratory & field) is mandatory & required for registration in all rice pests.**

7. Effect against stem borer's egg parasitoid is required for insecticide registration against all rice pests

8. Effect on the parasitoid of brassica's pest

Insecticide will be registered in brassica should be no negative effect vs *Diadegma semiclausum* (for >750 m above sea level) or *Cotesia plutelae* (for <750 m above sea level). **Local test is mandatory, can be done together with bio-efficacy trial.**

9. Effect on the larva parasitoid's *Spodoptera litura*

Insecticide will be registered should be no negative effect against larvae parasitoid of *Spodoptera litura*. **Local test is mandatory.**

10. Household Insecticide for All Type of Formulation

- Mosquito: must effective to control 2 genus of mosquito (*Aedes aegypti* & *Culex* sp.).
- Cockroach: must effective to control 2 kind of cockroach (*Blattella germanica* & *Periplaneta americana*).
- House fly, ants & others adjusted to applicant's claim.



Technical Requirement

- 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, lampion, net.
- Acute inhalation, chronic and sub chronic toxicity are **not required** for biopesticide, plant growth regulator, rodenticide, attractant/pheromone.
- Environment toxicity is **not required** for: household pesticide, vector control, veterinary/animal health, forestry, housing/wood preservative, transportation, quarantine/pre shipping, PGR, biopesticide, attractant/pheromone and rodenticide.



IMPORT/EXPORT PRODUCT

Via INSW portal:

A. Registered (have a permit)

→ should registered, can be registered as local use products or registered as a products for export.

A. Local use

B. Export only

B. Samples for development/registration purpose.

A. Limited quantity (<10 L + 5 Ha Accumulated treated area)

B. Should mention/submit the number of trials and the protocol.



Others Requirement on Import/Production

- Registrant that granted registration approval, at least within 1 (one) year must conduct import or production activities.
- Report on Import/Production must be completed with import/production document.
- Registrant that does not produce/import pesticide is registered and does not create report on production/import in 2 (two) consecutive years shall be liable to revocation of registration permit.
- Pesticide quality & information not in accordance with the requirement → Registration permit will be revoked.
- Grace period for Pesticide Withdrawal: 3 months after MoA decree released.
- Grace period for pesticide that are not being renewed, the license is legally expired: 6 months.



Registration Process & Flow

Advertising

- No Regulation on advertisement of Pesticide specifically
- Follow Code of Conduct by FAO

Transportation of Pesticide

- Not Regulate advertisement of Pesticide specifically
- Follow Code of Conduct by FAO

Information Sharing with the Public

- Publication of registered pesticide has renewal annually and deceminate to stakeholder.
- Publish via www.deptan.go.id



Labelling & Packaging of Pesticide

Mandatory information must be included in the label:

- Trade name of pesticide
- Type of pesticide
- Name & active ingredient content
- Content or net weight in packaging
- Safety warning
- Classification & hazard symbol
- Safety instruction
- Poisoning symptoms
- First aid
- Medical treatment
- Storage instruction
- Instruction of use
- Pictogram
- Registration number
- Name & adres of registration holder
- Batch number and expired date.
- Disposal guidance

Statement: **"READ THE LABEL BEFORE USE THIS PESTICIDE"**



Active Ingredients Banned

For All Uses

- 44 Products

For Household Pesticide

- Dichlorvos
- Chlorpyrifos

For Fishery

- Trichlorfon



Active Ingredients as Restricted Use Pesticide

No.	Chemical name	CAS Number	Use Field
1.	Aluminium phosphide	20859-73-8	Agriculture products storage
2.	Magnesium phosphide	12057-74-8	Agriculture products storage
3.	Methyl bromide	74-83-9	Quarantine & pre shipping
4.	Paraquat dichloride	1910-42-5	Crop Protection
5.	Zinc phosphide	1314-84-7	Crop Protection
6.	Sulfuril fluoride	2699-79-8	Agriculture products storage
7.	Diquat dibromide	2764-72-9	Crop Protection



Post-Registration Activities

1. Monitoring quality, monitoring illegal trade supervised by Sub-Directorate of Monitoring, in co-operation with others Department (Trade Department)
2. Environmental incident monitoring supervised by Ministry of Health
3. MRL establishment by country is on-going
4. Sharing information on pesticide regulatory matters (including IPM program and reduced pesticide risk) is published on website: www.deptan.go.id. Response from the public will be noted



Post-Registration Activities

1. Enforcement procedure by Sub-Directorate of Monitoring
2. Random check of quality analysis from available products in the market
3. Notification letter based on the field assesment and recommendation in the Plenary meeting
4. All registered, banned and restricted pesticides stored in Pesticide Management Information System data base



Notification Information from Overseas

1. Notification of final regulatory action and PIC procedure in compliance with Rotterdam Convention
 - Still in preparation process
2. In compliance with Stockholm Convention
 - Starting to implement with the baned active ingredient
3. In compliance with Montreal Protocol
 - Implemented accordingly
4. FAO Code of Conduct in Pesticide was not implemented yet
5. Residue and Monitoring input is still under preparation phase



Infrastructure and Human Capacity

Number of Qualified Personnel for Pesticide Registration

Pesticide Registration

☐ 12 people

Pesticide Monitoring

☐ 12 People

Quality control & Residue Monitoring, Trained Toxicologist

☐ None

Post-Registration Activities

☐ None



Assessment of Status of Pesticide Regulatory Management

1. Rotterdam Convention
 - Still in preparation process
2. In compliance with Stockholm Convention
 - Starting to implement with the banned active ingredient
3. In compliance with Montreal Protocol
 - Implemented accordingly
4. FAO Code of Conduct in Pesticide was not implemented yet
5. MRL establishment is still under preparation phase



Assessment of Status of Pesticide Regulatory Management

1. Constrains and Difficulties
 - Limited trained human resources
2. Recommendation
 - Training for expertise Regulatory People incorporated with international organization



Thank you

Pesticide Regulation System in Japan

Masashi Kusakawa
Agricultural Chemicals Office
Plant Production Safety Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture, Forestry and Fisheries

Contents

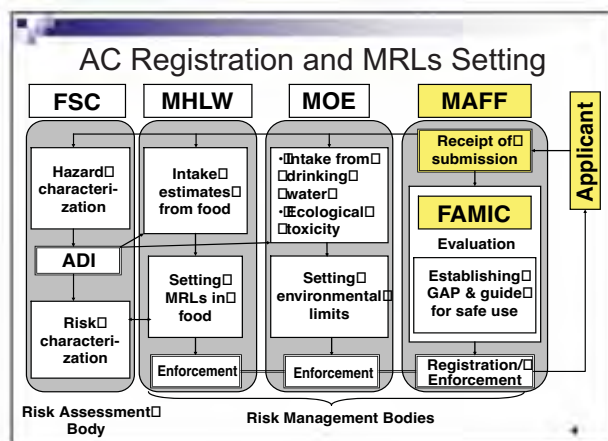
- ◆ Pesticide regulation system in Japan
 - Registration system
 - Post-registration activities/enforcement
- ◆ Reform of the registration system

Scope of "Pesticides" under the Law

Pesticides are used on "crops"
Incl. flower, tree, lawn, hay & grass

Protection against insects, disease, weeds and animals	Regulation of physiological functions of crops	Natural enemies
• Insecticide • Fungicide • Herbicide • Rodenticide • Repellent • Communication disruptor, etc.	• Growth promotion of fruit (for seedless fruits) • Root stimulator • Suppression of stem growth/ripening, etc.	Parasitic bee, Ladybug, etc.

Current Registration System



Required Data for Registration (1)

- ◆ Characterization of the formulation
 - Active ingredient & other ingredient (content, method of analysis)
 - Physical and chemical properties
 - Specification & samples (technical grade, formulation(s))
 - Stability
- ◆ Efficacy/Phytotoxicity
 - Field test results (>6 trials for major crops, >2 trials for minor uses)

Required Data for Registration (2)

- ◆ Safety
 - Toxicity (acute/sub-chronic/chronic toxicity, carcinogenicity, neurotoxicity, teratogenicity, mutagenicity, irritation, etc.)
 - Plant/animal metabolism
 - Residues in crops
 - Environmental fate (soil, water)
 - Ecological toxicity (small carp, water flea, algae)
- ◆ Use Pattern (GAP)

Required Data for Registration (3)

~ for microbial pesticides ~

- ◆ Specific Requirements
 - Biological characterization of the micro-organism
 - Single intravenous administration study
 - Cell culture study (for viral pesticides) ..., etc.
- ◆ Exemptions
 - Repeated dose (long-term)
 - Crop residue (if no adverse health effect expected)
 - Effects on non-target organisms (if adverse effects can be ruled out or exposure is unlikely) ..., etc.

Examples of MRL in Foods in Japan

◆ Pesticide A

Commodities	MRL (ppm)	Notes
Rice	0.5	
Tea	—	0.01 ppm provided that LOQ not higher than this is reasonably achievable
Milk	0.2	
Freshwater clam	0.2	Only if the pesticide accumulates in freshwater fishes

MRLs for Foods in Japan

- ◆ Responsibility of MHLW
- ◆ “Positive List”: pesticide/commodity combination to be tested
- ◆ Based on the results of supervised residue trials designed in accordance with GAP
- ◆ Harmonization with Codex MRLs as much as possible
- ◆ Portions to which MRLs apply are not the same as Codex MRLs

MRLs for Feeds and Foods of Animal Origin

- ◆ MRLs for feeds
 - Under the responsibility of MAFF
 - Estimated in the same manner as those for foods of plant origin
- ◆ MRLs for foods of animal origin
 - Estimated by MAFF following the JMPR method
 - Using the animal feeding table and residue concentrations in Japan
 - Submitted to MHLW for legalization

Post-registration Activities/ Enforcement

Label of Registered AC

- ◆ Manufacturers must indicate the following on the label of each container of registered AC formulation:
 - License number
 - Name (Common, Trade)
 - Contents of A.I.
 - Name and address of the manufacturer
 - Methods of application (GAP)
 - Guide for safe use & storage of AC

Examples of GAP

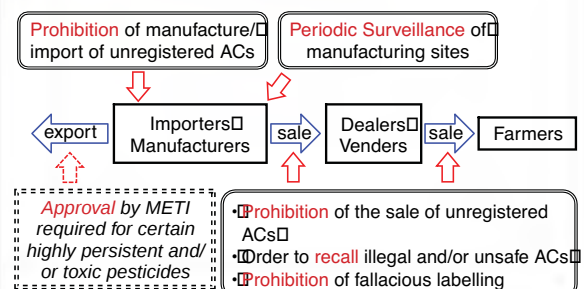
Emulsion

Crop	Target insects	Spray conc. (dilution fold)	PHI (day)	No. of appl.	Appl. method
Cabbage	Aphids, Cabbage moth	1 000	30	2	Foliar
	Green caterpillar	1 500			
Tomato	Aphids, Spider mites	1 000	1	2	Foliar

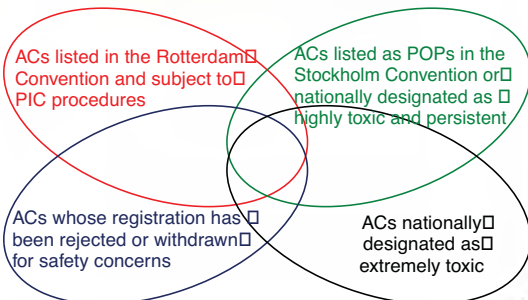
Examples of Guide for Safety Use

- ◆ When using in paddy fields, stop the flow of irrigation water for at least 7 days after application in order to avoid contamination of canal/river water.
- ◆ Do not use sprayed rice straw as feed.
- ◆ Do not harvest baby leaves as vegetables. (for certain ACs applied at or immediately after seeding)
- ◆ Take measures to reduce spray drift when used in areas of beekeeping.

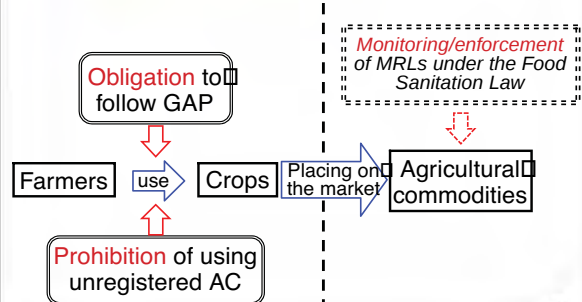
Regulations of Agricultural Chemicals (ACs) under the AC Regulation Law (1)



ACs whose Export is subject to Approval by Minister for Economy, Trade and Industry



Regulations of Agricultural Chemicals (ACs) under the AC Regulation Law (2)



Reformation of the Registration System

Historical Background of the AC Regulation Law

- Established in 1948 in order to prevent the distribution of ineffective and/or harmful pesticides (← growing demand for pesticides to feed the population after the WWII)
- Several amendments have been made to address risks against human health and the environment

Historical Background of the AC Regulation Law (continued)

- Major revisions
 - 1971
 - Data requirement for toxicity and residues
 - Regulation of persistent ACs (rejection of registration, restriction for use, etc.)
 - 2002
 - Prohibition of the use of unregistered pesticides
 - Legal obligation to comply with the GAP

Stocktaking of the Registration System

- Consultative review process (2007 ~) to identify issues and propose new approaches
- Involvement of various stakeholders:
 - Pesticide industry (manufacturer/distributor)
 - Plant protection specialists
 - Farmer organization
 - Consumer organization

Underlying Principles of the Review Process

- Rule-based & hazard-based → risk-based
 - Decision-making on the basis of scientific data and information taking into account magnitude of risk
- Participation in international rule-making in Codex Alimentarius Commission, OECD, etc.
- Harmonization with these rules
- Transparent decision-making through risk communication with all stakeholders

Identified Issues requiring Actions (1)

~ Data for evaluating risks of pesticide residues ~

- Number and quality of supervised residue trials
- Rotational crop studies
- Processing studies
- Metabolism and feeding studies on livestock

Identified Issues requiring Actions (2)

~ Effects to be evaluated ~

1. Health effects of short-term intake of pesticides (ARfD and NESTI)
2. Health risks to operators (Quantitatively based on AOEL and exposure model)
3. Adverse effects on by-standers

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Identified Issues requiring Actions (3)

~ Taking in updated scientific data/knowledge ~

Periodic reevaluation of registered ACs:

- ☐ review of all data submitted in accordance with the requirements at the time of reevaluation
- ☐ not renewal or extension of the registration

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Concrete Actions (highlights)

1. Increasing the number of supervised residue trials
2. Requirement for animal metabolism and transfer studies
3. Quantitative assessment of health risks to operators and bystanders
4. Procedural harmonization

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Number and Quality of Supervised Residue Trials

~ Comparison of Requirements ~

	JMPR	EU	USA	Japan
No. of trials (Major crop)	6-10	16 for 2 zones	8-20	2 or more
GLP	O1	O	O	O2

NB 1: GLP principles or in compliance with national regulations ensuring the quality of residue data.
2: Started in April 2008 and full compliance required from April 2011.

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Increasing the No. of Supervised Field Trials

~ *Considerations* ~

- ◆ Need for 7-8 trials for estimating NESTI and setting MRLs
- ◆ Agricultural, geographical and climatic conditions variable from north to south
- ◆ Number of test sites not sufficient
- ◆ Possibility of using trial data from other countries with the same GAP for registration
- ◆ Possibility of conducting trials in other countries with similar GAP

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Supervised Residue Trials ~ *Agreed New Approach* ~

- ◆ Increase of No. of trials (2014~)
 - ☐ Major crops 6 trials
 - ☐ Semi-major crops 3 trials
 - ☐ Minor crops 2 trials
- ◆ Burdens of the increase might be relieved by:
 - ☐ Development of crop groups (ongoing)
 - ☐ Accepting data on indoor trials conducted in other countries (same GAP)
- ◆ Harmonization of portions analyzed (2014~)
- ◆ Quality assurance of analysis (2011~)

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Ongoing Work on Crop Groups

- ◆ Development of Crop Groups
 - ☐ Based on the Codex Classification
 - ☐ Reflecting the commodities in Japan
 - ☐ Harmonization of portions to be analyzed with those of Codex
 - ☐ Accompanied by the selection of "representative crops" for each group for MRL setting and registration (No. of residue trials per each representative crop to be determined)
 - ☐ To be published in a stepwise manner

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Metabolism and Feeding Studies on Livestock

~ *Current Status* ~

- ◆ Metabolism study with livestock so far not required
- ◆ Feeding study required only on excretion in milk but not on residues in meat/eggs



Insufficient information for the definition of residue and establishment of MRLs in livestock products

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Animal Metabolism/Transfer Studies

~ *Agreed New Approach* ~

- ◆ Test Guidelines to be published soon
 - Required in principle for *new active ingredients* whenever residues are detectable on feed crops
 - For *registered ACs*, data submission prioritized taking account of maximum theoretical dietary burden and fat-solubility
- ◆ Animal Feeding Table already established and provided to OECD

Health Risk to Operators/Bystanders

~ *Current Status* ~

- ◆ Personal protective equipment for operators is selected largely by hazard-based assessment (e.g. toxicity of the AI)
- ◆ No operator-specific safety indicators taking account of inhalation and dermal exposure
- ◆ For the safety of bystanders, general “guidance” to reduce spray drift and to inform nearby residents well in advance

Health Risk to Operators/Bystanders

~ *Ongoing Activities* ~

- ◆ Measurement of pesticides on body surfaces and in the inhaled air (field study) for the purpose of modeling operator exposure
- ◆ Establishment of the protocol to derive acceptable operator exposure levels (AOELs)

Procedural Harmonization

~ *Ongoing Activities* ~

- ◆ Change in procedures:
 - Acceptance of application documents in OECD dossier format
 - Acceptance of electronic files
 - Acceptance of study reports in English (Summary dossier in Japanese)
 - Preparation of evaluation report for each AI (first report published on-line in September 2012): for increased transparency
- ◆ Education and training of evaluators

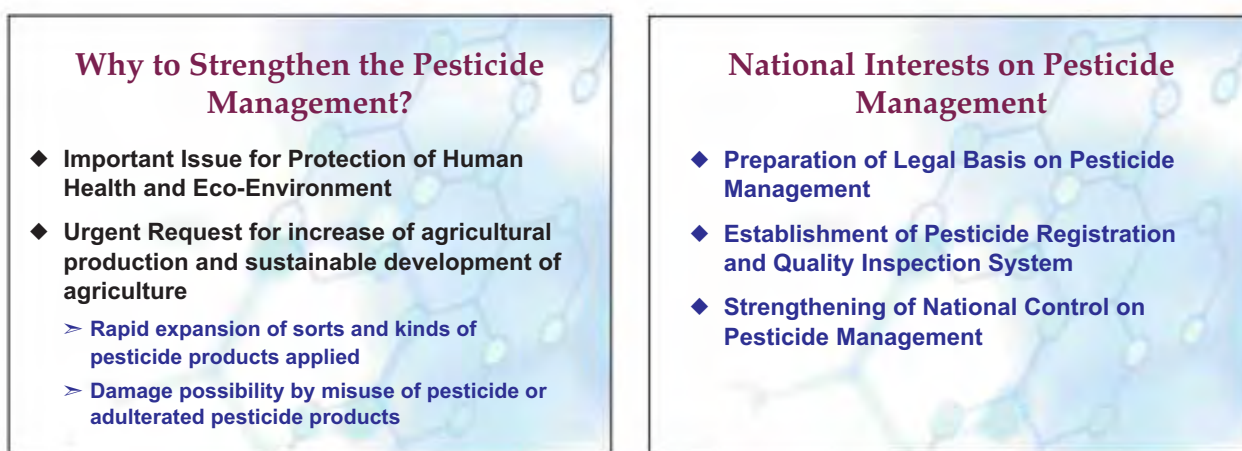
3.6 KOREA, DPR

Report on the Pesticide Regulatory Management

Health and environmental problems due to the use of different chemicals including pesticides are being seriously raised around world not in individual country or region, and one of the considerable solutions for them is to improve the pesticide management.

The pesticide management in Korea, DPR is done under the coordinated plan and leadership of the country, making it a principle to contribute to the protection of human health and environment and satisfy the qualitative and quantitative requirements of people to agricultural products.

This report is outlining the status of pesticide management in Korea, DPR including the legislations on pesticide management and their implementation.



1. Pesticide legislations and regulations in Korea, DPR

The main legislation for environment protection in Korea, DPR is “The Law of the Korea, DPR on the Protection of Environment” (9 April 1986).

It points out clearly the principles and activities needed to conserve, protect and improve the country’s environment, and to minimize any negative effects to human health or economic development due to the destruction and pollution of environment.

It was amended and renewed several times after its adoption, considering the contents of some international agreements and codes on the protection of ecological environment and safe management of chemicals (e.g. FAO Code of Conduct, Rotterdam Convention, Stockholm Convention, Basel Convention, Montreal Protocol and SAICM etc.).

The other legislations concerned with the management of chemical including pesticides are “Law on Land”, “Law on Rivers”, “Law on Agriculture”, “Law on Pomiculture”, “Law on Fish Breeding”, “Law on Quality Control”, “Law on the Conservation of Biodiversity” and “Law on Public Health”, and the articles to regulate a hazard pesticides and protect the health of persons treating or managing pesticides and ecological environment are included in these legislations.

The regulation for pesticide management is “Regulation on Pesticide Management in Korea, DPR” adopted in 1993. It was the first regulation to ensure the safe and effective use of pesticides by establishing system and order in production, distribution, use, storage and handling of pesticides.

Since 1990’s, there have been some changes in pesticide management such as decrease of pesticide production, increase of import amount and expansion of sorts and kinds of pesticide products applied, in the country, and the international requirement for safe management of pesticide has also been gotten stronger.

It has made the government do the work to prepare new legal mechanism needed for intensifying the management of pesticides and hazard chemicals, corresponding to international agreements including Rotterdam Convention, Stockholm Convention, Basel Convention, Montreal Protocol and SAICM.

Therefore, “Regulation on Pesticide Management” (Dec. 23rd, 2005) was amended, “Law on Pesticides in Korea, DPR” (Aug. 23rd, 2006) (further referred to as the Law on Pesticides) was adopted, “Enforcement Regulation of Law on Pesticides in Korea, DPR” (Aug. 6th, 2007) (further referred to as the Enforcement Regulation) and “Detailed Rule for Enforcement Regulation of Law on Pesticides in Korea, DPR” (Dec. 11th, 2007) (further referred to as the Detailed rule) were enacted. And “Regulation on Handling of Substances with Toxicity in Korea, DPR” (Jan. 2006) was enacted to intensify the control for toxic chemicals and pesticides.

The issues on the production, distribution, import/export, storage, use, registration and inspection of pesticides as well as the legal assurance for effectiveness, efficiency and safety in pesticide management are clearly mentioned in these legislations.

The pesticide management in Korea, DPR is held and guided by the Ministry of Agriculture in a unified way, and the inspection of pesticides is being carried out by the Agro-chemicalization Research Institute, according to the pesticide legislations.

The Agro-chemicalization Research Institute is responsible for inspecting the quality and bio-efficacy, preparing drafts or amendments of pesticide legislations, disseminating techniques on pesticide management and training persons, under the assignment of the Cabinet.

Upon the pesticide legislation, the procedures for registration and inspection of pesticides have been established and many pesticide products which were developed and manufactured domestically were registered newly.

The most important step for registration of pesticides is review and technical evaluation of application carried out in the Scientific and Technical Review Committee of Agro-chemicals Sector. The committee does the evaluation of the dossiers in its scheduled or un-scheduled review and submits the passed applications to the registration committee for registration.

The final decision for registration of pesticides is under the responsibility of the Consideration Committee for Introduction of Agricultural Sciences and Technologies.

The registration of pesticides is done in the Pesticide Board of Ministry of Agriculture, and the board informs the results of registration to applicants and issues the Pesticide Registration Certificate.

The registration of pesticide is completed only by passing the standard review procedure that is applied not only to pesticides but to all products.

The standard design and registration of pesticides are necessary and primary condition for their production, distribution and use in the country. In common with other, the standard design of pesticides is under the responsibility of the Standard Institute of the National Quality Supervision Committee.

The export and import of pesticide is strictly controlled in Korea, DPR.

Article 27 of the Law on Pesticides points out as follows;

“Any organizations, enterprises and units that are going to export or import pesticides have to get an acceptance from the central agriculture guidance organization. The inspection and quarantine organs should not make any pesticides without the acceptance pass through.”

And article 43 of the Law on Pesticides points out that, in the case of production, distribution, use, export or import of pesticides without inspection and registration, the action will be discontinued or the pesticides will be confiscated.

According to these, the detailed articles to regulate the export and import of pesticides have been mentioned in the Enforcement Regulation and Detailed Rule, and also the administrative procedure was built to implement them.

It is indicated that the state shall develop the exchange and cooperation with other countries and international organizations in the field of pesticide management, in article 7 of the Law on Pesticides.

Korea, DPR is a party of the main international agreements for protection of environment including Rotterdam Convention, Stockholm Convention, Basel Convention and Montreal Protocol, and the government is implementing its duty as a party.

The implementation of these international agreements is being done under the unified leadership of the cabinet, including not only the administrative organizations like the State Planning Committee, the National Quality Supervision Committee, the Ministry of Land and Environment Protection, the Ministry of Chemical Industry, the Ministry of Agriculture, the Ministry of Public Health, the Ministry of Electricity Industry, the Ministry of Machinery Industry, the Ministry of Metal Industry and Bureau of Customs but also scientific research institutes.

The development, introduction, production and use of biopesticides for agriculture and public health are widely encouraged and recognized as one of the important means for especially organic farming system by ring-type circulation agricultural production.

In article 5 of the Law on Pesticides, it is indicated that the state shall store and manage pesticides to match with their characteristics and encourage the use of biopesticides.

So the regulation on the botanical pesticides and micro-organism pesticides is less strong than that on chemical pesticides, and some biopesticides like plant-incorporated-protectants (e.g. Bt. in genetically modified plants) are not regulated by the pesticide legislations at present.

For example, the Detailed Rule is prescribing the botanical pesticides to be produced and used on the basis of regional technical condition in consonance with the realities of the region. This regulative alleviating measure is actively promoting the development and, production and use of botanical pesticides, and now 10 botanical pesticides have been nationally registered.

The advertisement of pesticides is being done concentrating to introduction for their effectiveness and safety, on the basis of sufficient scientific and technical data. The abuse of baseless data for only commercial purpose and excessive incitement to consumption appetite are not encouraged and regulated by legislations.

It regulated that the transport of pesticides should be done in the condition of acquiring a permit on pesticide transport and accompanied with a qualified person in Korea, DPR. (Article 30 of the Detailed Rule)

And the pesticides have not to be transported with other goods, especially foods, and it is required that necessary protection measure is taken in advance.

Legislations on Pesticide

- ◆ «The Law on Environment Protection»
(adopted on April 1984)
- ◆ «Regulation on Pesticide Management»
(enacted on 1993, and revised on 2005)
- ◆ «The Law on Pesticide»
(adopted on Aug. 2006)
- ◆ «Enforcement Regulation of Law on Pesticides»
(enacted on Aug. 2007)
- ◆ «Detailed Rule for Enforcement Regulation of Law on Pesticides»
(exhibited on Dec. 2007)
- ◆ «Regulation on Handling of Toxic Substances»
(enacted on Jan. 2006)

Scope of the Legislations

- Regulation of Pesticide Production
(Article 21–24, the law on pesticide)
- Controlling the Export/Import of Pesticide
(Article 27, the law on pesticides)
- Implementation of International Agreements on Pesticide
(Article 7 and 18, the law on pesticide)
- Development and Introduction of Biopesticides
(Article 5, the law on pesticide)
- Storage, Transportation and Use of Pesticide
(Article 26 and 28–38, the law on pesticide)

2. Registration application and data requirement

A lot of data are required for registration of pesticides in Korea, DPR.

The following is pointed out in article 15 of the Law on Pesticides;

“The registration of pesticides is done by the central agriculture guidance organization. Organizations, enterprises, units and citizens who want registration of pesticides should submit application document for registration to the central agriculture guidance organization. The document must include the name and address of applicant and reason for registration, and enclosed with pesticide inspection document and sample.”

The pesticide inspection documents required by the legislations have to cover all test data concerning the pesticides. The physico-chemical properties, toxicity, bio-efficacy and residues in food are the most important data required firstly for pesticide registration. These data should be originated from the nationally accredited research institutes or inspection institutes, through direct tests of themselves or their identification. The qualified institutes are Agro-chemicalization Research Institute of AAS, Plant Protection Research Institute of AAS, Central Hygienic and Anti-epidemic Institute, Hygienic Research Institute of Academy of Medical Sciences and so on.

And data concerning with the residues and fate in environment and human health exposure, should be examined in the Environment Protection Research Institute in the Ministry of Land and Environment Protection and the Industrial Medical Research Institute of the Academy of Medical Sciences.

The pesticide label has to be in the application document according to the Detailed Rule, with data including name of pesticide, contents of active ingredient(s), capacity of package, production date, name of manufacturer, expire date, toxicity classification, warning and use description in it.

The level of data requirement for registration of botanical pesticides and/or micro-organism pesticides is fairly low comparing with chemical pesticides.

Especially, in the case of plant extracts, physico-chemical property, bio-efficacy, attention in handling and label are required at the minimum for national registration, and the products developed and used in individual region or unit for their own consumption are not requested for submission of data except bio-efficacy and use safety.

The requirement data for registration of botanical pesticides and microbial pesticides is not strong as that of chemical pesticides, but the necessary data like bio-efficacy, toxicity, residual property, adverse effect, and hazard have to be provided.

The toxicological assessment of pesticides applied for registration has to be done in the nationally accredited examination institutes, or in the case of that the tests were done on applicant's own, the results and toxicology testing protocols should be submitted to the examination institutes to be evaluated.

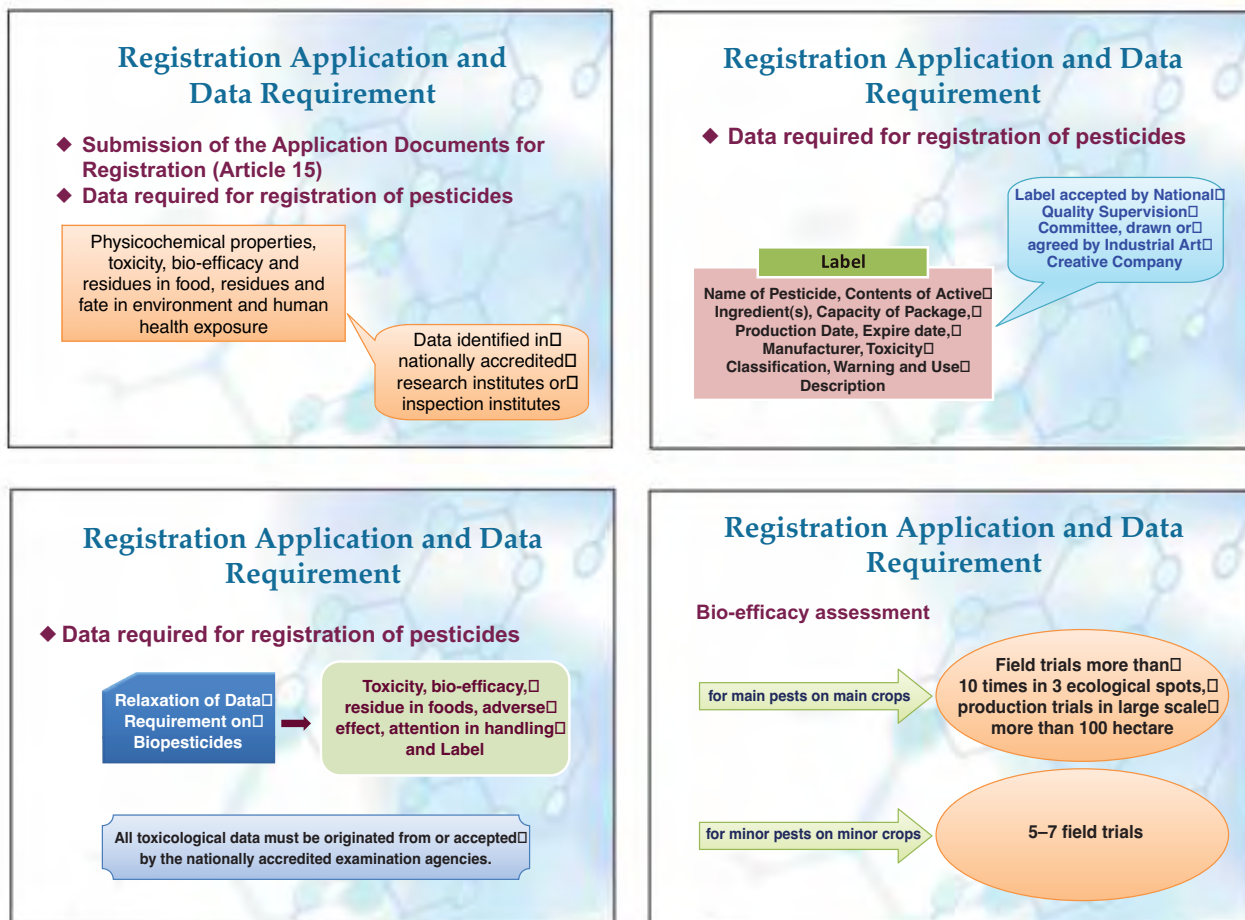
The field trials for bio-efficacy assessment of pesticides for major pests on major crops should be done in at least 3 ecological spots for totally more than 10 times including production trials in 100 hectare scale, and the bio-efficacy data of pesticides for minor pests on minor crops should be acquired from 5-7 field trials.

The examination of bio-efficacy of pesticides has to be done in the nationally accredited examination institutes (Agro-chemicalization Research Institute, Plant Protection Research Institute or Central Plant Quarantine Institute), or in the case of that the examinations were done on applicant's own, the results and testing protocols should be submitted to the examination institutes to be evaluated, and then the pesticide must be under minimum inspection by the examination institutes.

The labels of pesticides applied for registration should include necessary data on the design drawn in or agreed with the Industrial Art Creative Company, and especially is requested to be marked with red letter-“Poison”.

The label of pesticide has to be accepted by the National Quality Supervision Committee, and in the case of that the label is designed on applicant's own, it must be certified by the Industrial Art Creative Company for that it meets the norm for pesticide label design and is drawn not to attract children.

All above are the minimum and necessary data required for registration of pesticides.



3. Technical evaluation of application dossiers

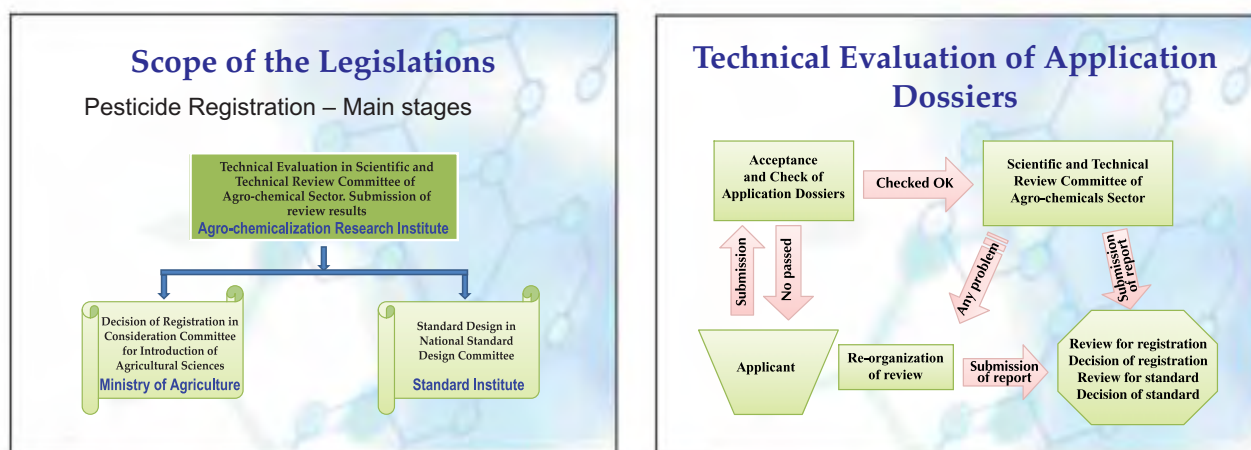
The application documents for registration are submitted to the Scientific and Technical Review Committee of Agrochemicals Sector which carries out the mission of technical committee, for technical evaluation of them.

Before review, officers in the committee check the completeness of the documents according to the regulated format and enclosure of necessities including experiment documents, and send back the application documents to applicants to be corrected and added.

The document for first registration has to include sufficient data needed for registration of pesticide, and the document for supplementary registration or re-registration has to include new information and basis of supplementary registration or re-registration. And the cancel of registration of severely hazard pesticides has to be accompanied with data of their effects on environment and public health, accident data and proposals of less risk alternatives.

The scientific and technical review on pesticides applied for registration covers data and methods of bio-efficacy examination, toxicity data and assessment methods, exposure data and assessment methods, and analysis data and method, comprehensively.

The proposals passed through the scientific and technical review are sent to the Ministry of Agriculture for registration review, and the other proposals not passed are sent back to applicants.



4. Pesticide registration and licensing

The article 17 of the Law on Pesticides points out as follows;

“The central agriculture guidance organization shall make a decision for registration or rejection after receiving and reviewing the application documents for registration. For this, the organization can ask the other institutes data provision and/or analysis, otherwise let experts participate in the review. It has to inform the results of registration review to applicants (organizations, enterprises, units and citizens).”

Via the review in the technical committee, the application documents for registration are sent to the Consideration Committee for Introduction of Agricultural Sciences and Technologies which plays a role of the registration committee to go through consideration for registration decision.

The registration committee considers and checks the review results of the technical committee and other necessary data to make decisions for pre-registration, provisional registration, full registration, supplementary registration, re-registration renewal of registration and cancel of registration.

The results on decision or rejection of registration are informed to applicants, and applicants can appeal to the committee in written statement in 180 days after the decision, for any objection to the decision.

The lengths of the validity period for registration are 1 year for provisional registration, 4-5 years for full registration, 1 year for conditional registration with restriction and 4-5 years for re-registration or renewal of registration.

The production and export/import can be permitted for the registered pesticides.

The following is indicated in the article 10 of the Detailed Rule;

“To do exactly the inspection and registration is necessary requirement for preventing possible accident by pesticides and assuring the safety of pesticides. Organization, enterprises and citizens that want to produce, export/import and use pesticides have to get the inspection and registration of pesticides.”

The production of pesticides can be done only for registered pesticides, under the condition of gaining agreement with the Ministry of Agriculture and the Ministry of Chemical Industry and approval from the State Planning Commission. But some biopesticides like botanical extracts can be produced on the basis of regional technical condition and used in consonance with the realities of the region.

The import of pesticides can be licensed by gaining agreement, ratification and approval in several steps. (Article 32 and 33 of the Detailed Rule)

Anybody to import pesticides gains an agreement with the Ministry of Agriculture and approval from the State planning Commission, first of all.

And it gains ratification from the Department of People's Security according to the Regulation on Handling of Substances with Toxicity and also gets agreement with the Ministry of Land and Environment Protection and the Ministry of Public Health in the case of problem for environment or public health. And then with agreement, approval and ratification of the Ministry of Trade, the National Quality Supervision Committee and the Bureau of Customs, the import of pesticides can be realized. All imported pesticides are analyzed in the Agrochemicalization Research Institute to enter distribution net. The distribution and sale can be done only in units that the government points specially, in the condition equipped sufficiently.

The pesticide registration organization will be responsible for protection of data in application documents according to requirement of applicants for 5 years.

5. Post-registration activities

The pesticide management in Korea, DPR is done through monitoring, controlling and reporting activities after registration of pesticides.

All pesticides produced, imported, exported and distributed in Korea, DPR pass through the quality control processes.

Concerning with the rapid development of pesticide industry, increase of the sorts of pesticide products and flow of sub-standard and adulterated pesticides in recent years, some difficulties and problems are raised in the quality control of pesticide products. Difference in quality of some pesticides from their label data makes the quality analysis not be carried out in time and bring disturbances to the use of pesticides, and sometimes the analysis of special pesticides isn't done because of lack of means and methods for analysis.

To minimize the possible accident and damage in the country, all pesticides which are going to be imported are requested to be passed quality control processes including analysis and experiment for their sample before import, although they have registered already and their constitution and bio-efficacy have been recognized, according to the legislations on pesticides.

The quality of pesticides produced domestically is controlled by the quality inspection agencies, and for low quality products, their production, distribution and use are stopped.

Violation of law like production of unregistered pesticides, production of pesticides without license and import of banned pesticides has not been reported.

The storage, transport and distribution of pesticides are normally monitored by the people's security agencies and other controlling agencies, and some public units participate in these activities, too.

The monitoring of illegal trade in pesticides is being performed by not only the customs and people's security agencies but also popular activities. Illegal trade of pesticides in small scale is expected, but not reported officially. No data for trans-boundary movement of hazardous wastes have been reported.

All policies in Korea, DPR are put into operation on the basis of principle to protect the lives and properties of the people and improve the people's health and living environment.

To protect human health and environment from the pesticides, the government has mentioned the clauses to restrict the production, treatment and use of hazard chemicals like pesticides and to protect the people treating the substances, in the national laws including "Law on Public Health", "Law on Protection of Environment" and "Law on Pesticides", and is requesting to implement the legislations thoroughly.

Article 36 of the Law on Pesticides points out as follows;

"Organization, Enterprises and citizens have not to let pesticides go into sea, river, lake or well. The containers and tools used with pesticides can not be washed in river, lake, water and somewhere like them."

Poisoning problems arising from exposure to pesticides in producers and users are under responsibility of the Industrial Medical Science Research Institute. The occupational poisoning cases have been not reported

seriously among pesticide producers or user, up to now. Although there have not been the acute poisoning phenomena by pesticides, it is expected that the chronic poisoning among people who have treated pesticides for a long time, can be occurred, so precautionary measures for that are being taken timely. All hospitals and clinics in every rural area of the country have the medical workers responsible for precaution and treatment of pesticide poisoning, and there are chemical poisoning treatment centres in hospitals of the big chemical factories including pesticide factories. Besides these rural clinics and poisoning centres, all hospitals have been prepared with technical capacities to treat specially the pesticide poisoning and the precaution examination to pesticide producers and users is being done regularly.

There is no national problem on environmental pollution presented by pesticide application. But, according to some investigation, it is evaluated that the population of aquatic organisms including fishes or frogs in paddy lands and streams is being decreased because of wrong use of pesticides and the surrounding soils of pesticide factories were polluted fairly. The issues on pollution and prevention of environment by toxic substances including pesticides and are under the responsibility of the Ministry of Land and Environment Protection, and the Research Centre of Environment Protection carries out the investigation and research for them. Regional environment monitoring posts were established to perform regular monitoring to environmental problems by pesticides.

The pesticide residues in foods and agricultural products in the country are restricted till permitted limits, and the limits coincide with the MRLs regulated by WHO. The analysis and monitoring to the residues in foods are being carried out by the Hygienic Research Institute and quality control agencies, but the national application level of pesticides is very low relatively comparing with world level, so almost no problems on pesticide residue in food and agricultural products are presented from the view of their resources.

The results of monitoring to residues in food and environment are reported to the pesticide registration committee through relevant ministries.

The government of Korea, DPR is actively trying to carry out its duty as a party of international agreements on environment and chemical management including Rotterdam Convention.

To implement Montreal Protocol, the government fully stopped the production and use of methyl bromide (MB) in 1999, and then the production and use of Carbon Tetra Chloride (CTC) which had been used for agricultural production and storage of cereals, and prohibited them with introduction of other alternatives, so completed the implementation of protocol in agriculture sector.

To fulfill the duty under the Rotterdam Convention, DNA has transmitted to the secretariat response concerning the future import for 30 pesticides among total 32 pesticides and is preparing to submit final regulation measures to pesticides to the Secretariat. DNA contacts with DNAs or other responsible agencies of exporting countries to import chemicals which are in Annex III but consent to import, to explain why to import and get approval of export. (e.g. Import of Monocrotophos from China, May 2004)

The National Implementation Plans for Stockholm Convention and Basel Convention have been prepared, and many activities are being played to perform the plans designed for SAICM implementation.

The government of Korea, DPR has officially expressed IPM policies in agricultural production from long time ago.

The government presented the agriculture policy to ensure the sustainable agricultural production by keeping the population of pests less than the threshold with applying all possible means controlling pests including farm-technological way, biological way, biotechnological way and physical way as well decreasing the use of chemical pesticides or using pesticides safe to eco-environment, and is paying special concerns to the realization of the strategy.

Since 1990's, the government has presented tasks for the Ministry of Agriculture and the Academy of Agricultural Sciences to play leading role in realizing the IPM strategy. The main research institutes for IPM are Plant Protection Research Institute, Agrochemicalization Research Institute and Plant Protection Laboratories in Provincial Branches of Academy of Agricultural Sciences, and administrative and economic works are under responsibility of the Ministry of Agriculture.

Nowadays, to develop the IPM Plan and accelerate the public participation like farmers and dissemination units, the government designs and plays many activities such as organization of new research institute and administration structure, concentration fund on IPM, dissemination of science and technologies on IPM through mass communication medium and strengthening of technical cooperation with international organization and advanced countries and so on.

The priority of IPM in the country is paying to the integrated management of main insects like rice stem borer, rice water weevil, maize stem borer, army worm, aphids damaging rice, maize and main leaf vegetables such as Korean cabbage.

The works to fix the thresholds of pests for leaf-vegetables, rice and maize and realize the integrated management for them for many years have been done by the Academy of Agricultural Sciences. During the time, many successes and experiences have been integrated, and on the basis of them, IPM protocols were prepared as one of the means to accelerate IPM dissemination. IPM works are being activated more and more in combination with ring-type circulation organic farming system. With this, many scientific and technical successes including seed coating technology and new pesticide products with less risk are applied to contribute for enhancing the effectiveness of pesticides and decreasing the dose of pesticides.

The all post-registration activities are playing a proper role in assuring the safe and effective use of pesticides legally, administratively and scientifically and minimizing possible adverse effect of pesticides to human health and environment.

6. Infrastructure and Human Capacities for Pesticide regulatory Management

National infrastructure for Pesticide regulatory Management has been arranged but not complete.

As the infrastructure for pesticide registration, there are the Pesticide Board of Ministry of Agriculture, the Agrochemicalization Research Institute of the Academy of Agricultural Sciences, and the Standard Institute of the National Quality Supervision Committee, and all of them are carrying out their role by sector in pesticide registration.

For monitoring and controlling pesticides, Central Plant Quarantine Institute, plant quarantine institutes by province, plant quarantine posts by county have been organized, and there are plant protection officers who are responsible for pesticide management and supervision. And every county has got an environment monitoring post to monitor the environment problems arising by misuse and abuse of pesticides and hazardous chemicals.

There are infrastructure and working system like these, but the capacity is so lack and the capacity building in the human, material and technical aspects is acutely needed for satisfactory monitoring and controlling activities on pesticides.

There are 14 laboratories for monitoring and controlling pesticide products quality and residue, and 4 among them acquired the national accreditation as examination institutes. But the overall analysis and monitoring ability is not high enough to treat all posed issues sufficiently.

The Central Hygienic and Anti-epidemic Institute, Hygienic Research Institute of Academy of Medical Sciences can prepare evaluate data on pesticide's toxicity, but the capacity is not big enough, too.

Domestic workshops had been organized twice for building capacity in the field of bio-efficacy inspection of pesticides for last 3 years, and no training for evaluation of toxicity/risk of pesticides and pesticide information sharing were organized.

These are emphasizing the necessity and acuteness of further activities for establishment and capacity building of infrastructure.

7. General Assessment of Status of Pesticide Regulatory Management

The pesticide management in Korea, DPR is being converted to comprehensive work that national organizations, science research agencies and public units participate, with legal basis and administrative working system, now.

But there are so many things to do for it to prevent the adverse effects coming from pesticides within the realm of possibility and contribute to protection of human health and ecological environment of country, moreover around world in proper level. Especially, to raise the pesticide management up to the world level, it is important to reflect the international guidelines and standards on national legislations by studying well and to do actively to complete the infrastructure of pesticide management and raise its capacity. And it is necessary to raise the implementation level of international agreements, generalize and disseminate widely successes achieved in pesticide management and enhance the sharing rate of the information on pesticide management and the rate of public participation to pesticide management.

The problems to do these works smoothly are that

- the responsibility for the integrated management of pesticide data is not clear, and the relationship between the relevant agencies is weak,
- the analysis and testing capacity is insufficient, horizontal relationship between the inspection and assessment institutes is not strong and there is no information centre for integrating data on pesticide management and improving social awareness, and
- that the financial and technical resources are not enough is presented as the most difficult problem.

To solve these problems and improve the pesticide management, it is important to strengthen mutual collaboration and cooperation between countries.

Especially, it is thought that there are problems in the responsibility of exporting countries. There has not been any collaboration mentioned in the Code of Conduct from the exporting countries or companies in pesticide management, specially testing field. For this, close relationship and cooperation with the pesticide inspection agencies in exporting and importing countries should be realized, and the role of international organizations including FAO is essential.

To improve the pesticide management and reduce the hazard by pesticide use is not for only and individual country or region or industry, but is international work for preventing the world environment pollution and offering human public welfare. Especially the developed countries should enhance their responsible role in this field, as they became main suppliers in world pesticide market. The government of Korea, DPR is recognizing the necessity of international cooperation in improving the national pesticide management and intensifying its material and technical foundation, and hopes the cooperation and collaboration to be more activated in the future.

Today, the country is entering on the important phase of powerful nation construction.

It is constant policy of the Worker's Party of Korean and the government of Korea, DPR to give new appearance of land and prevent in advance the possible damages and pollution by pesticides and hazardous chemicals, upholding the ideas and intension of the respected marshal **Kim Jong Un** to protect and improve the environment of the country and provide people with more convenient and cultured living condition.

The government of Korea, DPR will keep up making every endeavour to fulfill its responsibility in implementing the international legislations including "International Code of Conduct on the Distribution and Use of Pesticides", for protecting human health and eco-environment, and ensuring the sustainable development of agricultural production.

3.7 LAO PDR

APPPC Regional Workshop on Enhancement of
Regional Collaboration in Pesticide Regulatory Management
26–30 November 2012
Chiang Mai, Thailand

Pesticide Regulatory management in Lao PDR

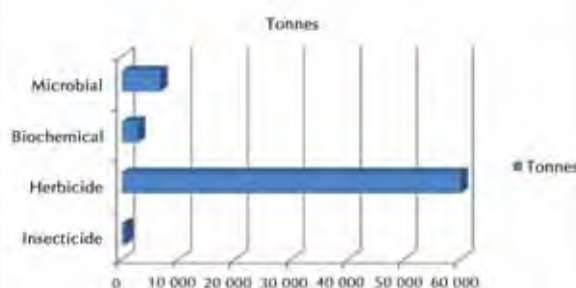
Presented by Khamphoui Louanglath
Department of Agriculture
Regulatory Division

Pesticide regulation

- ▶ Lao PDR have regulation on Controlling Pesticide in Lao PDR No. 2680/MAF, date 11 June 2010.
- ▶ The objective of this regulation defines the principles, rules, and measures for controlling activities that involve pesticides in Lao PDR in order to protect human, animal and plant health, and the environment, and to be harmonized with international obligations and regulations in which Lao PDR is contracting party.

Pesticide regulation (con't)

- ▶ This regulation is a tool for the monitoring and control of production, processing, import-export, distribution, transportation, storage, use, and proper disposal of pesticides to ensure the safety of people, animals, plants, and the environment.
- ▶ 55 banned pesticides.



Distribution or selling and storage of pesticides

- ▶ In regards to pesticide inspection that supported by FAO found that all shops did not meet the requirements of selling of pesticide:
 - did not have license from related sectors;
 - did not supply protective clothing to customers and some shops are still selling pesticide with other goods.
 - mainly pesticide selling did not register in Lao PDR.
- ▶ Specific storage facilities of pesticide are rare available and locate near houses.

Registration application and data requirement

- ▶ The Department of Agriculture of Lao PDR accepts all relevance documents from original country where registered products including folder of:
 - identity and properties,
 - toxicology data,
 - bio-efficacy data,
 - residue data,
 - human health or environmental fate and effect data,
 - labelling, packaging or storage data.

Application for registration

The registration application shall comprise the following documents:

1. Copy of enterprise registration certificate;
2. Copy of pesticide registration certificate of exporting country or/and country of origin;
3. Nomination letter for registration from manufacturer or exporting country;
4. Use instructions for the pesticide concerned; and
5. A sample of the pesticide.

Labelling of pesticides



Technical evaluation and of application dossiers

The Pesticide Registration Unit is a unit under the administration of the Department of Agriculture which has the following main roles and duties:

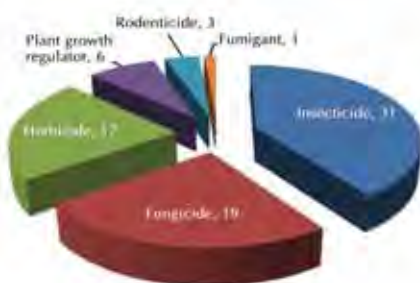
1. Review applications for the registration of pesticides and take registration decisions;
2. Regularly review the list of registered pesticide to determine whether these still meet the requirements, taking into consideration the latest scientific information;
3. Edit and approve labels of pesticides; and

Pesticide registration and licensing

Registration of pesticides

- ▶ All pesticides produced, imported, exported, distributed and used in Lao PDR must be registered with the Department of Agriculture, Ministry of Agriculture and Forestry.
- ▶ A pesticide registration certificate is an official document issued by the Director General of DOA, and remains valid for two years. Two months prior to expiration, the owner shall submit a request for renewal of the certificate to the DOA

Registration of pesticide



Import and export license, selling license

- ▶ Any person, juristic person or organization intending to import or export registered pesticides shall apply for a license from the Ministry of Agriculture or its provincial representatives at least 3 working days prior to import or export and 20 days prior to sale of pesticides.
- ▶ Agricultural Sector in Province is responsible for issuing license of pesticide importation.

Infrastructure and human capacities for pesticide management

- ▶ In Lao PDR has only one laboratory for residue analysis pesticide which belongs to Ministry of Public Health, but needs to improve the quality.
- ▶ Under the technical cooperation program FAO supported 5 people from Lao PDR for attending different training towards achieving greater for pesticide regulatory harmonization, and supplied one LCD projector, laptop and printer for regulatory Division

Infrastructure and human capacities for pesticide management (con't)

- ▶ In addition, under the Regional Program for Pesticide Risk Reduction in Southeast Asia (GCP/RAS/229/SWE), FAO supported DOA to implement activities on pesticide risk reduction:
- ▶ Set up manual pesticides inspectors and guidance for pesticide traders
- ▶ Organize training on pesticide inspection
- ▶ Training on pesticides risk reduction for shopkeepers

General assessment for of status of pesticide management

Main Progress is following:

- ▶ Ratified with Rotterdam and Basel Convention
- ▶ Updated banned pesticide
- ▶ Translated into Lao language on 5 guideline for harmonization of pesticide legislation requirements



General assessment for of status of pesticide management (con't)

Main constraints are following:

- ▶ Lack of infrastructure
- ▶ Lack of human resources, expertise
- ▶ Lack of facilities and
- ▶ Lack of financial resources

Recommendation

- ▶ Technical assistance are needed

Short and long term work plan

Short term work plan:

- ▶ Revise the process of pesticide management
- ▶ Draft the format of document for pesticide registration requirements

Long term work plan:

- ▶ Information exchange
- ▶ Risk assessment

Thank you for your attention

3.8 MALAYSIA

Recent developments on pesticides management

1. Pesticides regulations in Malaysia

1.1 Pesticides Act and Amendments to the Act

There are several laws, rules and regulations controlling pesticides in Malaysia. The Pesticides Act 1974 (Amended 2004) controls most of the major activities related to pesticides in the country and is implemented by the Pesticides Board, Malaysia. The objective of this Act is to ensure that pesticides imported, manufactured and sold in the country are of good quality and that they will not cause adverse effects to man, food crops and the environment.

Recently, a government initiative was introduced to reduce bureaucracy and create a business friendly environment in Malaysia. This initiative had resulted in a review of all laws controlling issuance of businesses licenses in Malaysia, including the Pesticides Act. The Pesticides Board is presently undertaking a major review of the Pesticides Act, its rules and regulations, not only to adhere to this new government initiative but also to make amendments to the Act in keeping with new developments and to improve pesticides control in the country. In 2012, the main focus of the Pesticides Board is an overall revision of the parent Act, plus two of its rules and regulations. The revision of the parent act, at present, is still in its first draft.



1.0 Pesticides Act

- ◆ Pesticides Act 1974 (Amended 2004)
 - implemented by the Pesticides Board
 - secretariat Pesticides Control Division
 - objective:
pesticides imported, manufactured and sold in the country are of good quality and will not cause adverse effects to man, food crops and the environment.

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1.0 Pesticides Act

- ◆ Pesticides Board comprise 13 members relevant agencies e.g. DOA, DOE, MOH, Forestry, Veterinary Services, Chemistry Dept., research agencies M'sian Rubber Board and Palm Oil Board

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1.2 Pesticides rules and amendments to the rules

The rules and regulations being reviewed are

- **Pesticides (Advertisement) Regulations 1996**

The Pesticides Board has completed its review on the Pesticides (Advertisement) Regulations, 1996, in line with the government initiative to reduce bureaucracy and create a more business friendly environment. This Regulation will be amended to implement a pesticides advertisement notification system in place of the present system i.e. application for approval for pesticides advertisement. The new system will also provide for a more detailed advertisement guidelines and place more emphasis on post-advertisement enforcement activities and the disbandment of the Pesticides Advertisement Committee. The new Regulations are expected to be implemented in 2013.

- **Pesticides (Pest Control Operator) Rules 2004**

The Pesticides Board of Malaysia has completed its review on this Rule which controls Pest Control Operators (PCO) who carry out pest control services in commercial and residential areas. The new rules to be implemented will result in a reduction in the application time required to obtain a PCO license, the choice of a short or longer duration license and the establishment of a PCO Committee to facilitate the approval of a PCO license. The new amendments are expected to be implemented in 2013.

- **Pesticides (Licensing for Manufacturing) Rules 2011**

The Rules were gazetted on the 1st July 2011, with the objectives to control the manufacture of pesticides, the pesticides manufacturer and also the contract manufacturer of pesticides. The implementation of the rules have been delayed in order to allow for changes that need to be made to the parent Act for the effective implementation of the Rules. The Rules will only be implemented when the revision of the Pesticides Act is completed.

1.3 Government notifications and amendments to the notifications

None

1.4 Other regulations/notifications relating to pesticides/biopesticides and amendments

None

1.5 Designated authority for:

1.5.1 *Registration of pesticides/biopesticides*

The designated authority for registration of pesticides is the Pesticides Board, Malaysia.

1.5.2 *Issuance of registration certificates*

A registration certificates will be issued for a product that has successfully completed all three levels of evaluations i.e. technical evaluation, laboratory sample evaluation and label evaluation and consequently is granted approval for registration by the Pesticides Board (valid 5 years).



1.5 Designated authority for:

1.5.1. Registration of pesticides
Pesticides Board, Malaysia

- Technical Committee
- Pesticides Advertisement Committee
- Anti-smuggling Committee
- Pesticides Consultative Body

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1.5. Designated authority for:

1.5.2. Issuance of registration certificates
Application for registration

- Use categories agriculture, household, public health, veterinary, manufacture, industrial use (preservatives in industries)
- Full registration and re-registration
- Category
- Commodity and proprietary

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1.5.3 *Issuance of license to import, manufacture, sale, use of pesticides, PCO, etc. in Malaysia.*

i. Import

Upon issuance of a registration certificate, the company that registered the product is allowed to import, manufacture and sell that product in Malaysia. Application for an import permit can be made by subscribing to the e-permit system, which is an on-line application system connected to the Customs Information System (valid 6 months). In the application to import pesticides the Pesticides Board is the verifier and approver in this system.

ii. Pest Control Operators (PCO)

Pest Control Operators (PCO) must be licensed under the Pesticides Act. Each PCO company must have at least one licensed Pesticides Applicator or Assistant Pesticides Applicator plus a valid premise Sales license and/or premise license for Storage for Sale before it can apply for a PCO license. Pesticides Applicators and Assistant Pesticides Applications must be certified by the Pesticides Board. They are required to sit for an examination and upon passing the examination they will be issued with a license to operate.

iii. Sales and storage for sale license

New applicants for the premise Sales and Storage for Sale License are required to attend a training course on safety and safe handling of pesticides before a license is issued to them. They must also comply to all conditions set in the sales license guidelines.

2. Pesticides Regulatory Harmonization Aspects

2.1 Status of the initiatives made so far, constraints and suggestions

Actions to harmonize pesticides regulations will be carried out in tandem with the future revision of the rules, regulations and guidelines of the Pesticides Act which have been planned from 2013 onwards.

2.2 Role of ASEAN on Pesticide Regulatory Harmonization among SEA member countries

The Third Project Management Committee (PMC3) meeting on pesticide regulatory harmonization was held in Kuala Lumpur, Malaysia on 31 October – 4 November 2011. A total of 21 delegates from Cambodia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand and Viet Nam attended the meeting. The meeting was also attended by representatives from FAO and CropLife Asia and consultants involved in the preparation of the 5 harmonization guidelines. Amongst the actions proposed from that meeting was for the guidelines and test protocols to be applied immediately plus a review of each country's regulatory system in order to identify gaps within the system and address the deficiencies. Options were proposed for the continued functioning of the PMC beyond the project period as a formal forum for the ASEAN Pesticides Regulatory Authorities through periodical meetings; for the pesticides regulatory harmonization activities to be included as a standing agenda of relevant ASEAN meeting such as the SOM_AMAF i.e. through the formation of a new ASEAN Working Group on Pesticides or for the harmonization activities to be reported under the Standing Committee on Pesticides Management under Asia and the Pacific Plant Protection Commission (APPPC) of FAO. Subsequent to the meeting, the FAO RAP circulated copies of the "Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia" in August 2012 for adoption by all participating countries to facilitate in the harmonization of regulatory processes in each country.

3. Implementation of ...

3.1 Code of Conduct

Malaysia is committed to ensuring that pesticides are controlled and managed within the context of sustainable development by taking into account human health and the environment as outlined in the FAO Code of Conduct of the Distribution and Use of Pesticides. The provisions of the FAO Code of Conduct has been implemented through the enforcement of the Pesticides Act 1974 (Amendment) 2004 and its rules and regulations.

3.2 Rotterdam Convention

Malaysia acceded to the Rotterdam Convention on 4 September 2002 and ratified on 24 February 2004. The Pesticides Board recently submitted 3 import response notifications on the 31 July 2012, to the Secretariat of the Rotterdam Convention. These responses are its final decision of no consent for import of endosulfan and aldicarb, as well as an interim decision of consent (subject to specific conditions) for import of alachlor pending the Pesticides Board review on the registration status of alachlor. Endosulfan has been banned since 2005, while aldicarb has never been registered in the country.

3.3 Stockholm Convention

Malaysia is a signatory to the Stockholm Convention and has yet to ratify this Convention pending a final decision by the government. Malaysia, however, actively participates in the meetings of the Stockholm Convention. At the moment, Malaysia is in the process of considering actions on the additional 9 new POPs which have been adopted by the Conference of the Parties to the Convention at its fourth meeting in May 2009 and entered into force on 26 August 2010. Of the 9 new POPs, 5 are pesticides of which 2 i.e. chlordecone and lindane are already listed in Schedule 1 of the Pesticides Act 1974 and therefore are subject to the Act. Registration for lindane has been banned since 1999 and chlordecone has never been registered. Alpha-hexachlorocyclohexane, beta-hexachlorocyclohexane and pentachlorobenzene have yet to be listed in Schedule 1 and steps will be taken for their listing in the Schedule whereby they can be controlled by prohibiting their usage or trade in Malaysia.

3.4 Basel Convention

Malaysia acceded to the Basel Convention on the control of Trans-boundary Movement of Hazardous Wastes on 8 October 1993, the implementation of which came into force on 6 January 1994. Under this Convention, Malaysia controls the import, export and transit shipment of hazardous wastes into its borders. Malaysia does not allow the import of hazardous waste into the country unless it is being used as raw material. Only two type of waste have been allowed for import i.e. gypsum for cement plants and copper slag for cement plants and blasting works. Exports are only allowed if Malaysia does not have the facilities or technology to recycle or recover from waste, export is allowed for metal hydroxide sludge, spent catalyst and cadmium nickel battery for the precious metal recovery.

3.5 Chemical Weapons Convention

Malaysia signed the CWC on 13 January 1993 and ratified it on 20 April 2000. In 2010, control of export, transit and transshipment of three pesticides listed in the CWC i.e. amiton, chloropicrin and hydrogen cyanide were placed under the Strategic Trade Act 2010. The Secretariat for this Act is under the Ministry of International Trade and Industry, Malaysia. The control of import for these 3 pesticides, however, are still with the Chemical Weapons Convention Secretariat which is under the Foreign Ministry and registration with the Pesticides Board is required before any import can be allowed.

3.6 Montreal Protocol

Malaysia ratified the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer on 29 August 1989 and is listed as a developing country under Article 5 Countries. Of the 96 substances ozone depleting substance, Methyl bromide is the only agricultural pesticide, was introduced into the Protocol in 1992. The 1992 Meeting of the Parties in Copenhagen agreed to a Phase-out Schedule for Article 5 Countries which would result in a complete phase-out in 2015. In Malaysia, methyl bromide is mainly used for quarantine purposes and free shipment, of which both of these uses are exempted from the phase-out. Monitoring for non-QPS use is carried out by the Crop Protection and Plant Quarantine Division, Department of Agriculture and Malaysia is in compliance to the phase-out schedule.

3.7 SAICM

The Ministry of Natural Resources and Environment (NRE) is the SAICM National Focal Point for Malaysia while the Pesticides Board is the reference point for matters of pesticides control under SAICM. Malaysia has submitted its proposal for the SAICM Quick Start Programme Trust Fund in support of the project proposal entitled '*Preparation of the National Action Plan (NAP) for the Implementation of the Rotterdam Convention in Malaysia*'. The SAICM Secretariat has confirmed its approval for the proposal in May 2012 for the implementation of this project. NRE is currently in the process of obtaining final approval from the Malaysian Cabinet for the implementation of this project.

3.8 Others

Others like Inter-organization Programme for the Sound Management of Chemicals (IOMC), 2nd International Conference on Chemical Management (ICCM-2) – None

3.9 Initiatives planned for effective implementation

Action has been taken to inform the industry on the need for Prior Informed Consent notification for import and exports of products containing Annex 3 chemicals. Prior Informed Consent notification requirement for export of products containing methamidophos and monocrotophos will be implemented in 2013.

3.10 Constraints for implementation of the Conventions

Amongst the challenges faced in implementing the Conventions are related to personnel and expertise

- i. Lack of expertise in conducting risk evaluation/assessment.
- ii. Lack of local data and scientific evidence on adverse effects of chemical/pesticide to man and environment.
- iii. Lack of manpower and resources to comply with all provisions of the Conventions.

3.11 Suggestions to hasten the process of implementation of the provisions of the Conventions,

- i. Capacity building in risk evaluation and assessment.
- ii. Establishment of resources and manpower to carry out studies required.
- iii. Establishment of specific unit with adequate manpower and resources to handle all provisions of Conventions.

4. Updates on the following aspects ...

4.1 Information Exchange

4.1.1 Contact points for information exchange on pesticide matters

Name : Nursiah binti Mohamad Tajol Aros
Designation : Secretary, Pesticides Board Malaysia
Telephone : 603-20301472
Fax : 603-26917551
Mobile : 6012-3997682
E-mail : nursiah@doa.gov.my

4.1.2 Status of website URL on information exchange on pesticide matters

4.1.3 Guidelines established for information exchange related to pesticide matters

4.1.4 Pesticide data base established for exchange of information with member countries

www.doa.gov.my Registered Pesticides List

4.1.5 Updated list of approved, restricted and banned pesticides/pesticide mixtures and biopesticides

List of Banned/Prohibited Pesticides

Pesticides	Usage	Status	Action Taken (Year)
1. 2, 4, 5-T	Herbicide	Banned	1998
2. Binapacryl	Fungicide, Acaricide	Banned	Never registered
3. Aldrin	Insecticide	Banned	1994
4. Captafol	Fungicide	Banned	1997
5. Chlordane	Insecticide	Banned	1997
6. Chlordimeform	Insecticide, Acaricide	Banned	1994
7. Chlorobenzilate	Insecticide, Acaricide	Banned	Never registered
8. DDT	Insecticide	Banned	1999
9. Dieldrin	Insecticide	Banned	1994
10. DNOC	Insecticide, Herbicide, Acaricide	Banned	Never registered
11. Dinoseb	Herbicide	Banned	1993
12. EDB	Fumigant	Banned	1994
13. Ethylene dichloride	Fumigant	Banned for agricultural use	2001
14. Ethylene oxide	Fumigant	Banned for agricultural use	2001
15. Gamma BHC	Insecticide	Banned	2001
16. Fluoroacetamide	Rodenticide	Banned	Never registered
17. Lindane	Insecticide	Banned	1999
18. HCH (mix isomers)	Insecticide	Banned	1994
19. Heptachlor	Insecticide	Banned	1993
20. Hexachlorobenzene	Insecticide	Banned	Never registered
21. Mercury compounds	Insecticide	Banned	1994
22. Monocrotophos	Insecticide	Restricted	1990, Plantation crops only

Pesticides	Usage	Status	Action Taken (Year)
23. Parathion	Insecticide	Banned	Never registered
24. Sodium PCP	Fungicide	Banned	2000
25. Toxaphene	Insecticide	Banned	Never registered
26. Phosphamidon	Insecticide	Banned	Never registered
27. Methyl-parathion	Insecticide	Banned	Never registered
28. Methamidophos	Insecticide	Restricted	2004, Plantation crops only
29. Acephate	Insecticide	Restricted	2004, Plantation crops only
30. Endosulphan	Insecticide	Banned	2005
31. Tributyltin compound	Anti fouling agent/ Wood preservative	Banned	2011

4.1.6 Information exchanged among the participating countries since the inception of this FAO-TCP Project.

Furnish the type of information exchanged/frequency of information exchanged and countries with which information exchanged and mode of information exchange

4.2 Quality Control of Pesticides

All pesticides that are submitted for registration with the Pesticides Board are analysed to verify the active ingredient and concentration as claimed by the applicant. If the pesticide sample analysed does not comply with the claims, the pesticide is refused registration. Pesticides that have passed the analysis as well as the technical and label evaluations are subsequently registered with the Board. Post-monitoring checks are also carried out where market samples are taken from time to time and analysed to ensure they comply to specifications. Pesticides that have been registered which proposed for government tender (for use by government agencies) are also analysed to ensure they meet the specifications claimed.



4.2 Quality Control of Pesticides

- ◆ Pre-requisite to registration
 - All pesticides submitted for registration are analysed for a.i. and concentration
 - Applications to register not in compliance with specifications are rejected by the Pesticides Board

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4.2 Quality Control of Pesticides

- ◆ Post-registration checks
 - By enforcement officers for market samples and registered products for govt. tender
 - Analysed comply with specifications
 - Legal action taken against registrants for off-specs registered products and licensed premise owners if products deemed contraband or illegal pesticides.

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4.3 Maximum Residue Limits for pesticides established so far

Pesticides MRLs are determined by a National Committee comprising of technical experts from the Department of Agriculture, the Ministry of Health and several agricultural research bodies using data obtained from studies as well as from scientific literature and the Codex MRLs. The MRLs that have been determined are gazetted under the Food Act 1983. At present, there are a total of 839 pesticides MRLs already gazetted and another 149 due to be gazette.

4.4 Pesticide poisoning/observance of safety requirements in handling hazardous pesticides/public awareness programmes on human safety and health hazard of pesticides.

Administrative arrangement for poisoning reporting caused by pesticides between the Ministry of Health, Malaysia and the Pesticides Board. Public awareness programmes are held by the Department of Agriculture and other stakeholders.

4.4.1 Initiatives on risk reduction of Highly Hazardous Pesticides (HHPs)

Initiatives include the implementation of the Highly Toxic Pesticides Regulations 1996 (Amended 2004), registration of less toxic or reduced risk pesticides and implementation of Integrated Pesticides Management (IPM) through the Good Agriculture Practice Certification Scheme (SALM) and the Organic Certification Scheme (SOM).

4.5 Disposal of obsolete/date-expired pesticides/Trans boundary movement of hazardous wastes (Stocks of obsolete/date expired pesticides disposed off so far):

The Pesticides Board periodically disposes pesticides that have been seized by enforcement officers of which the cases have been settled in court. Disposal is carried out as per Environmental Quality Act 1974 (Hazardous Waste) and at licensed incinerator premises.

4.6 Capacity building of staff viz. Insecticide Inspectors/Insecticide Analysts, field staff and farmers in pesticide management

Courses attended by staff

Analyst-Laboratory Capacity Building and Method Development,

Hands-on training on quenchers technique for pesticides residue analysis

Technical Evaluation-Seminar on Risk Assessment on Chemicals

Enforcement-Lab Focus Group Business Process Reengineering

Agris-Geoportals Licensing Course, Course on Safe Use of pesticides

Field staff and farmers-are trained by the State Agriculture Department in collaboration with Pesticides Control Division staff in the state offices.

Capacity building needs:

- i. Evaluation, classification and analysis of biopesticides.
- ii. Capacity building in data requirement and technical evaluation for:
principle of equivalence, substitution principle and precautionary principle.

4.7 Workshops/Training organized on enforcement of pesticide regulations and pesticide management

- i. Seminar on regulating pesticides-Towards increased awareness and better compliance

3.9 MYANMAR

1. Pesticide Legislation and Regulations

The Pesticides Law was enacted on 11th May 1990 as the State Law and Restoration Council Law No. 10/90. Procedures' relating to the pesticide law was issued by Ministry of Agriculture and Forests on 8th July 1991 by Notification No. 4/94. Formation of Pesticide Registration Board (PRB) was issued by the Government of the Union of Myanmar on 25th February 1992 by Notification No. 2/92.

Under the Pesticide Law, the Government has constituted the Pesticide Registration Board with various ministerial officers in 1992. The technical committees was formed under the Registration Board, where it consists of specialists of various fields for bio-efficacy evaluation and advice on other technical supporting data of the pesticides and must include its members as well as non-member specialists.

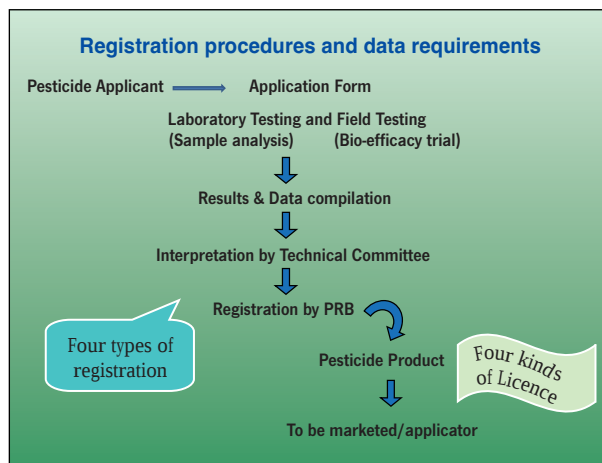
Any person desirous of importing formulated pesticides and active ingredients or registered pesticides of the same has to submit an application in the prescribed registration form to the secretary, registration board along with the particulars viz. i) address of the premise of the storage place; ii) type and area of the storage building; iii) names and addresses of wholesale dealers/organizations and other supporting data, if required.

2. Registration Application and Data Requirements

The Registration Board takes decisions on all applications for registration or for amendment of registration of any type of pesticide based on the technical and toxicological data submitted along with the applications taking into consideration the effectiveness of the pesticides, the benefits of their use and the likely side effects on human health and environment.

3. Technical Evaluations of Application dossiers

Pesticide technical sub-committee and bio-efficacy sub-committee have been formed under the PRB to recommend and evaluate technical data in pesticide registration requirements such as chemical identity and specification, Bio-efficacy data and pest information, Toxicological data, Human health exposure and safety, Environmental fate and residue on foods, Precautionary statements, and Complete label descriptions.



4. Pesticide Registration and Licensing

When a pesticide applied for the registration, considerations are being made to assure those were environmentally safe or less dangerous to human beings and its environment. Thorough scrutinization is made for each and every pesticide compound to be registered. The validity period of registration certificate vary with type of the registration namely;

- i) Full registration for 10 years,
- ii) Provisional registration for 5 years,
- iii) Experimental registration for 2 years,
- iv) Amended registration for 5 years and
- v) Special use permits for 1 year.

Licensing for pesticide import, sale and pest control operators

An applicant who desirous of engaging in pesticide formulation and sale in the country from imported active ingredients, and pest control operation has to submit in the prescribed application form to the Director General, DOA for a license.

The Registration Board recognized by the Government Departments and Organizations is authorized to carry out fumigation of agriculture products for export as well as forest products and other commodities.

PRB has under consideration status for data protection periods in compliance with WTO-TRIPS Agreement.

5. Post-Registration Activities

Monitoring of product quality in marketing, residue in food and environment was performed by working group of inspectors. The high hazard of judicious use of pesticides is also educated to end users and farmers as a part of extension programme under the DOA, and collaboration with the working group. The results from laboratory shall propose to the secretariat of registration board for perusal. The decision of board shall be the final regulatory action.

Myanmar has notified a list of banned and restricted products. Myanmar does not have much stock piles of pesticides and private sector had been granted to participate in marketing of pesticides after 1990s. The pesticide marked had steadily grown-up and not much obsolete pesticides were in hand. PRB has considered change in the consumption of methyl bromide in compliance with the Montreal Protocol. However, methyl bromide consumption is small amount and is used as agrochemical for fumigation only by certified pesticide applicator.

6. Infrastructure and Human Capacities for Pesticide Regulatory Management

Although pesticide analytical laboratory is carrying on the quality control tasks it is still limited and needs to be recruited with the qualified personnel for QC, residue control as well as for pesticide registration and enforcement.

Collaboration with the networking countries will be needed to build the capacity of PRB members in order to develop the technically sound on the course of this pesticide regulatory management.

7. General Assessment of Status of Pesticide Regulatory Management

Progress and Achievements towards harmonization (TCP countries)

- **Training and Education**

To achieve towards the harmonization section, training and education has been managed by PPD, with support mainly from DOA. The PPD has conducted the training of inspectors, government staffs and other concerned individuals from private pesticide company for pesticide labelling and bio-efficacy evaluation at central agricultural training centre.

- **Constraints and difficulties**

Currently, need to update the procedures' relating to the pesticide law due to amendment and additional types of registration need to be placed in the current pesticide law and the additional procedures related to these types of registration need to be identified.

At the meantime, PPD has managed to seek advices from experts or regulatory officer who are working on new pesticide harmonized regulatory trends. Not much assistances were obtained for pesticide regulations, however PPD has launched harmonization programmes together with law enforcement activities and implementations.

- **Recommendations and suggestions**

The use of POPs likes aldrine, endrins and control of illegal trade crossing the border should be totally eliminated in the country by legal means as well as through surveillance to inspect *as specific agency*.

Alternative chemicals or other measures should be supervised for pest control programme to be used in areas of agro-ecosystem.

The pesticide law enforcement, such as prohibiting the use of POPs should be strengthened with an interest not only to protect the environment from being contaminated with such hazardous chemicals but also to ensure food safety.

- **Short and long term targets and work plans**

The PPD is now trying to improve the installation of guidelines for pesticide regulatory management between the government authorities.

The PRB/Technical Committee has prepared to assign the additional and amendment of registration types to be placed in current law. Fortunately, this amendment course needs to be recommended from Minister of Agriculture and Irrigation accordingly will be submitted to Attorney & Parliament office.

Even though two guidelines were translated and proposed to PRB have not officially published yet, other remaining guidelines will be continued to generate.

Legislation of pesticides in the country has improved the pesticides safety use in the country. Most toxic (WHO toxicity classification Ia = GHS Category 1) products have been rejected for registration and less toxic formulation are allowed.

Problems/constraints presently faced in control of pesticides crossing the border without proper registration, and some retailers selling mixed pesticides or fake ones or illegally repacked pesticides. Repacked pesticides are one of the sources of fake products in the country and the authorities are now trying to establish better controlled guidelines. Local PPD staff (inspectors) is authorized to make regular inspection upon the retailer's shops.

There is not yet any specific agency *to inspect the illegal trade and distribution* of such chemicals but only a temporary joint body formed by local authorities, police and PPD staff conduct surveillance only when it is considered needed.

Myanmar is an agriculture country with relatively low pesticide consumption and considered favourable for adoption of *IPM* strategy for many crops. Consequently, the authorities are very keen to conserve the nature and aim to have IPM computable and environmentally friendly pesticide used, as long as economically justified. Thus, the control of pesticides through the regulation is considered of significantly important issue for the benefit of the country. In addition, further development through cooperation and coordination among ASEAN countries is highly recognized.

**Technical Committee Meeting for 22nd PRB
on 19 November 2012**



Discussion on 5 Guidelines and Action Plan



Guideline for Pesticide Registration requirements



3.10 NEPAL

Introduction

Nepal is a sovereign, landlocked, mountainous South Asian country having land area of 147 181 km. It is rich in biodiversity and water resources. It is physically located between 26°22' to 30°27' North latitude and 80°4' to 88°12' East longitude. The east-west length of Nepal is 885 km and North to South width is not uniform whose mean is 193 km. It lies in between two huge countries – China is in North and India is in South, East and West. World's highest mountain peak (8 848 meter), the Mount Everest, is belongs to Nepal. The country has great variety of topography, which is reflected in the diversity of weather and climate. Ecologically, Nepal is divided into three geophysical region – the mountain region, hill region and tarai (plain) region. Thus, it is a country of **geophysical, biological and cultural diversity**.

Its population is 27 million with a growth rate of 1.4 percent in 2012. There is increasing trend of population and its concentration is increasing in urban areas. Around 86 percent of the people live in rural areas. Agriculture employs 80 percent of economically active labour force, and nearly 70 percent of the total population depends on it for livelihood. The contribution of agriculture to GDP is about 33.5 percent. Despite past investment in this sector, 25.4 percent of the people are still under poverty and majority of the poor living in rural areas.



Figure 1. Map of Nepal

Despite its immense natural resources and the great capability of its human resources possessing their strength in terms of culture, habitats and indigenous knowledge, and more importantly of their willingness to utilize and adapt new frontiers of knowledge from the global community, it is facing several socio-economic and environmental problems. Insecure and highly vulnerable food security situation and widespread poverty are the foundation of all problems of Nepal.

Agriculture and status of farmer in Nepal

Agriculture in Nepal is unique in many ways. The uniqueness of physiographic and climatic diversity favours to grow almost all plant and animal species of economic importance. Socio-economically, it is basically organized into family farms (2.7 million holdings, with average holding size of 0.96 ha), where production is still predominantly subsistent. Agriculture in Nepal is far away from the goal of commercialization to join hands with the developed and fast developing economies of WTO member countries. This is mainly due to low land and labour productivity, specially in case of small farmers who are less competitive in global as well as domestic markets particularly due to their poor access to technical, bio-physical, social

and economic resources. More importantly, due to poor quality of human capital caused by mass under-nourishment, low education, and overall low quality of social standards, such farmers always lag behind in economic activities.

Table 1: Cultivated land distribution in Nepal

Physical region	Area in sq. km		% of cultivated area of Nepal	% of cultivated area of the region
	Total	Cultivated		
Himalayan	51 313	1 436	4.0	2.8
Hills	61 816	9 337	26.0	15.0
Teraï	33 851	25 138	76.5	17.0
Total	147 181	35 912	100.0	24.0

Farmers are facing challenges of managing insect pests, diseases and weeds of plants in current decade in Nepal. A large quantity of food is being lost annually in pre and post harvest activities either by pest or by other mishandling process. In Nepal it is ranged from 20-35 percent (Progress report, 2005/07, PHMD). This is the situation in one hand; on the other hand, it is necessary to intensify agriculture production productivity to meet the need of growing population keeping in mind the environment concern.

Such qualitative and quantitative loss, if can be reduced, there would be a significant increase in the availability of food grain thereby considerable contribution to food security. Pesticide plays a major role in pest management in agriculture. Research and development brought about hundred of new agro-chemicals of varying toxicity to control pest, diseases and weed needed to increase agriculture production and eliminate vector borne disease like Malaria, Dengue and Fileria. Many older, non-patented, more toxic, environmentally persistent and inexpensive chemicals are used intensively in developing nations (Ecobichon, 2001 in Kishor atrey, 2007).

At earlier in Nepal, government policy emphasized increased production in the agriculture sector with maximum use of chemical fertilizer and pesticide and set yearly programme of importing increasing amount of pesticide nationwide. Extension services promoted the use of pesticide and supplied through local cooperatives. Over the years, pesticide dealers and formulators sprang up in India along the Indo-Nepal border to supply pesticide in both countries. Now there are around 60 pesticide dealers and more than 3 000 licensed pesticide retailer in the country.

The agro-pesticide used at the moment are mainly organophosphate, carbamates, synthetic pyrethroides, fungicides, herbicides, rodenticides, botanical pesticides, biopesticides and pesticide used in public health. As our country is not industrialized yet and has very few registered pesticide formulator yet therefore quantity and types of chemicals and hazardous waste generated are limited. Moreover organ chlorine pesticides (except endosulfan) are not use in the country. In general, quantitative used of pesticide in Nepal is quite small, on an average 142 g/ha as compared to other countries in the Asia-Pacific region but the trend is increasing in present days. Pesticide is being extensively used in Terai region, Kathmandu valley and places that have greater access to market.

For example, the application of pesticides in cotton (2 560 g/ha), tea (2 100 g/ha) and vegetables (1 400 g/ha) appears excessive and without the consideration of applicators (farmers) and consumers. Pesticide problems have been reported to in many non-target organisms such as fishes, wild life, natural enemies, and residue has been detected in food grains, fresh vegetables and milk.

Pesticide Use in Nepal (imported & formulated)

According to the provision of Pesticide Act 1991 and Rules 1993 (1st amendment in 2006), the pesticide formulator and pesticide importers of Nepal should provide data of formulation and imports of pesticides 3 months later the end of each fiscal year. From the data available in pesticide registration office, it is seems that the amount of pesticide imported and use in the country is increasing in recent years. According to latest estimate in 2011 Nepal imported about 297.98 metric tonnes and formulated about 37.69 metric

tonnes of different pesticides. The cost incurred for this amount of pesticides was about US\$4.6 million (Annex 1). The trend of pesticide consumption is seemed to be in increasing trend except a slight erratic form in between (Annex 2).

Formulation of pesticide in the country

Most of the pesticides used in Nepal are imported from India. Besides, pesticides are also imported from China, Japan, England, Italy, Australia and Singapore as well. There is no any pesticide manufacturer industry in the country. Presently, there are five license holder pesticide formulator that formulating some insecticides, fungicides and micro-nutrients. At present no pesticide is exported from Nepal to other countries.

The pesticide formulators of Nepal are not formulating the extremely hazardous pesticide in the country. The domestic formulator should also register their products in pesticide registration office for their notification in the Gazette. In Nepal, around 38 mt of pesticide are formulated in EC and WP formulation in the year 2011.

Stock of obsolete pesticide in Nepal

Nepal had about 75 metric tonnes of obsolete pesticides stored in different parts of the country. POPs (Persistent Organic Pollutants) Enabling Activities Project, Ministry of Environment Science and Technology (MoEST) prepared the inventory of obsolete pesticides and made good packaging that is safe to store and dispose. Recently, with the technical and financial support of GIZ and joint initiation of MoAD and MoEST, that much amount of obsolete pesticide was successfully transported to the Germany for safe disposal. Similarly, on the spot obliteration of 43 cylinder of methyl bromide was also accomplished very safely through GIZ technical team.

Pesticide policy and organizational structure for the enforcement of pesticide act

Still no formal pesticide policy in Nepal. Pesticide act 1991 and pesticide regulation 1993 are acting as the policy guideline for the pesticide management. Agriculture Policy 2004 of MoAD has also emphasized on eco-friendly production system, organic farming and IPM practice for sustainable agriculture development and food safety. Considering these issues the Pesticide Registration and Management Division has also emphasized for the registration of biopesticide/botanical pesticides, gradually reducing extremely hazardous pesticides.

Since 1990, most work on pesticides has been on the policy making front focusing on legislation regarding pesticide imports, sales and use in Nepal. The pesticide act, 1991 and pesticide rules 1993 (1st amendment in 2006) were formulated and came in to force from July 16th, 1994 throughout the country. Now pesticides are registered and regulated under the pesticide act and rules. The act regulates the imports, production, sale, distribution, marketing and use of pesticides with an objective of rational and appropriate management of pesticides and preventing pesticide risk to human beings, animals, birds and environment. Under the pesticide act 1991, **a pesticides board/committee** is constituted. It composed of members from various Ministries, pesticide association of Nepal, scientists and consumers group for the purpose of discussing pesticide related issues. The above committee is mandated to:

1. Advise Nepal government in the formulation of national policy regarding pesticide,
2. To maintain coordination between private and government sectors in the production and distribution of pesticides,
3. For the rational encouragement of the private sectors to invest in the industry,

Pesticide use	
Current scenario	
♦ A.I.: 335 tonne (in 2010/11)	
♦ Worth of: 397.78 million NRs. (4.6 million US\$, rate 1 \$ = 87 npr.)	
♦ Insecticides (Including botanicals): 28.63%	
♦ Fungicides: 54.78%	
♦ Herbicide: 13.91%	
♦ Rodenticides: 1.65%	
♦ Biopesticides: 0.023%	
♦ Acaricide: 0.323%	
♦ Public health: 0.68%	
Imported from:	Mainly India and then China, Japan, England, Italy, Thailand, Australia and Singapore

4. To regulate or control the quality of produce by the industry operated by private/government sectors, and
5. To establish standard for pesticide

Under the board, two sub-committees have been constructed

1. Technical sub-committee (with 7 member)
2. Legal sub-committee (with 3 member)

The Act 1991 & Pesticide regulation 1993

These are almost more than 20 years old legal instrument and comparatively more incompatible and less harmonized with international treaties, laws and guideline related to pesticide management and regulatory actions. So that are not sufficient to address new emerging issue related to pesticide management (Punishment and fine are very minimum, narrow definition and narrow coverage). No provision of separate regulation for pesticide import and export. We have similar procedure, checklist and data requirement for the registration of all type of pesticide so far. So, Nepal government now realized the urgent need of a complete and internationally harmonized pesticide act and regulation and has formulating the new draft of act and that is almost final.

The Pesticide Registration and Management Division

The pesticide registration and management division has been established in 1994 under the act to operate the pesticide registration and management activities. Plant protection officers of respective district have been designated as pesticide inspectors who are given legal authority to carry out their work, monitor and inspect pesticide resellers and dealers. They are also responsible for training and educating resellers and users about safe handling, use and storage for of pesticide. The function duties and power of Pesticide Registration and Management Division are as follows:

- To register pesticides and issue certificate after making inquiries upon the application received for registration of pesticides
- To ascertain the criteria for capable, rational and appropriate use of pesticides.

The registration procedure requires some comprehensive documents. The Pesticide Registration and Management division does not allow import of extremely hazardous pesticides. According to the pesticide act, the pesticide formulator, resellers and professional applicators should also get license from Pesticide Board.

Pesticide Registration Procedures

Registration is required for each formulation and even brand of a single technical compound. The pesticides are registered in the name of Trade Product for 5 years with or with out provision/condition. Therefore, in order to ensure quality assurance of pesticides to the users (farmers), the Pesticide Registration and Management Division (PRMD) mandatory demands the following documents for registration of pesticides:

1. Application form for registration of pesticides with 10 rupees ticket
2. Pesticide registration fee Rs. 1 000/-
3. Letter of Authorization from the Manufacture/Formulator Company
4. A statement of the need to use in Nepal
5. Summary of intended use pattern
6. Ecotoxicological data
7. Efficacy data
8. Residue analysis data
9. Copies of at least one foreign registration certificate (evidence that the product is registered overseas)
10. Three copies of the original label
11. Approved labels
12. Leaflets in Nepali Language – for importers
13. Labels and leaflets in Nepali Language – for domestic formulators
14. For research no attachments are necessary

Present situation of pesticide management and registered pesticides in Nepal

A large number of persistent chemical pesticides and also hazardous pesticides have been banned for agriculture and public health from 9th April 2001. At present, prohibition on the use of Quinalphos, Ethion and Phorate in the tea field is being campaigned and implemented from 9th May 2005 because these pesticides are highly toxic. The pesticides to imported, distributed, traded and used should be friendlier and less hazardous to health and environment. More emphasis has been given to use organic pesticides as an alternative of chemical pesticides to control crop pests. Some microbial pesticides are registered and use in little quantity like *Bacillus thuringiensis*, *Beauveria bassiana*, *Trichoderma viridae* etc. Some kind of lures and biological agents are also being used in Nepal. But the import and use of these botanical and biopesticide is very nominal.

Regarding the registration of pesticide, up to October 2011, in total 859 trade products of 102 technical names have been registered in the country. There are some technical of hazardous group registered with condition that they must be sold under official recommendation of Plant Protection Officer in District Development Office. The restricted pesticides are dichlorovos, carbofuran, triazophos and zinc phosphide. The list of 15 pesticides which were already banned to registered in Nepal are Chlordane, DDT, Dieldrin, Endrin, Aldrin, Heptachlor, Mirex, Toxafen, BHC, Lindane, Phosphamidon, Organo mercury fungicides, Methyl parathion, Monocrotophos and Endosulphan.

Licensing Mechanism

The licensing control of hazardous chemicals prevents unauthorized persons from handling of chemicals (pesticides). The licensing control is implemented under the Pesticide Act 1991 and Pesticide Rule 1993 (1st amendment in 2006). Any person who formulates, distributes, sales or uses the notified Pesticides in a commercial way shall obtain a license from the Pesticide Board by paying the prescribed fee. No person may manufacture, import, supply or retail the registered Pesticides unless he/she in possession of a valid license.

Procedures for the Pesticide Retailer's Licensing:

If any person, institution body submits to the committee an application, according to pesticide act 1991, for obtaining a license to retail the pesticides, the Board may, subject to the standards fixed by it in regard to pesticides and knowledge to its use, if it seems fit to grant a license after making necessary inquiries in this regard in such a form as prescribed by the committee. The pesticide retailer shall have to abide by the terms and conditions specified in the license. Following procedure are used for licensing pesticide resellers:

1. Training of Retailers for safe use and storage of pesticides.
2. Exam to be passed.
3. Application form should be filled up in the DADO in concerned district.
4. The Pesticide Inspectors should fill up checklist of pesticide premises/shop/warehouses.
5. Bill/Voucher of Rs. 500/- for the Pesticide Retailer License.

After completing all above formalities, Pesticide Inspector recommends for the license and sends applications, checklist ad bill/voucher to Pesticide Board and the Pesticide Board issues a license for 3 years.

Post-registration Activities

In case of violation of pesticide act and regulation, Nepal government has the provision of pesticide inspector over 75 district of the country to carryon and files the case in District administration office against person or party who violate the act. During filing the case they are mandatorily assisted by government lawyer. According to pesticide act 1991, the pesticide inspectors are acquainted with full of power to monitoring and supervision, to cease the shop and captured the illegal pesticide as well. Regarding the control of trans-boundary movement of hazardous waste and their disposal, Nepal government is fully committed to follow the rule of Basel Convention. Occasionally, PRMD conduct the residue monitoring activities for PIC listed compounds and POPs compounds to fulfill the obligation of Stockholm Convention and Rotterdam Convention. For instance recently Endosulfan has been deregistered in Nepal to fulfill the

obligation of Stockholm Convention. Similarly in 2007, two technical, Monocrotophos and Methyl parathion had been banned to fulfill the obligation of WTO. PRMD conduct the activities of Pesticide registration and maintenance of database regarding registered and banned pesticides, annual pesticide use scenario, importers and formulators lists, professional applicators as well as licensed retailers. Nepal government is in the line of searching other safe alternatives for Methyl bromide with technical and financial support of WTO. Still there is restricted use of methyl bromide for plant quarantine purpose to fumigate wooden packaging material and some pulses only according to the requirement of importing country.

Infrastructure and Human capacities

Pesticide Registration and Management Division is the sole central organization for pesticide registration and pesticide management in Nepal. Above PRMD under DOA we have Directorate of Plant Protection to formulate programme and policies of whole national plant protection activities that supervise all its sister origination including PRMD-1, RPPL-5, NPQP-1 (with 16 plant quarantine check post), PHLRP-1.

PRMD has two registration officers and one enforcement officer (Pesticide Registrar). Besides, we have one pesticide inspector in each of all 75 District Agriculture Developments Office, who is fully responsible for overall management of pesticide trade and use including monitoring and supervision within the district. PRMD do not have any quality control as well as residue monitoring laboratory. Till date PRMD has 2 trained personal (1 officer and 1 non-officer) in 1 month training on “pesticide analysis and GC operation” from IPFT, India. We have some laboratory equipments including GC machine but are not used so far because of lack of laboratory building, continues power supply and operation cost. DFTQC do have food analysis and quality control laboratory but still on the process of accreditation. NAST do have pesticide quality control and pesticide residue monitoring laboratory but not sufficient for all type of compounds. Similarly we have some private laboratory with GC, GCMS and HPLC as well, but none of them are complete and accredited so far.

Government policies and programmes on effective pesticide management:

S.N.	Activities	Government policies
1.	Research and development of new pesticides	• Promotion of IPM programme • Promotion of biopesticide and botanical pesticides • Promotion of safe and environment friendly formulation of pesticides
2.	Institutional support for laboratory analysis	• Establishment of central pesticide tests laboratory – on the process
3.	Adequacy of legislative measure	• Strengthening legal framework – on the process • Establishment of full fledged pesticide registration office – on the process • Formulating new pesticide act – on the process
4.	Incentive to domestic production	• Encouragement to private sector for the formulation of environment friendly pesticide
5.	Trainings and awareness programme	• Training on safe handling of pesticide to JT/JTA, farmers and retailers • Circulation of documents with appropriate use of pesticides • Conducting awareness programme on negative impact of hazardous pesticide to living and non-living environment
6.	Restriction of pesticides	• Pesticides falls on Ia and Ib of WHO classification should gradually be removed from the recommended list and to be deregistered
7.	Quality assurance and quality control of pesticides	• With the collaboration of Private Laboratory, PRMD started collaborative programme for quality monitoring and residue analysis of pesticides which are imported from out side and formulated within the country.

Implementation Status of International Treaties

Basel Convention (May 1992)

The Convention was opened for signature on 22 March 1989, and entered into force on 5 May 1992. Nepal has already ratified the treaty on August 15, 1996 and was fully effective from January 13, 1997. Focal point (DNA) for this convention is assigned to Ministry of Environment, Science and Technology.

Rotterdam Convention (February 2004)

This treaty was approved on September 11, 1998 and came into force on February 24, 2004. Nepal has ratified the Rotterdam Convention on PIC in 2007 and became party to this convention. Focal point (DNA) for this convention is assigned to Ministry of Agriculture development.

Stockholm Convention (May 2004)

The Stockholm Convention was approved on 22 May 2001. The treaty was entered into force from 17 May 2004. Nepal showed its commitment to this convention by signing the treaty on 5 April 2002 and ratified this convention in 2007 to become the party. Focal point (DNA) for this convention is also assigned to Ministry of Environment, Science and Technology.

Problems and Constraints:

The problems and constraints identified for the implementation of Pesticide Act and Rules for the pesticide management in the country are summarized as follows:

- Inadequate legal and regulatory frames work.
- No guidelines and formal policy documents for safety measures for occupational health safety in pesticide business.
- Ineffective control and monitoring mechanism.
- Inefficient transfer of technology and poor information dissemination.
- Trans-boundary issues (smuggled pesticides) due to the long, open and porous border with India.
- Lack of government laboratory facilities for pesticide quality/residue analysis and toxicological analysis.
- Dealers/retailers take up intensive and aggressive marketing strategies.
- The perception that there are no other alternatives for pest control except the use of chemicals.
- Unavailability of user and environment friendly formulation of pesticides/alternatives to chemical and if available, they are more expensive than conventional formulations and found in very low volume.
- Lack of awareness about pesticide dose, method of use, waiting period, pesticide hazards to mankind and environment etc.
- Farmer's addiction to chemical pesticide use.

Conclusion and Recommendations:

In order to address the problems associated with effective implementation of Pesticide Act and Rules for sound management of pesticides in Nepal government should have focus on:

- Awareness creation by training, publication, mass media about the hazards of unwanted and extremely hazardous pesticides and judicious use of pesticides.
- Strong monitoring system for formulation, import, sale, storage, distribution and use of pesticides where violation of legislation may occur and provision of punishment/fines for selling low quality pesticide and illegal disposal of pesticides.
- Deregistration and banning of highly toxic pesticides (extremely hazardous) falling in IA and IB of WHO classification and need to be removed from the recommendation list. The pesticides trade and use should be more eco-friendly and less hazardous to human being and environment.
- Promotion of Biopesticides/Biocontrol agents, which are non-polluting (Eco-friendly), should get priority in Government's plan.
- Promotion of integrated pest management (IPM) and other alternative pest management strategies to mitigate the misuse of pesticides.

- Development of well equipped central level Laboratory for quality, residue and toxicology analysis of pesticide.
- Training and education to pesticide importers, resellers and farmers about the pesticides hazard, safe use, storage and transportation as well as for the environment friendly formulation of pesticides.
- Promotion of user and environment friendly formulation of pesticides by integrating them with IPM programme.
- Need of fully fledged “Pesticide Registration Office” with adequate well skilled personnel.
- Proper storage and disposal facility for the obsolete/date expired pesticides accumulated in the country.

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Websites for important information:

Websites

www.moacwto.gov.np
www.spsenquiry.gov.np
www.ppdnepal.gov.np

Information

List of pest, regulations, policies
SPS-Enquiry point
Plant Protection Directorate

Current pesticide consumption scenario of Nepal

S.N.	Pesticide	Total a.i. (kg or L)	Formulation			Total monetary value NRs (000)
			Liquid (L)	Solide (kg)	Total (kg/L)	
A.	Agriculture and HH purpose					
1.	Chemical Insecticide					
1.1	Organochlorine	14 031.85	40 059.00	280.00	40 339.00	21 868.19
1.2	Organophosphate	40 148.42	71 924.50	17 595.00	89 519.50	40 296.37
1.3	Carbamate	2 127.95	669.00	48 233.00	48 902.00	6 276.70
1.4	Syn Pyrethroids	9 313.615	72 498.00	15 300.00	87 798.00	34 112.40
1.5	Mixture	16 463.24	32 053.00	450.00	32 503.00	20 913.28
1.6	Others					
	<i>1.6.1 Avermectin</i>	<i>5.8</i>		<i>116.00</i>	<i>116.00</i>	<i>929.20</i>
	<i>1.6.2 Diamide</i>	<i>19.675</i>	<i>50.00</i>		<i>50.00</i>	<i>42.50</i>
	<i>1.6.3 Pyrazole</i>	<i>83.2</i>	<i>180.00</i>	<i>23 883.20</i>	<i>24 063.20</i>	<i>2 644.21</i>
	<i>1.6.4 Nicotinoid</i>	<i>1 696.509</i>	<i>3 193.00</i>	<i>3 156.70</i>	<i>6 349.70</i>	<i>17 914.37</i>
	<i>1.6.5 Nerestoxin (Cartap)</i>	<i>7 840</i>		<i>191 400.00</i>	<i>191 400.00</i>	<i>13 395.67</i>
	<i>1.6.6 IGR</i>	<i>0.501</i>	<i>5.00</i>	<i>100.00</i>	<i>105.00</i>	<i>59.22</i>
	<i>1.6.7 Misc (Al. phosphide)</i>	<i>4 384.5648</i>		<i>7 829.58</i>	<i>7 829.58</i>	<i>8 120.18</i>
	Sub total	96 115.3248	220 613.50	308 343.48	528 974.98	166 572.28
2.	Acaricide	1 085.25	3 170		3 170.00	2 815.67
3.	Bactericide	1.6		16.00	16.00	47.3
4.	Fungicide	183 893.02	4 590	258 016.00	262 606.00	162 189.86
5.	Herbicide	46 696	88 160	20 738.00	108 898.00	29 034.96
6.	Rodenticide	5 528.07		8 310.00	8 310.00	4 245.92
7.	Biopesticide	78.26	2 997	4 229.00	7 226.00	1 922.57
A.	Agriculture and HH Total	333 397.52	319 548.5	599 652.48	919 200.98	366 828.5575
B.	Public health (Insecticide)	2 276		45 520.00	45 520.00	30 953.6
	Grand total	335 674	319 549	645 172.48	964 721	397 782.1575

Pesticide consumption TREND (1997/98–2010/11)

Year	Quantity (kg a.i.)	Rupee (NRs. 000)	Remarks
Fy.1997/98	56 172.56	51 387.94	
Fy.1998/99	77 856.87	66 059.84	
Fy.1999/2000	108 427.82	84 517.61	
Fy.2000/01	196 064.58	147 438.8	
Fy.2001/02	146 152.48	148 620.34	
Fy.2002/03	177 591.10	183 535.85	
Fy.2003/04	176 372.81	123 158.14	
Fy.2004/05	154 082.05	131 022.80	
Fy.2005/06	131 270.43	130 025.60	Imported + formulated
Fy.2006/07	131 284.55	133 128.45	”
Fy.2007/08	347 494.50	272 681.30	”
Fy.2008/09	356 345.64	351 672.48	”
Fy.2009/10	211 079.34	207 688.05	”
Fy.2010/11	335 673.52	397 782.15	”

Banned/prohibited Pesticides in Nepal

Chlordane	Toxafen
DDT	BHC
Dieldrin	Lindane
Endrin	Phosphamidon
Aldrin	Organo mercury fungicides
Heptachlor	Methyl parathion
Mirex	Monocrotophos

Summary of registered pesticides up to October 2011

S.N.	Types of Pesticides	Trade names	Common Name
1.	Insecticides	500	40
2.	Fungicides	229	33
3.	Rodenticides	10	2
4.	Weedicides	88	15
5.	Biopesticides	19	7
6.	Bactericides	6	2
	Total	852	99

Composition of pesticide board/committee

- | | |
|--|--------------------|
| a. Secretary, Ministry of Agriculture Development | – Chairperson |
| b. Joint Secretary, Ministry of Environment, Science and Technology | – Member |
| c. Director General, Department of Agriculture | – Member |
| d. Director General, Nepal Bureau of Standards and Meteorology | – Member |
| e. Executive Director, Nepal Agriculture Research Council | – Member |
| f. Chief, Epidemiology and Disease Control Division,
Department of Health Science | – Member |
| g. Programme Director, Industrial Entomology Directorate, DOA | – Member |
| h. Chief Food Quality Control Division, Department of Food
Technology and Quality Control | – Member |
| i. Chief Plant Pathology Division, NARC | – Member |
| j. Chief Entomology Division, NARC | – Member |
| k. One Agriculture Scientist nominated, by Nepal government | – Member |
| l. One Animal Scientist nominated, by Nepal government | – Member |
| m. One Forest Scientist, nominated by Nepal government | – Member |
| n. One Pesticide Entrepreneur, nominated by Nepal government | – Member |
| o. One user farmer, nominated by Nepal government | – Member |
| p. Programme Director, Plant Protection Directorate, DOA, Nepal,
Designated by Nepal government | – Member Secretary |
| q. Pesticide Registrar | – Invitee Member |

3.11 PAKISTAN

In the Name of Allah



Briefing by
MUHAMMAD AKHLAQUERANA

PLANT PROTECTION ADVISOR & DIRECTOR
GENERAL

DEPARTMENT OF PLANT PROTECTION

MINISTRY OF NATIONAL FOOD SECURITY
AND RESEARCH, PAKISTAN

GEOGRAPHY OF PAKISTAN

□ CONTINENT	ASIA
□ REGION	SOUTH ASIA
□ AREA	[880 940 KM ² (340 132.8 SQ MILES)]
□ BORDERS	[6 975 KM (4 334.1 MILES)]
□ HIGHEST POINT	MOUNT GODWIN-AUSTEN (K2) [8 611 m (28 251 ft)], 22 nd highest in world.
□ LOWEST POINT	INDIAN OCEAN [0 m (0.0 ft)]
□ LONGEST RIVER	INDUS RIVER
□ LARGEST LAKE	MANCHAR LAKE

MAJOR CROPS

- Basically, Pakistan is an agricultural country.
- **Cotton and Rice** are our two major cash crops.
- **Apart from meeting domestic/local requirements, these are also valuable and major sources of foreign exchange earnings.**
- Pakistan consists of 4 provinces.
 - Punjab
 - Sindh
 - Balouchistan
 - Kyber Pakhtunkhawa

LAST FIVE YEARS AVERAGE AREA UNDER RICE IN PAKISTAN

YEAR	BASMATI 000 hectares	IRRI 000 hectares	OTHERS 000 hectares	TOTAL 000 hectares
2007– 2012	1 410.6	901.3	222.9	2 534.8

LAST FIVE YEARS AVERAGE PRODUCTION OF RICE IN PAKISTAN

YEAR	BASMATI 000 tonnes	IRRI 000 tonnes	OTHERS 000 tonnes	TOTAL 000 tonnes
2007– 2012	2 721.4	2 779.2	1 173.9	6 674.5

LAST FIVE YEARS AVERAGE AREA & PRODUCTION OF COTTON IN PAKISTAN

YEAR	AVERAGE AREA 000 hectares	AVERAGE PRODUCTION Million bales (of 375 lbs each)
2007–2012	3 254.2	129.6

LAST FIVE YEARS AVERAGE AREA AND PRODUCTION OF WHEAT IN PAKISTAN

YEAR	AVERAGE AREA 000 HECTARES	AVERAGE PRODUCTION 000 TONNES
2006–2011	8 950.8	23 226.8

LAST FIVE YEARS AVERAGE AREA AND PRODUCTION OF SUGARCANE IN PAKISTAN

YEAR	AREA 000 HECTARES	TOTAL PRODUCTION 000 TONNES
2007–2012	1 120.9	54 929.6

LAST FIVE YEARS AVERAGE AREA & PRODUCTION OF CITRUS IN PAKISTAN

YEAR	AVERAGE AREA	AVERAGE PRODUCTION
	000 HECTARES	000 TONNES
2007-2012	202.8	2 298.8

LAST FIVE YEARS AVERAGE AREA & PRODUCTION OF MANGO IN PAKISTAN

YEAR	AREA	TOTAL PRODUCTION
	000 HECTARES	000 TONNES
2007-2012	172.2	1 880.8

RICE CROP

INSECT PESTS OF RICE IN PAKISTAN

Major Insect Pests

- ❑ Yellow stem Borer (*Scirpophaga incertulus*)
- ❑ White stem Borer (*Scirpophaga innotata*)
- ❑ Rice Leaf Folder (*Cnaphalocrocis medinalis*)
- ❑ Grass Hopper (Toka) (*Aiolopustamulas*)

Minor Insect Pests

- ❑ Pink Gramineous Borer (*Sesamia inferens*)
- ❑ The Striped stem borer (*Chilo suppressalis*)
- ❑ White Backed Plant Hopper (*Sogatella furcifera*)
- ❑ Rice Gall midges (*Animala dilatata*) & (*Animala dorsalis*)
- ❑ Rice Thrips (*Thrips spp.*)

DISEASES OF RICE IN PAKISTAN

Major Diseases

- ✚ Bacterial Blight (*Xanthomonas compastris*)
- ✚ Foot Rot/Bakanai (*Gibberella fujikuroi*)
- ✚ Brown Leaf Spot (*Alternaria padwikii*)

COTTON CROP

SEEDLING DAMAGING INSECT PESTS IN PAKISTAN

- ❑ Surface grasshopper (*Chrotogonus trachypterus*)
- ❑ Crickets (*Acheta domesticus*), (*Gryllotalpa orientalis*)
(House cricket, Black headed filed cricket & Red Headed field cricket attack Cotton crop)
- ❑ Termites (*Odontotermes obesis*)

MAJOR BOLLWORM PESTS OF COTTON IN PAKISTAN

BOLLWORMS

- ❑ American BollWorm (*Helicoverpa armigera*)
- ❑ Spotted BollWorm (*Earias insulana*)
(*Earias vitella*)
- ❑ Pink BollWorm (*Pectinophora gossypiella*)
- ❑ Army Worm (*Spodoptera litura*)
(*Spodoptera exigua*)



MAJOR SUCKING PESTS OF COTTON

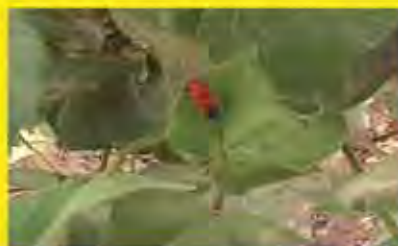
SUCKING PESTS

- ♦ *Bemesia tabaci*
(White fly)
- ♦ *Amrasca bigutella bigutella*
(Jassid)
- ♦ *Thrips tabaci*
(Thrips)
- ♦ *Phenacoccus spp.*
(Cotton Mealy Bug)



MINOR PESTS OF COTTON

Red Cotton Bug



MINOR PESTS OF COTTON

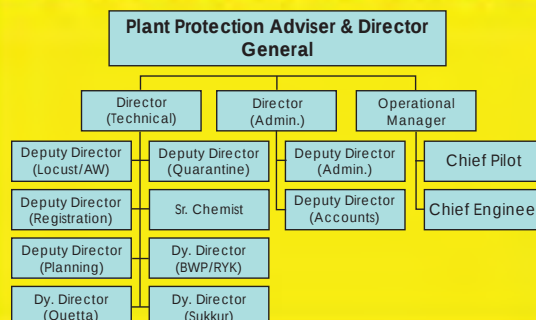
- Dusky Cotton Bug
- Cotton Grey Weevil
- Cotton Aphid
- Cotton White Weevil
- Cotton Semi Looper

MAJOR DISEASE OF COTTON IN PAKISTAN

- ★ Cotton Leaf Curl Virus
(Gemini Virus & Burewala Virus)
 - ✓ Major cause of decline in Cotton yield in Pakistan.
 - ✓ No virus resistant variety is currently available in Pakistan.
 - ✓ However, virus tolerant varieties of cotton are being cultivated in Pakistan.

REGULATION OF PESTICIDES BUSINESS IN PAKISTAN

ORGANIZATIONAL CHART OF DEPARTMENT OF PLANT PROTECTION



OBJECTIVES OF DEPARTMENT

- ❑ To ensure Food Security through Productivity Enhancement of food crops, fruits and vegetables by introducing different development Projects.
- ❑ To maintain hazardous free environment, water reservoir and human health in Pakistan in collaboration with International Organizations by banning hazardous pesticides and judicious use of pesticides at Economic Threshold Level.

- ❑ To Prevent introduction, establishment and spread of harmful exotic plant pests & diseases in Pakistan.
- ❑ To Ensure pest and disease free export of plant and plant material.
- ❑ To enhance yield of field crops, orchards, vegetables by controlling native and exotic insect pests and diseases by introducing and encouraging new chemistry pesticides and extending advisory services.
- ❑ To save country from Locust plague.

MAJOR FUNCTIONS OF THE DEPARTMENT

- ❑ Registration and Import permission of Pesticides.
- ❑ Enforcement of Agricultural Pesticides Ordinance 1971 ammended in 1997.
- ❑ Enforcement of Plant Quarantine Act 1976.
- ❑ Advise the Government on all aspects of plant protection including international obligations.
- ❑ Disinfestations of fruit pests like Fruit fly with Vapor Heat Treatment plant.
- ❑ Locust survey and control in desert areas, international coordination with FAO and other locust affected countries.

FUNCTIONS OF PESTICIDES REGISTRATION SECTION

1. Registration of pesticides under the Agricultural Pesticides Ordinance, 1971 and Rules 1973.
2. Regulation of import, manufacture, formulation, refilling/repacking, sale, use & advertisement of pesticides.
3. Facilitate meetings of the Agricultural Pesticides Technical Advisory Committee & its Sub-committees.
4. Coordination with Federal and Provincial Agricultural Agencies, Private sector and International Organizations.
5. Pesticides quality control.

PESTICIDES REGISTRATION IN PAKISTAN

- ❑ Three Kinds of Pesticides Registrations and import permission of pesticides In Pakistan
 1. FORM - 1
 - ✓ Registration and import of pesticides after two crop season local bio-efficacy test and trials and standardization in Pakistan.
 2. FORM - 16 (Fast Track)
 - ✓ Registration and Import of 43 notified generic pesticides without standardization.

- ✓ Import permission is just on the basis of analysis of pesticides to check whether it meets the registered specification or not provided by the manufacturer as per its registration in its country.

3. FORM - 17 (Fast Track)

- ✓ Registration and import of newly developed pesticides/molecules having trade name in the country of manufacturer.

- ✓ Import permission is just on the basis of
 - a) Documentary proof of registration in the country of manufacturer.
 - b) Its use in Organization of Economic Co-operation and Developed Countries or China.
 - c) Its extensive use in the Country of Origin or Organization of Economic Co-operation and Developed Countries or China.

PESTICIDES BUSINESS IN PAKISTAN

❑ Total No. of Importers	=	25
❑ Total No. of Distributors	=	510
❑ Total No. of Dealers	=	25 119
❑ Total No. of Refilling Units	=	160
❑ Total No. of Formulation Plants	=	114
❑ Total No. of Manufacturing Plants	=	01

LAST FIVE YEARS AVERAGE IMPORT OF PESTICIDES AND ITS VALUE IN PAKISTAN

YEAR	AVERAGE IMPORT	AVERAGE VALUE OF IMPORT
	KG/LTS	BILLIONS
2007-2012	49 399 197	28 TO 30

REGISTRATIONS OF PESTICIDES

TOTAL PESTICIDES REGISTERED UNDER FORM - 16	4 561
TOTAL PESTICIDES REGISTERED UNDER FORM - 17	1 082
TOTAL PESTICIDES REGISTERED UNDER FORM - 1	565
TOTAL	6 208

LIST OF 236 REGISTERED MOLECULES

Insecticides	87
Fungicides	54
Herbicides	82
Acaricides	08
Biopesticides	02
Others	03
Total	236

LIST OF 26 BANNED PESTICIDES IN PAKISTAN

- | | |
|--------------------|-------------------|
| 1. BHC | 11. DICROTOPHOS |
| 2. BINAPACRYL | 12. DISULFOTON |
| 3. BROMOPHOS ETHYL | 13. DISULFOTON |
| 4. CAPTAFOL | 14. ENDRIN |
| 5. CHLORDIMEFORM | 15. LEPTOPHOS |
| 6. CHLOROBENZILATE | 16. MEVINPHOS |
| 7. CHLORTHIOPHOS | 17. TOXAPHENE |
| 8. CYHEXATIN | 18. ZINEB |
| 9. DALAPON | 19. HEPTACHLOR |
| 10. DDT | 20. METHAMIDOPHOS |

21. DIBROMOCHLOROPROPANE +
DIBROMOCHLOROPROPENE
22. ETHYLENE DICHLORIDE +
CARBON TETRACHLORIDE
23. MERCURY COMPOUND
24. METHYL PARATHION
25. MONOCROTOPHOS
26. ENDOSULFAN

Thanks
The End

3.12 PHILIPPINES



COUNTRY REPORT: PESTICIDE MANAGEMENT & HARMONIZATION STATUS IN THE PHILIPPINES (2009–2012)

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*(Presentation to the APPPC Regional Workshop on Enhancement of Regional Collaboration in Pesticide Regulatory Management
26–30 November 2011, Chiang Mai, Thailand)*

THE FPA...

- ★ The FPA is the **FERTILIZER AND PESTICIDE AUTHORITY OF THE DEPARTMENT OF AGRICULTURE**, mandated by **Presidential Decree (PD) 1144** to do the following:
 1. To regulate both fertilizers and pesticides and other agricultural inputs during its entire cycle of importation, formulation, distribution, storage, use and disposal.
 2. For FPA to serve as a catalyst in the improvement of farmers lives by helping them become better informed, more efficient and conscientious in the management of their plant nutrition and crop protection through trainings and information dissemination campaign.

AGENCIES INVOLVED IN CROP PROTECTION

- ★ Fertilizer & Pesticide Authority of the Department of Agriculture (FPA-DA)
 - ◆ Responsible in the regulation of agricultural chemicals & establishment of maximum residue level (MRL)
- ★ Food & Drug Administration of the Department of Health (FDA-DOH)
 - ◆ Responsible in the regulation of household pesticides
- ★ Bureau of Agriculture & Fishery Product Standards of the Department of Agriculture
 - ◆ Responsible in the regulation of organic chemicals as defined in the Organic Act of 2010
- ★ Bureau of Plant Industry of the Department of Agriculture
 - ◆ Plant health and pesticide residues

FPA INTRA & INTER-AGENCY BODIES FOR AGRICHEMICAL REGISTRATION

- ★ FPA Board (all agrochemicals)
- ★ PPTAC
- ★ PRC
- ★ Biotech Core Team
- ★ Technical Evaluators for Pesticide Data Requirements
- ★ Technical Evaluators for biotech based pesticides

FPA PESTICIDE REGULATORY POLICIES AND THE IMPLEMENTING GUIDELINES GREENBOOK

Defines

Describes

Delineates

all existing and applicable laws, rules and regulations in the rational and judicious use of pesticides in the Philippines

FPA WEBSITE

- ★ List of Registered fertilizer products
- ★ List of registered pesticide products
- ★ Licensed handlers of fertilizer and pesticide products
- ★ Schedule of Training for Accreditation
- ★ Downloadable forms

E-mail Address:
fpa_77@yahoo.com

Website:
<http://fpa.da.gov.ph>

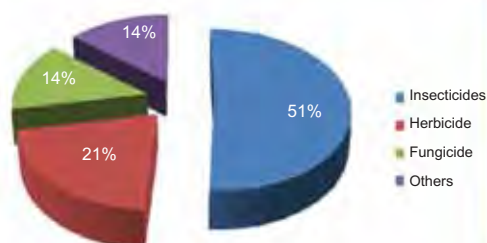


FPA Pesticide Regulatory Policies and Implementing Guidelines, otherwise known as the Greenbook



- mandate and functions of the FPA
- registration of chemical pesticides
- policy guidelines on biorational pesticides
- licensing
- certification and accreditation of pesticide handlers
- product stewardship and responsible care
- post-registration activities
- penalties for violations

TOTAL CROP PROTECTION PRODUCTS IN THE PHILIPPINE MARKET 2010



Current Situation and Developing Trend of Philippines' Pesticide Importation

Trend on the Importation of Pesticides

Type/Use	2009 Volume A.I. (MT)	2010 Volume A.I. (MT)
Insecticide	668.086	782.283
Fungicide	119.357	208.840
Herbicide	1 993.449	2 485.360
Nematicide	41.300	129.550
Rodenticide	0.105	
Molluscicide	117.600	
Termiticide	0	
Others		
TOTAL	3 606.033	2 939.897

IMPORTATION OF PESTICIDE

The FPA in cooperation with Bureau of Custom, the importation of pesticides in the country is not allowed unless the agency will issue an appropriate Certificate Authorizing Importation of Pesticides (CAIP)

- ✧ The importer must be licensed by FPA
- ✧ The pesticide product(s) and active ingredient(s) must bear a registration number, or covered by an appropriate Experimental Use Permit.

IMPORTATION OF PESTICIDES...

- ✧ The following must be specified in the request for importation:
 - ✧ product, specifying % purity if technical material or active ingredient if formulated product
 - ✧ unit price
 - ✧ quantity
 - ✧ payment terms
 - ✧ country of origin
 - ✧ destination
 - ✧ carrier/vessel

IMPORTATION OF PESTICIDES...

- ✧ The pro-forma invoice must be attached. This shall enable FPA to correlate the source of supply to the registration of the product.
- ✧ The bill of lading, which verifies that the above transaction transpired at the term(s) and price(s) stated on the pro-forma invoice, must be attached to the subsequent request for importation.

Online Application for Pesticide Import & Export: Philippine National Single Window

The Philippines National Single Window (NSW) will facilitate trade through efficiencies in the Customs and authorization processes. Strongly supported by the Office of the President and mandated to be implemented via Executive Order 482, the NSW will allow single submission and accelerated processing of applications for licenses, permits and other authorizations required prior to undertaking a trade transaction.

It includes the application of permit to import and export pesticides including the inert ingredients under the Fertilizer & Pesticide Authority of the Department of Agriculture.



LICENSED PESTICIDE HANDLERS

HANDLERS	2010	2011	2012 (11 th SEM)
AGRICULTURAL	314	338	179
HOUSEHOLD	(2006 = 187)	(2007 = 393)	–
DEALERSHIP	130	125	80
FUMIGATOR	230	211	82
EXTERMINATOR	153	135	135
Manufacturers	–	2	–
Formulators	–	7	–
Repackers	–	7	–

● LICENSING OF PESTICIDE HANDLERS

Duly accomplished and notarized *application form* (original copy) For:

- ✧ Corporation/Partnership
 - ✧ copy of *SEC Registration*
- ✧ Cooperative-copy of *CDA Registration*
- ✧ Single Proprietorship
 - ✧ copy of *Certificate of Registration of Business Name* with the DTI
 - ✧ copy of latest *Income Tax Return* and *Financial Statement*
- ✧ For Distributor/Area Distributor:
 - ✧ Distributorship Agreement/Certification from the pesticide supplier
 - ✧ Recommendation from the FPA Provincial Officer
- ✧ For Indentor
 - ✧ copy of contract with Manufacturer/Supplier

PESTICIDE HANDLERS/PRODUCTION PLANT REQUIREMENTS

For Formulator/Repacker/Treatment Plant/Recycling Plant:

- ✦ Environmental Compliance Certificate (ECC) from DENR
- ✦ Production process/flow chart
- ✦ Recommendation/inspection report from FPA Provincial Officer
- ✦ Written authority to repack/formulate from the supplier
- ✦ Pre-licensing inspection report by the Pesticide Audit Team
- ✦ Registration of Pesticide Warehouse/s
- ✦ Xerox copy of Responsible Care Officer (RCO)/Accredited Responsible Care Officer (ARCO) ID
- ✦ Product registration of pesticide to be sold
- ✦ License fee

LAGUNA LAKE DEVELOPMENT AUTHORITY (LLDA): DISCHARGE PERMIT

The discharge permit effectively allows the firm to discharge its wastewater to the lake or through its main tributaries. The discharge permit gives the establishment a legal right to dispose their waste water in the Laguna de Bay Region.

Storm water is a nonresidential source and carries trash and other pollutants from streets, as well as pesticides and fertilizers from yards and fields

Wastewater is basically, sewage, storm water and water used for various purposes around the community, including firms. Wastewater can either be domestic or non domestic. Domestic wastewater includes black water, or wastewater from toilets, and gray water, which is wastewater from all sources except toilets. Black water and gray water have different characteristics, but both contain pollutants and disease-causing agents that require monitoring.

LAGUNA LAKE DEVELOPMENT AUTHORITY (LLDA) DISCHARGE PERMIT

- ✦ According to the Clean Water Act of 2004, the DENR (through the LLDA) shall "implement a wastewater charge system in all management areas including the Laguna Lake region and Regional Industrial Centers through the collection of wastewater charges/fees.

DENR LICENSES

- ✦ ENVIRONMENTAL COMPLIANCE CERTIFICATE (ECC)
- ✦ DISCHARGE PERMIT
- ✦ PERMIT TO OPERATE (AIR POLLUTION SOURCE)
- ✦ HAZARDOUS WASTE ID
- ✦ CHEMICAL PERMITS

LGU (LOCAL GOVERNMENT UNITS)

- ✦ Mayor's Permit

The local government units (LGU), being at the forefront of development in the countryside, are more in a position to determine the acceptability of projects within their respective areas.

PESTICIDE PRODUCT REGISTRATION

- ✦ Types of Pesticide Registration Granted
- ✦ There are two types of registration granted: full and conditional.



PESTICIDE PRODUCT REGISTRATION

It is in the provision of the guidelines that the following are types of pesticide products that shall be registered at FPA:

- ✦ New End Use Products or Formulation
- ✦ Modification in the Registration of a Registered Product
- ✦ Registered Pesticides with Changes in Formulation
- ✦ New Technical Grade Active Ingredient or a New Source
- ✦ Permit for an Off-Label Use of Pesticide



PESTICIDES, AS DEFINED IN PO 1144

- Any substance or product, or mixture thereof, including active ingredients, adjuvants and pesticide formulations, intended to control, prevent, destroy, repel or mitigate directly or indirectly, any pest.
- It includes insecticide, fungicide, bactericide, nematocide, herbicide, molluscicide, avicide, rodenticide, plant regulator, defoliant, dessicant, and the like.

PESTS

Organisms, such as insects, weeds, fungi, rodents, nematodes, viruses, terrestrial or aquatic plants, etc., which cause damage to crops or foodstuffs.

FPA REGISTERED PESTICIDE PRODUCTS 2011

- Active ingredients = 201
- Formulated Products = 1 176

FPA REGISTERED FORMULATED PESTICIDE PRODUCTS 2010–2012

Type Registration	2010	2011	2012 (1 st Sem)
Registered	477	534	221
Renewed	580	642	360
Total	1 057	1 176	581

LIST OF REGISTERED AGRICULTURAL PESTICIDES as of 31 JANUARY 2011

NAME OF COMPANY	ACTIVE INGREDIENT	PRODUCT NAME	CONCENTRATION	FORMULATION TYPE	AREA	TECHNOLOGY	REGISTRATION NO.
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10
Agro-Pharm (Punjab)	CHLORPYRIFOS	AGRO-CHLOR	450g/L	EC	10	1	10/10/10

A. CLASSIFICATION BASED ON PEST CONTROLLED:

Pesticide	Pest controlled
1) Acaricide	1. mites, ticks and spiders
2) Algicide	2. algae
3) Arboricide	3. trees, bushes, shrubs
4) Avicide	4. birds
5) Fungicide	5. fungi
6) Herbicide	6. weeds
7) Insecticide	7. insects, mites, ticks
8) Ixodicide	8. Ticks
9) Larvicide	9. larvae
10) Miticide	10. mites, ticks, spiders
11) Molluscicide	11. slugs and snails
12) Nematocide	12. nematodes
13) Ovicide	13. eggs
14) Piscicide	14. fish
15) Rodenticide	15. rodents
16) Termiticide	16. termites

B. Classification of Pesticide based on Effects on Pest:

- Anti-feedant – inhibits feeding of treated plants resulting to death due to starvation.
- Anti-transpirant-reduces transpiration.
- Attractant-lures pests to a treated location e.g. sex attractant.
- Chemosterilant-destroys the ability of the insects to reproduce.
- Defoliant-removes unwanted plant growth without immediately killing the whole plant.
- Disiccant – dries up parts of plants or insects.
- Dissinfectant – destroys or inactivates harmful micro-organisms.
- Feeding stimulant – causes insects to feed more vigorously.
- Growth regulatory – stops, speeds up or retards growth processes of plant and insects.
- Repellent – drives pests away from treated objects without killing them.
- Semiochemical – pheromone, allomone and kairomone; substances emitted by plants or animals which stimulate or inhibit certain behavioural activities of insects.
- Synergist – enhances the effectiveness of a pesticide, it is by itself not toxic.

C. Classification based on Mode of Action or Entry

- Stomach poison:**
Generally enters the pest through the mouth by ingestion and absorption in the digestive tract.
- Contact poison:**
penetrates the insect body as result of contact of the legs and other parts of the body on treated surfaces.
- Fumigant:**
Poison is volatile and enters the body through the respiratory system of the insects

D. BASIC CLASSIFICATION OF PESTICIDE BASED ON WHO-FAO GUIDELINES

Category & Signal Words	Color band, symbol	Acute LD ₅₀ for Rats (mg/kg body weight)			
		Oral		Dermal	
		Solid	Liquid	Solid	Liquid
Category I	Red	50 or less	200 or less	100 or less	400 or less
Category II Warning: Harmful	Yellow	50-500	200-2 000	100-1 000	400-4 000
Category III Caution	Blue	500-2 000	2 000-3 000	Over 1 000	Over 4 000
Category IV	Green	Over 2 000	Over 300	NA	NA



Toxicity is the innate property of the pesticide compound to produce harm, while hazard is the risk or the likelihood of an adverse effects in using the particular compound.

Pesticides are classified into different categories (I to IV) based on LD_{50} 's of the technical material or the formulated product. A low LD_{50} value indicates a more toxic compound.

E. CLASSIFICATION BASED ON FORMULATION TYPES:

Most pesticide active ingredients are not used as such mixed with other materials to aid in their effectiveness or ease of application. Most common formulations are either; 1) for dilution with water, 2) applied undiluted, 3) or applied for special purposes.

- 1) Formulations for dilution with water:
 - a) Emulsifiable Concentrate (EC) – a solution of active ingredient in non-water miscible solvents.
 - b) Flowable (F) – stable suspension of active ingredient in fluid intended for dilution in water. This is for active ingredients soluble in neither oil or water.
 - c) Wettable Powder (WP) – applied as suspension after dispersion in water. Active ingredient is blended with an inert material like ground talc or clay mixed with wetting and dispersing agent.

F. Classification based on name of pesticide:

Pesticide can be classified on; 1) chemical name, 2) common name and, 3) trade name.

- 1) Chemical name – name given by the International Union of Pure and Applied Chemist (IUPAC) standard as based on the chemical structure of the compound.
- 2) Common name – adapted name accepted by the international organization like ISO and BSI e.g. carbaryl, monocrotophos and carbofuran.
- 3) Trade name – name given by the manufacturer of the pesticide formulation e.g. monocrotophos marketed as Azodrin and Nuvacron.

EXPERIMENTAL USE PERMITS

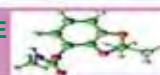
- ✳ Pesticide products, chemicals and biorationals intended for registration shall be tested for efficacy under local conditions. For field-testing necessary to generate data for registration purposes or other uses, Experimental Use Permit (EUP) shall be applied for and under no circumstance shall the test be conducted without the approved EUP.
- ✳ The experiment shall be conducted by researchers accredited by FPA following the standard protocols for biological efficacy testing. Data submitted without the necessary permit/conditionalities shall not be accepted for registration.

PD 1144, SECTION 9:

Registration and Licensing

- ✳ No pesticides, fertilizers or other agricultural chemicals shall be dealt with, anywhere in the country, unless it has been duly registered at FPA.
- ✳ No person shall engage in any business or activity involving of any pesticides, fertilizers and other agricultural chemicals except under a license issued by the FPA.
- ✳ The FPA may suspend, revoke or modify the registration of any pesticide, fertilizer and agricultural chemicals after due notice and hearing.

DATA REQUIREMENTS FOR THE REGISTRATION OF PESTICIDE



- ✳ Chemical Pesticides
 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

DATA REQUIREMENTS

GENERAL

- ✳ Name/address of applicant
- ✳ Product Trade/Brand Name
- ✳ Manufacturer of Technical Pesticide
- ✳ Description of Production Process³

SPECIFICATIONS

- ✳ Common Name of Active Ingredient (Proposed or Accepted ISO name)
- ✳ Chemical Name of Active Ingredient (IUPAC designation)
- ✳ Chemical Abstract Service Number
- ✳ Formula (empirical and structural)
- ✳ Composition of Technical including Impurities (all materials present at or over 0.1%)⁴
- ✳ List of ingredients and percent variations of each⁵
- ✳ Appearance, color, state, odor
- ✳ Melting point
- ✳ Boiling point
- ✳ Vapor pressure
- ✳ Density or Specific Gravity
- ✳ Octanol Partition Coefficient

TOXICOLOGY

- ✳ Estimation of Acute Oral LD_{50}
- ✳ Estimation of Acute Dermal LD_{50}
- ✳ Inhalation LC_{50}
- ✳ Skin Irritation/Corrosivity
- ✳ Dermal Sensitization
- ✳ Allergic Sensitization
- ✳ Sub-chronic toxicity (21 days, dermal)
- ✳ Sub-chronic toxicity (90 days, oral)
- ✳ Sub-chronic toxicity (90 days, dermal)
- ✳ Teratology
- ✳ Reproduction
- ✳ Chronic toxicity
- ✳ Oncogenicity
- ✳ Mutagenicity



HUMAN EXPOSURE AND SAFETY

- ✳ Assessment of applicator exposure
- ✳ Assessment of farm worker exposure
- ✳ Signs and symptoms of acute human poisoning
- ✳ Recommended first aid procedures
- ✳ Recommended medical treatment for poisoning, include antidote if any
- ✳ Proposed Acceptable Daily Intake
- ✳ Protective equipment
- ✳ Other precautions

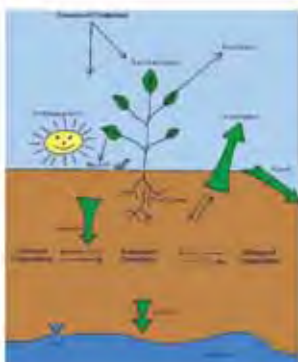


ENVIRONMENTAL EFFECTS

- ✳ Avian acute oral toxicity
- ✳ Avian dietary acute toxicity
- ✳ Fish acute toxicity
- ✳ Sub-acute fish toxicity
- ✳ Aquatic acute toxicity
- ✳ Accumulation in fish
- ✳ Avian reproduction
- ✳ Fish reproduction
- ✳ Acute toxicity to honey bees
- ✳ Contact toxicity to honey bees
- ✳ Soil non-target micro-organisms
- ✳ Soil non-target macro-organisms



ENVIRONMENT FATE AND TRANSPORT



- ✳ Volatility
- ✳ Adsorption/desorption
- ✳ Leaching
- ✳ Degradation in soil
- ✳ Biodegradation
- ✳ Hydrolysis
- ✳ Aqueous photolysis
- ✳ Analytical method – residues in soil
- ✳ Analytical method – residues in water

RESIDUES IN FOOD

- ✳ For food use only
- ✳ Identity of principal residues, metabolites and degradation products in edible crops, foods or feeds
- ✳ Residue decay curves for residues on crops to be treated
- ✳ Residues of active ingredient and principal metabolite in animals fed treated feeds or grazed on treated fields or pastures
- ✳ Effects of food processing or home preparation on residues
- ✳ Analytical method for detection of principal residues, metabolites on treated commodities
- ✳ Proposed maximum residue level for each crops, food, feed or animal expected to contain residues



LABELLING

- ✳ Proposed toxicity category
- ✳ Draft label (3 copies)



DATA REQUIREMENTS OF OTHER PESTICIDE REGISTR

Other Chemicals	Data requirements			
	Specifications & Bio-efficacy Only	Specifications, Bio-efficacy, MSDS and acute toxicity studies	Specifications and MSDS	FPA Data Requirements for Pesticide Products
Insect growth regulator				X
Defoliant				X
Desiccant				X
Wood preservative				X
Plant growth regulator	X (minimum requirements)			X (if shown as hazardous or has any other uses)
Synergist		X		
Pheromone		X		
Surfactant		X (as lone material/product)	X (as component of product formulation)	
Emulsifier		X (as lone material/product)	X (as component of product formulation)	
Penetrant		X (as lone material/product)	X (as component of product formulation)	
Wetting agent		X (as lone material/product)	X (as component of product formulation)	
Safener		X (as lone material/product)	X (as component of product formulation)	
Adjuvant		X (as lone material/product)	X (as component of product formulation)	

DATA REQUIREMENTS FOR BIORATIONAL PESTICIDES

- ✳ BIOCHEMICAL PEST CONTROL AGENTS
- ✳ MICROBIAL PEST CONTROL AGENTS
- ✳ BIOTECH BASED PESTICIDES
 - ✳ Plant-Incorporated-Protectant-considered as 3rd generation biorational pesticides
 - ✳ Regulated under the Department Order No. 8, series of 2002

POST-REGISTRATION ACTIVITIES

- ✳ Product Stewardship & Responsible Care
- ✳ Information & Education Campaign
- ✳ Pesticide Waste Disposal
- ✳ Occupational Health & Safety
- ✳ Monitoring (field) of pesticide handlers and pesticide products



PRODUCT STEWARDSHIP & RESPONSIBLE CARE

- ✧ Recognizing the role of the Industry in pursuing product stewardship programs, FPA coordinates with the pesticide stakeholders and other professional organizations to work out a sustainable scheme towards continuous efforts in educating pesticide handlers, particularly farmers, in the judicious and safe handling of crop protection products.



INFORMATION AND EDUCATION CAMPAIGN



- ✧ Farmers Trainings
- ✧ Use of Pamphlets



- ✧ ACTUAL DEMONSTRATION
- ✧ ADVICE ON USE OF PROPER ATTIRE

PROPER PESTICIDE WASTE DISPOSAL



- ✧ The Company concerned shall provide the necessary training on the safe handling and use of its product (including proper waste disposal) to dealers and users following FPA approved modules.

Disposal of Pesticide Containers

1. Combustible container: burning with license from municipality
2. Non combustible containers
 - Large containers (50-200 L, drums)
 - Decontaminate by rinsing before:
 - ▶ Returning to supplier
 - ▶ Selling
 - ▶ Bringing to sanitary landfill type of dump
 - Small container
 - ▶ Dispose at public dump
 - ▶ Buried at least 1/2 m deep
 - Herbicide containers
 - ▶ Retrieval of herbicide container is part of company's product stewardship program.



OCCUPATIONAL HEALTH

- ✧ Occupational Health Personnel
 - ✧ Nurses and Physician are accredited by DOLE.
 - ✧ Other paramedical staff should be trained and accredited by Phil. Nat'l Red Cross (PNRC) or by SOPI (Safety Org. of the Phils.)
- ✧ Workers
 - ✧ Have periodic training on
 1. Proper & safe handling of pesticides
 2. Proper use of personnel protective clothing & equipment
 3. Basic knowledge on chemicals they are handling.
 4. First aid procedure in case of poisoning

REQUIREMENTS FOR PEST CONTROL ESTABLISHMENTS

- ✧ Emergency Equipment
 - ✧ Emergency shower
 - ✧ Eyewash facility
 - ✧ Firefighting equipment in strategic location (e.g. fire extinguisher)
- ✧ Regular inspection and maintenance of equipment (records shall be kept for inspection)
- ✧ Emergency clinic with trained health personnel
- ✧ Fire exit

LIST OF BANNED AND RESTRICTED PESTICIDES



- ✧ **BANNED PESTICIDES** are not to be brought into and used in this country, under any circumstances.

- Banned Pesticides**
1. Parathion-ethyl
 2. Copper aceto-arsenite (Paris Green)
 3. DDT containing mosquito coil
 4. DBCP
 5. Nitrofen
 6. Leptophos
 7. EPN
 8. Endrin
 9. Mercuric fungicides
 10. Toxaphene
 11. Elemental phosphorus (white and yellow)
 12. Thallium sulfate
 13. 1-Naphthylthiourea (ANTU)
 14. Gophocide
 15. Sodium fluoroacetate
 16. Sodium fluoroacetamide (1081)
 17. Strychnine
 18. 2, 4, 5-T
 19. Aldrin
 20. Dieldrin
 21. Heptachlor
 22. Chlordimeform
 23. EDB
 24. HCH/BHC
 25. Methyl parathion
 26. Organotin compounds
 27. Azinphos Ethyl
 28. Chlordane

RESTRICTED PESTICIDES...

GUIDELINES ON RESTRICTED PESTICIDES

A restricted pesticide is covered by two basic guidelines:

- A. They may not be allowed for distribution, sale and use in certain crops and/or areas of the country, and;
- B. They may be used only by and under the supervision of certified applicators, or under such conditions as the FPA Administrator may require.

CLASSIFICATION OF RESTRICTED PESTICIDES

The list of restricted pesticides is categorized as follows:

1. Those which are not for importation except in cases of emergency. Such cases are to be determined by the Authority.
2. Those to be used for termite control only.
3. Those to be used under specific limitations.
4. Fumigants and other chemicals for use only by certified fumigators.

LIST OF BANNED AND RESTRICTED PESTICIDES...

Restricted Pesticides

- A. Importation Not Allowed Except in Cases of Emergency as Determined by the Authority
1. Aldicarb
 2. Chlorobenzilate
- B. For use Under Specific Limitations
1. DDT
 - All uses cancelled except for malaria control purposes by the Department of Health.
 2. Endosulfan
 - Not for use near aquatic system and in paddy rice. The concentration will be reduced to 5% EC or lower for other uses (FPA Board Resolution No. 01, 1993).
 3. Monocrotophos
 - Allowed use is for beanfly control on legumes only (FPA Board Resolution No. 01, 1993).

RESTRICTED PESTICIDES...

4. Too Hazardous for General Use (For Institutional Use Only)
 - a. Paraquat
 - Restricted for Institutional Use Only. Approval of use will be based on strict compliance by the importer/end-user of the requirements set for its use.
 - b. Phenemiphos
 - For use in banana and pineapple plantations only.
 - c. Ethoprop
 - For use in banana plantations only.
 - d. Methidathion
 - For use in banana plantations only.
 - e. Inorganic Arsenicals (Arsenic Trioxide)
 - For use by FPA accredited wood treatment and wood preserving plants only.
 - f. Lindane (Gamma/BHC)
 - The only allowed use to date is on pineapple plantations by soil pre-plant application.
 - g. Pentachlorophenol
 - For use in wood treatment only by FPA accredited wood treatment plants and institutions.

RESTRICTED PESTICIDES...

Fumigants and Other Chemicals for Use Only by Certified Fumigators

Adequate time for aeration is required after treatment before commodities are processed into food or feed.

1. Methyl bromide
2. Carbon disulfide
3. Phosphine generating compounds
4. HCN-generating materials
5. Carbon tetrachloride
6. Chloroform
7. Ethylformate

PHILIPPINE COMMITMENT TO INTERNATIONAL TREATIES & STANDARDS

- ✧ Stockholm Convention on POPs
 - ✦ Adopted 23 May 2001
 - ✦ Entered into force 17 May 2004
 - ✦ Banned POPs pesticides-aldrin, dieldrin, endrin, heptachlor, toxaphene, hexachlorobenzene, chlordane & DDT
- ✧ GHS (Globally Harmonized System) on Labelling & Classification
 - ✦ Commitment-Voluntary
 - ✦ Agriculture Sector-FPA as lead implementor is waiting for the FAO Guidance Document with integrated principle of GHS.

PHILIPPINE COMMITMENT TO INTERNATIONAL TREATIES & STANDARDS

- ✧ Rotterdam Convention on PIC for certain hazardous chemicals & pesticides in international trade.
 - ✦ Ratified 27 Feb. 2006
- ✧ Montreal Protocol (ODS)
 - ✦ Ratified 17 July 1991
 - ✦ Philippine Ozone Desk-Methyl bromide
- ✧ Kyoto Protocol
 - ✦ Ratified 16 Feb. 2005
 - ✦ "clean development mechanism for investment in renewable energy"

ACCEPTABLE PROTOCOL

- ✧ Bio-efficacy Test Protocols, FPA Revised Guidelines, 1985.
- ✧ FAO Guidelines for the Submission and Evaluation of Pesticide Residue Data for the Estimation of Maximum Residue Levels in Food and Feed. FAO, Rome, 1997.
- ✧ FAO Guidelines:
 - ✦ Crop Residue Data
 - ✦ Packaging and Storage of Pesticides
 - ✦ Good Labelling Practice for Pesticides
 - ✦ Disposal of Waste Pesticides and Containers on the Farm
- ✧ Environmental Criteria for the Registration of Pesticides.
- ✧ FAO Harmonized Test Protocols, 1994.
- ✧ Good Analytical Practices, Report of the Fifteenth Session of the Codex Committee on Pesticide Residues, The Hague, 3-10 October 1983. (attached as Annex VI)
- ✧ Good Laboratory Practice, C (81) 30. Organization for Economic Cooperation and Development, Paris.
- ✧ Guidelines on Pesticide Residue Trials to Provide Data for Registration of Pesticides and the Establishment of Maximum Residue Limits. FAO of the United Nations; Rome, 1986.
- ✧ Guidelines for Testing of Chemicals, Organization for Economic Cooperation and Development, Paris, 1981.
- ✧ Guidelines for Registering Pesticides in the U.S., Environmental Protection Agency

- ✧ Internationally Accepted Guidelines
- ✧ Principles for the Toxicological Assessment of Pesticide Residues in Food, Environmental Health Criteria, No. 104. 1990, 117 pages ISBN 9241571047.
- ✧ Pesticide Residues in Food. FAO-WHO Joint Meeting on Pesticide Residues in Foods Part I: Pesticide Residues Evaluation, Part II: Toxicology Evaluation.

- ✧ The Use of FAO Specifications for Plant Protection Products, FAO Plant Protection and Protection Paper 13, Rome, 1979.
- ✧ WHO Specifications for Pesticides Used in Public Health, Sixth Ed., Geneva, Rome, 1985.
- ✧ Codex Recommended National Regulatory Practices to Facilitate Acceptance and Use of Codex Maximum Limits for Pesticide Residues in Foods, ALINORM 85/24A - Add. 2, FAO, 1985

3.13 SINGAPORE

1. Pesticide Legislation and Regulations

1.1 The Agri-Food and Veterinary Authority of Singapore (AVA) controls 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. Pesticide products meant for use in the agricultural farms are required to be registered with AVA. Non-agricultural use pesticides are not required to be registered under the legislation. In addition to pesticide registration, the application of pesticides in the agricultural farms is required to be carried out or supervised by an AVA certified pesticide operator under the Control of Plants (Cultivation of Plants) (Licensing and Certification) Rules.

1.2 A pesticide is defined under the Control of Plants Act as, any substance or mixture of substances prepared or used for preventing, destroying, repelling or mitigating any pest and any substance or mixture of substances prepared or used as a plant regulator, defoliant or desiccant.

1.3 Singapore registered companies which manufacture, import, distribute, supply or sell pesticide products intended for agricultural use can apply for the registration of the pesticide products. The applicant is required to submit a duly completed application form together with the required documents as mentioned in the registration guidelines. A copy of the registration form and guidelines on the registration can be found on AVA website: www.ava.gov.sg.

Import of Chemical Pesticides

1.4 The import, sell or export of hazardous substances (HS) including pesticides is regulated by the National Environment Agency (NEA) under the Environmental Protection and Management Act (EPMA). The Hazardous Substance Requirements are:

- I. Any person who wishes to import, sell or export, any hazardous substance controlled under the EPMA must obtain a Hazardous Substances Licence.
- II. Any person who wishes to purchase, store and/or use any hazardous substance controlled under The Environmental Protection and Management (Hazardous Substances) Regulations must obtain a Hazardous Substances Permit.
- III. Any person who wishes to transport any hazardous substance in quantities exceeding those specified in The Environmental Protection and Management (Hazardous Substances) Regulations must possess a valid Hazardous Substances Licence before applying for transport approval. The requirements for the transport approval are available in the NEA website: www.nea.gov.sg.

1.5 The applicant is required to check with NEA to see if the pesticide is allowed for import and local use prior to registering the pesticide product with AVA.

Import of Biological Control Agents

1.6 The import of biological control agent is regulated by AVA under the Control of Plants (Plant Importation) Rules. A “biological control agent” (BCA) is defined as a natural enemy, an antagonist or a competitor of a pest, or any other self-replicating biotic entity, used for pest control. AVA will conduct an Import Risk Analysis (IRA) on the organism to be imported. Import will be granted only when the risk is considered acceptable. (refer to Annex A)

2. Registration application and data requirements

2.1 For registration, the applicant has to pay a one-time registration fee of \$465 and submit the application form together with the registration dossier consisting of technical information on the product and active ingredient, including toxicology, efficacy, environmental effects and ecotoxicity data for AVA's evaluation. Details on the data requirements can be found in the AVA website: <http://www.ava.gov.sg/> (or Annex B)

2.2 The data submitted is treated as confidential. The provisions for data protection periods are under Section 15 of the Control of Plants Act and Section 7 of the Control of Plants (Registration of Pesticides) Rules.

Control of agricultural pesticides by AVA

- ◆ Pesticides for use at the local agricultural farms must be registered.
 - Legislation: the Control of Plants Act and the Control of Plants (Registration of Pesticides) Rules
- ◆ Application of pesticides at the farms must be carried out by AVA certified pesticide operators
 - Legislation: the Control of Plants Act and the Control of Plants (Cultivation of Plants) (Licensing and Certification) Rules

Registration Procedures & Requirements

- ◆ Manufacturers, importers, distributors or suppliers can apply for the registration
- ◆ Applicant must register with the Accounting and Corporate Regulatory Authority (ACRA) under the Business Registration Act (Cap. 32)
- ◆ Submit application form and required information (available from the AVA website: www.ava.gov.sg)
- ◆ Registration fee \$465.00

3. Pesticide Evaluation and Registration

3.1 During the registration process, AVA carries out assessment of the pesticide product based on the information provided in the registration dossier to ensure that the pesticide product does not pose unreasonable adverse effects on humans, wildlife and the environment before registration is granted. The dossier can also be further assessed by the AVA Technical Working Group on Pesticide Registration where expertise evaluation and assessment are needed.

3.2 Once a pesticide product is approved, a Certificate of Pesticide Registration with the registration number will be issued to the registrant. The registration of the pesticide product is a product-based registration and is life-time. The registration takes effect from the date stated in the certificate.

3.3 The registrant is required to comply with the labelling requirements listed in Annex C and print the registration number on the pesticide product's label. The registration of a pesticide is also published in the Gazette and an updated list of AVA registered pesticides is available in the AVA website.

Evaluation & Approval

- ◆ Evaluation of dossier by the AVA Technical Working Group on Pesticide Registration
- ◆ Approval
 - Issue a Certificate of Pesticide Registration with a designated AVA Registration Number
 - AVA Registration Number has to be printed on the product label
 - Gazette
 - A list of registered pesticide products are available in the AVA website

Number of registered pesticide products

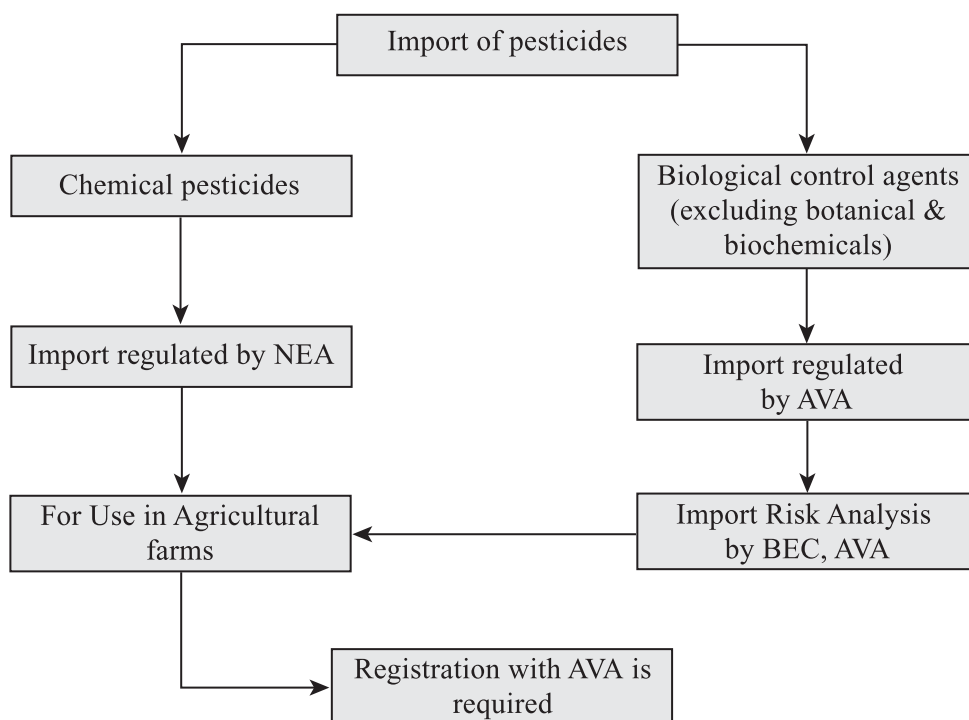
No. of chemical pesticides	301
No. of microbial pesticides	10
No. of botanical pesticides	3
No. of biochemical pesticides	0

4. Post-Registration Activities

4.1 Once the pesticide products are registered with AVA, they are allowed for use in the agricultural farms. Only AVA certified pesticide operators are allowed to apply or supervise the application of pesticides at the farms. This is in accordance to Section 11 of the Control of Plants Act.

4.2 Pesticide Operator Certification (POC) training and proficiency test were conducted as part of the requirements for certification of competent pesticide operators in local farms.

4.3 AVA officers also carried out farm inspection to ensure that pesticide use at the farms complies with requirements under the Control of Plants Act, the Control of Plants (Cultivation of Plants) (Licensing and Certification) Rules and the Control of Plants (Registration of Pesticides) Rules. Samples from locally produced food crops are also collected for pesticide residue testing. Enforcement actions can be taken against the farm licensee, pesticide operators, the pesticide product's registrants or suppliers for non-compliances (such as using unregistered pesticide at the farms) under the legislation.

Regulation of Agricultural Pesticides

Data Requirements

1. Data Requirements for Chemical Pesticides

- 1) Information on the active ingredient(s)
 - Chemical name
 - Common name
 - Other name (if any)
 - Empirical and structural formula
 - Molecular weight
 - Physical properties
 - Chemical properties
 - Method of analysis of active ingredient(s)/technical material
 - Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the manufacturing process
- 2) Information on the technical grade active ingredient(s) added to product
 - Source; name and address of manufacturer
 - Appearance (physical state, colour and odour)
 - The minimum (and maximum) active ingredient content in g/kg
 - Complete manufacturing process, including all raw materials, reagents and solvents
 - Identity and amount of isomers, impurities and other by-products, together with information on their possible range expressed as g/kg
 - Maximum limits for impurities present in the technical material at 1 g/kg or greater
- 3) Information on the formulated product
 - Manufacturer's name and address
 - Complete composition including chemical identities of inert ingredients
 - Physical condition and nature of the formulation
 - Stability and shelf life of the formulation
 - Corrosiveness towards packing materials and application equipment
 - Flammability under storage and application conditions
 - Method of analysis of the formulation
 - Method of analysis of residue in plant and foodstuff
 - Incompatibility with other pesticides
 - Decontamination/neutralising agent
 - Disposal method for the formulation and its containers
 - Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the formulation
- 4) Information on the usage
 - The control efficacy of the pesticide, including details of efficacy studies, its designated use against the target pest(s) and disease(s) in relation to crops
 - Instruction for use, recommended dosage and application method
 - Mode of action
 - Phytotoxicity on plants
 - Compatibility with other pesticides
 - Precautionary measures
 - For pesticide used on food crops
 - pre-harvest interval
 - maximum residue level and acceptable daily intake in other countries where the same pesticide has been registered should be included
- 5) Residue data in agricultural produce

- 6) Information on the toxicity in mammals
 - Acute oral (LD_{50})
 - Acute dermal (LD_{50})
 - Inhalation toxicity (LC_{50})
 - Degree of irritation to eye
 - Degree of skin irritation and sensitization
 - Chronic toxicity of active ingredient
 - No observable effect level of active ingredient
 - Supplementary studies of toxicity (long/short term studies) of active ingredient(s)
 - Carcinogenicity
 - Reproductive toxicity including teratogenicity
 - Mutagenicity
 - Neurotoxicity
 - Persistence and metabolic breakdown pathway of the active ingredient
 - Endocrine disrupting properties that may be of toxicological significance in humans
- 7) Information on environmental effects and eco-toxicity
 - Toxicity to beneficial insects, non-target pests, avian and fish
 - Endocrine disrupting properties that may be of toxicological significance on non-target organisms
 - Impact on soil ecology
 - Residual effect in soil
 - Leaching, degradation of product in the soil and possibility of accumulation
- 8) Information on measures to be taken in case of poisoning
 - Antidote(s) for the active ingredient/formulation
 - First aid treatment for active ingredient/formulation
- 9) A copy of the analysis report of the pesticide product stating the composition of the constituents particularly the active ingredient(s).
- 10) Other technical literature, data, and supporting documents related to the pesticide product must be enclosed with this application form.
- 11) Registration status in other countries (Copies of registration documents should be attached)
- 12) Approval from relevant local and overseas authorities for manufacture, import, distribution, sale, supply, transport, storage and usage of the pesticide product

2. Data Requirements for Microbial Pesticides

- 1) Information on the active substances(s)
 - Common name (including alternative and superseded names)
 - Taxonomic name and strain indicating whether it is a stock or a mutant strain; for viruses, taxonomic designation of the agent, serotype, strain or mutant
 - Methods, procedures and criteria used to establish the presence and identity of the organism (e.g. morphology, biochemistry, serology, etc.)
 - Biological properties of the organism
 - History of the organism and its uses including as far as is known its general history and, if relevant, its geographical distribution
 - Relationship to existing pathogens of vertebrates, plants or other organisms
 - Effects on target organism. Pathogenicity or kind of antagonism to the host. Details of host specificity range should be included
 - Transmissibility, infective dose and mode of action including information on presence, absence or production of toxins with, if appropriate, information on their nature, identity, chemical structure and stability and potency

- Possible effects on non-target organisms closely related to the target organism including infectivity, pathogenicity and transmissibility
 - Transmissibility to other non-target organisms
 - Any other biological effects on non-target organism when properly used
 - Infectivity and physical stability when properly used
 - Genetic stability under environmental conditions of proposed use
 - Any pathogenicity and infectivity to man and animals under conditions of immunosuppression
 - Any allergic reactions to human/mammals
 - Pathogenicity and infectivity for known parasites/predators of the target species
 - Physical properties
 - Chemical properties
- 2) Information on the technical grade active ingredient(s) added to product
- Source, name and address of manufacturer including location of plants
 - Occurrence in nature or otherwise
 - Isolation methods for organism or active strain
 - Culture methods
 - Production methods including details of containment and procedure to maintain quality and ensure a uniform source of active organism. For mutant strains, detailed information should be provided on production and isolation, together with all known differences between the mutant strains and parent occurring strains
 - Composition of the final active organism material i.e. nature, purity, identity, properties, content of any impurities and extraneous organisms
 - Methods to prevent contamination of seed stock and loss of virulence of seed stock
 - Procedure for waste management
- 3) Information on the formulated product
- Manufacturer's name and address
 - Detailed quantitative and qualitative information on the composition (active organism, inert ingredients, extraneous organisms, etc.)
 - Concentration of active organism in material used
 - Known contaminant(s) or impurity(ies) associated with the active ingredient(s)/organism in the formulation
 - Physical condition and nature of the formulation
 - Stability and shelf life of the formulation
 - Corrosiveness towards packing materials and application equipment
 - Flammability under storage and application conditions
 - Methods of detection and identification:
 - Methods for establishing the presence and identity of the organism
 - Methods for establishing the identity and purity of seed stock from which batches are produced and results obtained, including information on variability
 - Methods to show the microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, the results obtained and information on variability
 - Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35°C and other relevant temperatures)
 - Methods to determine viable and non-viable (e.g. toxins) residues in or on treated products, foodstuffs, feeding stuffs, animal and human body fluids and tissues, soil, water and air, where relevant
 - Incompatibility with other pesticides
 - Recommended methods and precautions concerning handling, storage, transport and use
 - Any circumstances or environmental conditions under which the active organism should not be used

- The possibility of rendering the active organism non-infective and any method for doing so
 - Decontamination/neutralising agent for the product and its packaging
 - Disposal method for the formulation and its containers
 - Consequences of the contamination of air, soil and water, particularly drinking water
 - Possibility of destruction or decontamination following release in or into the following: air, water, soil, others if appropriate.
- 4) Information on the usage
 - The control efficacy of the pesticide, including details of efficacy studies, its designated use against the target pest(s) and disease(s) in relation to crops
 - Instruction for use, recommended dosage and application method
 - Mode of action
 - Phytotoxicity on plants
 - Compatibility with other pesticides
 - Precautionary measures
 - For pesticide used on food crops
 - pre-harvest interval
 - maximum residue level and acceptable daily intake in other countries where the same pesticide has been registered should be included
 - 5) Residue data in agricultural produce
 - 6) Information on the toxicity in mammals
 - Acute oral (LD_{50})
 - Acute dermal (LD_{50})
 - Inhalation toxicity (LC_{50})
 - Degree of irritation to eye
 - Degree of skin irritation and sensitization
 - Chronic toxicity of active ingredient
 - No observable effect level of active ingredient
 - Supplementary studies of toxicity (long/short term studies) of active ingredient(s)
 - Carcinogenicity
 - Reproductive toxicity including teratogenicity
 - Mutagenicity
 - Neurotoxicity
 - Immunotoxicity studies (e.g. allergenicity)
 - Persistence and metabolic breakdown pathway of the active ingredient
 - 7) Information on environmental effects and eco-toxicity
 - Toxicity to beneficial insects, non-target pests, avian and fish
 - Impact on soil ecology
 - Residual effect in soil
 - Leaching, degradation of product in the soil and possibility of accumulation
 - 8) Information on measures to be taken in case of poisoning
 - Antidote(s) for the active ingredient/formulation
 - First aid treatment for active ingredient/formulation
 - 9) A copy of the analysis report of the pesticide product stating the composition of the constituents particularly the active ingredient(s).
 - 10) Other technical literature, data, and supporting documents related to the pesticide product must be enclosed with this application form.
 - 11) Registration status in other countries (Copies of registration documents should be attached)
 - 12) Approval from relevant local and overseas authorities for manufacture, import, distribution, sale, supply, transport, storage and usage of the pesticide product

3. Data Requirements for Biochemical Pesticides

- 1) A biochemical pesticide is a pesticide that is a naturally-occurring substance or structurally-similar and functionally identical to a naturally-occurring substance.
- 2) Examples include, but are not limited to:
 - a) Semiochemicals (insect pheromones and kairomones)
 - b) Natural plant and insect regulators
 - c) Naturally-occurring repellents and attractants
 - d) Enzymes
- 3) AVA may review, on a case-by-case basis, submission of biochemical pesticides registration that does not clearly meet the above-mentioned descriptions.
- 4) Information on the active ingredient(s)
 - Chemical name
 - Common name
 - Other name (if any)
 - Empirical and structural formula
 - Molecular weight
 - Physical properties
 - Chemical properties
 - Method of analysis of active ingredient(s)/technical material
 - Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the manufacturing process
- 5) Information on the technical grade active ingredient(s) added to product
 - Source; name and address of manufacturer
 - Appearance (physical state, colour and odour)
 - The minimum (and maximum) active ingredient content in g/kg
 - Complete manufacturing process, including all raw materials, reagents and solvents
 - Identity and amount of isomers, impurities and other by-products, together with information on their possible range expressed as g/kg
 - Maximum limits for impurities present in the technical material at 1 g/kg or greater
- 6) Information on the formulated product
 - Manufacturer's name and address
 - Complete composition including chemical identities of inert ingredients
 - Physical condition and nature of the formulation
 - Stability and shelf life of the formulation
 - Corrosiveness towards packing materials and application equipment
 - Flammability under storage and application conditions
 - Method of analysis of the formulation
 - Method of analysis of residue in plant and foodstuff
 - Incompatibility with other pesticides
 - Decontamination/neutralising agent
 - Disposal method for the formulation and its containers
 - Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the formulation
- 7) Information on the usage
 - The control efficacy of the pesticide, including details of efficacy studies, its designated use against the target pest(s) and disease(s) in relation to crops
 - Instruction for use, recommended dosage and application method
 - Mode of action
 - Phytotoxicity on plants

- Compatibility with other pesticides
 - Precautionary measures
 - For pesticide used on food crops
 - pre-harvest interval
 - maximum residue level and acceptable daily intake in other countries where the same pesticide has been registered should be included
- 8) Residue data in agricultural produce
- 9) Information on the toxicity in mammals
- Acute oral (LD_{50})
 - Acute dermal (LD_{50})
 - Inhalation toxicity (LC_{50})
 - Degree of irritation to eye
 - Degree of skin irritation and sensitization
 - Chronic toxicity of active ingredient (*required if there is evidence of a potential adverse effects*).
 - No observable effect level of active ingredient
 - Supplementary studies of toxicity (long/short term studies) of active ingredient(s) (*required if the use is likely to result in significant human exposure or the active ingredient/ its metabolites is structurally related to a known mutagen/belongs to any class of compounds containing a known mutagen or there is evidence of adverse health effects as a result of use*)
 - Carcinogenicity
 - Reproductive toxicity including teratogenicity
 - Mutagenicity
 - Neurotoxicity
 - Persistence and metabolic breakdown pathway of the active ingredient
- 10) Information on environmental effects and eco-toxicity
- Toxicity to beneficial insects, non-target pests, avian and fish
 - *The following is required on a case-by-case basis if available data shows an adverse effects:*
 - Impact on soil ecology
 - Residual effect in soil
 - Leaching, degradation of product in the soil and possibility of accumulation
- 11) Information on measures to be taken in case of poisoning
- Antidote(s) for the active ingredient/formulation
 - First aid treatment for active ingredient/formulation
- 12) A copy of the analysis report of the pesticide product stating the composition of the constituents particularly the active ingredient(s).
- 13) Other technical literature, data, and supporting documents related to the pesticide product must be enclosed with this application form.
- 14) Registration status in other countries (Copies of registration documents should be attached)
- 15) Approval from relevant local and overseas authorities for manufacture, import, distribution, sale, supply, transport, storage and usage of the pesticide product

Labelling requirements

A dual languages pesticide product label, stating clearly in English and one of the other official languages of Singapore containing the following information:–

- a) the trade name or the brand name under which the pesticide product is to be sold or supplied
- b) the composition of the pesticide product and the chemical name of every constituent, whether active or inert
- c) the type of formulation of the pesticide product
- d) the type of crop in the cultivation of which the pesticide product may be used or applied
- e) the directions for the use of the pesticide product together with the safety measures to be taken when applying the product
- f) the re-entry periods into the area after spraying
- g) in the case of a pesticide to be used on food crops, the recommended interval before the last application of the pesticide product and the harvest of the crop
- h) the relevant hazard and caution statements and graphic symbols recommended by the FAO guidelines on good labelling practice for pesticides
- i) the antidote to the pesticide, if any, and first aid instructions in case of poisoning by the pesticide
- j) the storage conditions of pesticide products
- k) the disposal method for the formulation and its containers
- l) the net weight and volume of the pesticide product in the container in which it is sold or supplied
- m) the name and address of the Singapore company that has registered the pesticide product with AVA.

3.14 SRI LANKA

APPPC regional workshop on Enhancement of Regional collaboration in Pesticide Regulatory Management

Country report – Sri Lanka
Lasantha Ratnaweera – Research Officer, Office of
the Registrar of Pesticides, Peradeniya, Sri Lanka.

Regulation of Pesticides

- All pesticides related matters in the country are regulated by Control of Pesticides (COP) Act No. 33 of 1980.
- The Act has been amended twice in 1994 & in 2011.
- Regulations could be made under the section 26 of the act & they have to be published in the Government Gazette.

Following regulations have been made

- Control of Pesticides (Sales and Offer for sale) Regulation No. 01 of 1999.
- Control of Pesticides (Pest Control Services) Regulations No. 01 of 2010.
- Control of Pesticides (Sales and Offer for sale) amendment Regulation of 2011

There are three major changes taken place during this year (2012)

- Each dossier has to be submitted along with the heavy metal report. (Cd, As, etc.)
- Trade name could be used only for new products (Only one party sells the product). Once the product is sold by more than one party, Trade name has to be changed as mentioned below.

“Company name + Common name” But both parts of the name should be in same font type, size & colour.

Three new sub-committees formed under the “Pesticides Technical & Advisory Committee” (PeTAC).

- “Agricultural Pesticides sub-committee” (APS)
- “Public health Pesticides sub-committee” (PPS)
- “Industrial pesticides sub-committee” (IPS)

After evaluation of data, a summary with Registrar of Pesticides (ROP's) comments will be presented to relevant sub-committee to get the decision for registration/Rejection.

Pesticides Technical & Advisory Committee (PeTAC)

- PeTAC is the authority to get the decisions on any issue related to pesticides.
- The committee consists of fifteen members, ten ex-officio members & five members appointed by the minister of Agriculture.
- The committee meet at every two months interval

The ten ex-officio members are

- | | |
|----------------------|-------|
| • DGA | • ROP |
| • TRI | • CRI |
| • RRI | • CEA |
| • Government Analyst | |
| • SLSI | |
| • Health Ministry | |
| • Labour Ministry | |

Registration

- Any pesticide has to be registered in the country before importing.
- Prior approval has to be taken from the ROP for importation of each & every consignment after registration.
- The custom will not release any consignment until they get the approval from ROP.
- Still there are no regulations made for registration of microbial biocontrol agents and no such registrations exist.

Advertisements

- A prior approval has to be taken from ROP for advertising of pesticides through any media (Radio, TV, Posters, News papers, Hand bills etc.)
- This is controlled under the section 18 of COP Act. Any Advertisement should not mislead the farmers & should be accordance with the guide lines prepared by ROP.

Registration application and data requirement

- Details of the registrant (Local party)
- Details of the manufacturer of the technical grade (TG) material
- Details of the manufacturer of the formulation
- Physico-chemical properties
- Storage stability data
- Detailed composition
- Toxicological data
- Method of analysis
- Method of residue analysis
- Bio-efficacy data
- Fate in the environment
- Draft label prepared according to the section 8 of the COP act.

Acceptance of applications

- Any pesticide which is registered nowhere will not be accepted for registration
- WHO class 1 pesticides are not accepted for registration.
- But we still use some WHO class 1 pesticides under restricted category.
- E.g. – Methyl bromide – Restricted for use only by Pest control operators registered with ROP and only for fumigation purpose on quarantine aspects.

Technical evaluations of application dossiers

- Once an application for registration is received, it will be forwarded to relevant sub-committee to decide whether it is needed or not.
- Local Bio-efficacy is tested in the research fields first and then in the farmer fields. These tests are done accordance with the test protocols.
- Toxicological data are required on Acute oral, acute dermal, acute inhalation, eye irritation, skin irritation, skin sensitization, sub-acute toxicity reports & chronic toxicity reports.

Pesticide registration and Licensing

- If all the requirements are fulfilled, a regular registration, which is valid for three (3) years, is granted.
- Provisional registration, which is valid for one year, is granted if some data are missing or to be clarified.
- Me too registrations are not granted in Sri Lanka.
- Re-registration has to be done after 3 years for all products.

Selling of Pesticides

A certificate for pesticides sales has to be obtained from the Authorized officer This certificate is issued only if

- a trained person is involved in selling of pesticides
- shop has been arranged to minimize the risk of contamination to human beings & the environment and
- Due fee is paid. (Rs. 500 annually)

Post-registration activities

- Every person contravenes the act shall be guilty of an offence and shall be liable to imprisonment for a period of two years or to a fine (Rs. 50 000 - Rs. 500 000)
- Authorized officers (AUO) nominated (about 75) under the section 21 of the Act in order to check any contravention.

International conventions

- We follow the prior informed consent procedure in compliance with Rotterdam Convention.
- Lists of banned & restricted use pesticides in the country in compliance with the Stockholm Convention are published in the government gazette. as well as in the website.
- Consumption of methyl bromide (MeBr) in the country is maintained in compliance with the Montreal Protocol.
- All the international guide lines & standards (FAO, WHO, OECD, Codex, etc.) are followed in pesticide management in the country.

Quality control

- Before importing any consignment of pesticides registrant has to submit a quality certificate of the stock to be imported from the manufacturer.
- If it is in par with the specifications, import approval is issued.
- Further once the consignment reach the port, a sample is drawn to check the quality in the ROP's Lab.
- If only it is satisfactory, the consignment is released to market.

Residue analysis

- A program is scheduled to take vegetable samples from the market and check the residues of major pesticides used.
- This is done twice a year in the ROP's lab.
- Further water samples are drawn from the tanks & residues of major pesticides are checked annually.
- These results are published in the annual report of Department of Agriculture.

Reducing Pesticide risk

- IPM is practiced mainly for paddy which is the major crop. Farmer field schools are held to teach the farmers on IPM.
- Pesticides could be sold only by the registered dealers.
- Dealer shops are registered only if they have a trained person having a NVQ level 3 certificate.
- This certificate is issued once they complete the one year training course which include theory & practical as well as continuous assessment and pass the exam held at the end.

Disposal of outdated stocks

- Earlier no method available. So stocks were piled in the factories
- Now Done by incinerating in the kiln of "Holcim" cement factory.
- "Holcim" charge from the companies for incineration.

Training needs

- Availability of trained people for evaluation of registration dossiers is low and hence there may be some delays in registration process.
- Training on pesticide residue analysis is needed as there are sophisticated equipments available in the lab.

Website

- Lists of registered, banned & severely restricted pesticides
- COP act
- Application for registration of pesticide
- Guidelines related to pesticides published in the DOA website (www.agridept.gov.lk)

3.15 THAILAND



APPPC Regional Workshop on Enhancement of Regional Collaboration in Pesticide Regulatory Management
26–30 November 2012

Country Report: Thailand



New registration procedures and data requirements in the past 3 years

- Toxicity of technical grade material and finished product must be generated by the GLP Certified Laboratory according to OECD Standard
- The registration and license certificate in the manufacturing country must be certified by the competent authority, representative the country and shall be recognized as an international document.
- Not allowed to use the letter of authorization as the substitution for submission of toxicological data.

2



New registration procedures and data requirements in the past 3 years (con't)

- one concentration for one formulation except PGR and biopesticides
- one formulation in not more than three trade names for one registrant
- separation of data requirement for synthetic chemical, botanical, microbial pesticides and pheromones
- authorization of efficacy trial result is not allowed

3



New registration procedures and data requirements in the past 3 years (con't)

- amendment of registration certificate approved by Sub-committee for pesticide registration
- tox data of same formulation but different concentration is accepted
- exempted tox data for more products
- allowed smaller packing size
- for data requirement of biopesticide, adopted OECD and EU recommendation since 2009

4



Pesticide Committees

- Hazardous Substance Board
- Pesticide Registration Sub-committee
- Toxicity and Residue Evaluation Working Group
- Biopesticide Data Evaluation Working Group
- Pesticide Surveillance Working Group

5



Implementation of international treaties and conventions

1. Rotterdam Convention
 - Custom and Quarantine officials training
 - Publicized Rotterdam Convention to government and private agencies
 - Introduced SHPF survey form to concerned agencies
 - Local community training on hazard of pesticide

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Implementation of international treaties and conventions (con't)

2. Stockholm Convention
 - DOA will totally ban endosulfan this year
 - MOPH banned lindane in August 2011
3. Montreal Protocol
 - Registered alternatives for MBr such as sulfuryl fluoride, ECOfume, Al and Mg phosphide
 - Set quota for MBr import

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Registration Procedure

- (1) Submission and checking of dossiers
- (2) Quality analysis and efficacy trial
- (3) Evaluation of data – efficacy, toxicity, residues
- (4) Compilation of results of efficacy/ residue trial, quality analysis, data evaluation and label
- (5) Seek approval from Sub-committee for pesticide registration
- (6) Issuance of registration certificate

8



Toxicology testing and protocol requirements

- Toxicology testing – toxicity of technical grade material and finished product must be generated by the GLP certified laboratory according to OECD Standard
- Bio-efficacy protocol requirements – experimental conditions/design, treatments, data collection and analysis of result

9



Labelling requirements

Adopted FAO Guidelines for Good Labelling Practice. Label shall include trade name, common name, formulation, concentration, appearance, use category, colour band, phrase and symbol for safety, benefit, application method, storage method, container disposal, precaution statement, symptoms of poisoning, first aid treatment, advice to the physician, chemical class, name and address of the producer, importer, distributor, packing size, date of production or expiration and registration number.

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Pesticide Registration and Licensing

Type of registration – regular registration

Type of license

- production
- import
- export
- having in possession (for sale or service)
- notification of type 2 hazardous substance

11



Detection and control of illegal trade

1. Limited number of entry points, take sample for quality analysis and check label
2. Randomly inspect pesticide producing factory and shop throughout the country. Take sample for quality analysis and check label.
3. Report violation to police.

12



Pesticide quality report (2010)

	Import	Production factory	Market
No. of sample	753	306	786
Meet standard	753	292	719
Sub-standard	0	8	67

13



Residues monitoring

DOA monitors pesticide residues in food commodities in the market, GAP farm, packing house and port of export. Reported in DOA annual conference.

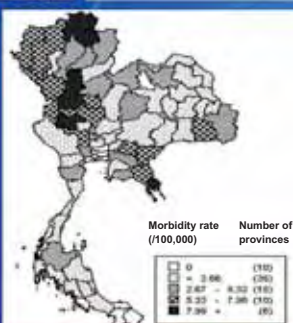
Food and Drug Administration, MOPH monitors residues in/on import food commodities and in the market. Reported through media such as newspaper, newsletter, journal and website.

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Health and environmental incidents

Reported Cases of Pesticide poisoning per 100,000 Population, by Province, Thailand, 2009



Top Ten Leading Rate

1. Kamphaeng Phet 24.91
2. Uthai Thani 11.90
3. Trat 9.51
4. Chiang Rai 9.41
5. Sukhothai 9.12
6. Phayao 8.00
7. Nakhon Sawan 7.64
8. Mae Hong Son 7.28
9. Chanthaburi 6.87
10. Si Sa Ket 6.58

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Health and environmental incidents (con't)

Pesticide residues contaminated in five main rivers of Thailand in 2009 were

- organochlorine 0.01-0.21 µg/l,
- organophosphorus 0.01-0.11 µg/l,
- carbamate 0.03-0.14 µg/l
- 1, 3, 5-triazine 0.07-0.12 µg/l.

below maximum allowable concentration (MAC).

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Information exchange posted on the FAO RAP-APPPC website

Unofficial translation of Thai regulations relating to pesticide have been posted on the FAO RAP-APPPC website. Some pesticide statistics including registered, restricted and banned pesticide shall be put soon.

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Public participation in the pesticide regulatory process

- Before issuance of notification concerning pesticide regulation, DOA has to undertake public hearing. The list of pesticides concentration and formulation allowed for registration had been agreed upon by members of TABA and TCPA.
- The Working Group has been set up comprising members from official and private sectors to solve problems on pesticide regulation.

18



Infrastructure and qualified personnel

Personnel

- checking dossiers = 9
- quality analysis = 23
- residue analysis = 19
- tox and residue evaluation = 21
- efficacy trial = 64
- inspectors = 245

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Infrastructure and qualified personnel (con't)

Infrastructure

- residue analysis – 9 laboratories in the central and regional offices equipped with 7 GC, 4 GC/MS, 1 LC/MS and 4 HPLC
- quality analysis – 2 laboratories in the central equipped with 4 GC, 1 GC/MS and 4 PHLC

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Trainings in past 3 years

- 1) Training GAP Inspectors
- 2) Training on residue monitoring (FAO/TCP)
- 3) Training on risk assessment (FAO/TCP)
- 4) Training on pesticide sampling techniques
- 5) Technical workshop on GLP application for supervised residue field trials (SRFT) and laboratory analysis
- 6) Training on principles of pesticide toxicology and OECD GLP

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Pesticide regulatory harmonization constraints and difficulties

1. Promulgation of new Act needs to amend existing regulations on pesticide registration
2. Accelerate registration of pesticide under new Act
3. Limited number of officials, received large number of registration application
4. Rules and regulations had been amended not long ago. To adopt FAO/TCP guidelines also needs to amend rules and regulations again.

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Work plan

- 2012 – distribute guidelines to concerned agencies
- 2012–2015 – amend rules and regulations, prepare for AEC
- 2015 – adopt guidelines

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THE END

THANK YOU FOR YOUR ATTENTION

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APPPC Regional Workshop on Enhancement of Regional Collaboration in Pesticide Regulation management Thailand, 26–30 November 2012

PESTICIDE MANAGEMENT IN VIET NAM

Presented by Vuong Truong Giang
Pesticide Management Division
Plant Protection Department – MARD

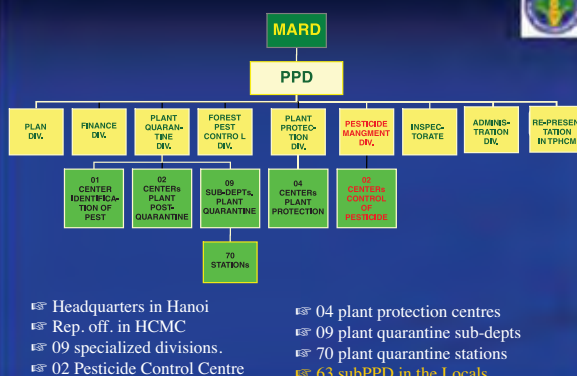
Pesticide Legislation and Regulation

1. Ordinance on Plant Protection and Quarantine, 2001.
2. Decree No. 58 on Plant Protection, Quarantine and Pesticide Management, 2002
3. Chemical Law, 2007
4. Circular No. 38 regulates on Pesticide Management, 2010
Circular No. 18, 2011 (which replace with new one, December, 2012)
5. List of pesticides permitted, restricted and banned to use in Viet Nam (every year)
6. The Pesticide Law is building up and submit the Parliament in 2013.

Pesticide Board

- ❑ Ministry of Agriculture and Rural development
- ❑ Plant Protection Department (PPD)
- ❑ National Pesticide Advisory Committee (9 members)
- ❑ Technical Committee for bio-efficacy evaluation (7 members)

Organization Chart of PPD



Authority for Pesticide Management

Designated authority – PPD

- Submit regulations
- Registration
- Licensing
 - + Import pesticide (PPD)
 - + Manufacturer, sale, using...(Local PPD)
- Inspection
 - + Manufacturer, formulated
 - + Distribution, using...

REGULATIONS ON PESTICIDE REGISTRATION

General principles (1)

- One manufacturer – one applicant
- One pesticide – one trade name
- One applicant – one pesticide
- Applicant is entitled to change the manufacturer
- Applicant is entitled to transfer the registered pesticide

Manufacturer means one who manufacture the technical grade a.i.

General principles (2)

- Chemical pesticide register to use for **pest control on vegetable, fruit trees and tea** are required to test PHI
- Chemical pesticide which has:
 - a.i. in class III of the WHO recommended classification of pesticides by hazard
 - a.i. outside the group of organochlorine
 - PHI of maximum 7 days in Viet Nam **are to be registered to use for pest control on vegetable, fruit trees and tea.**

PESTICIDE NOT TO BE REGISTERED

- Pesticide banned to use in Viet Nam
- **Pesticide restricted to use in Viet Nam (for crops)**
- A.i. invented by foreign individuals and organizations, but not yet registered for use in foreign countries
- Finished products in Class I
- Finished products in Class II but their a.i. in Class I (except for special case)
- Pesticides are in annex III of Rotterdam Convention.
- Methyl Bromide

TYPES OF REGISTRATION (1)

- Registration for pesticide field trial
- Pesticide registration
 - Full registration
 - Supplementary registration
- Renewal Registration

Validity period time: 5 years

Pesticide Registration Registration for pesticide field trial

- All pesticides registry to use in Viet Nam should be registration for pesticide field trial
- The chemical pesticide (full registration, “me too” product and mixture product) should be conduct large- and small-scale trials
- The chemical pesticide (Changes in Scope, Dosage, Method of use, Forms, Contents of active ingredients) should be conduct large-scale trials
- The biopesticide should be conduct large-scale trials
- The chemical pesticide (registration to use in tea, fruit, vegetable) should be conduct large-scale trials

Pesticide Registration Full registration

- a.i. recently invented domestically, approved and recognized as a pesticide by the State competent council of scientists
- a.i. have already become commodities in foreign countries, but introduced into use for the first time in Viet Nam

Data protection time is 5 years since approved registration

Pesticide Registration Supplementary registration

- Pesticides containing approved active ingredients
- Pesticides have the same type of the one no longer effective of data protection.
- Pesticides with a mixture together two or more than two active ingredients to be developed into new products
- Pesticides with use purposes changed
- Changes in Scope, Dosage, Method of use, Forms, Contents of active ingredients

Pesticide Registration Re-registration

- When the registration license is expired
- The application form shall be submitted 3 months before the expiry date.

The expiry of certificate is 5 years

Documents for Pesticide Registration Registration for pesticide field trial

For full registration, me too product, mixture product

- Application form for pesticide field trial
- Letter of authorization
- Certificate of manufacturer
- Technical data
- Draft label
- Copy of certificate for pesticide registration (full registration)
- Copy of trade-mark registration certificate decision on formally acceptance issued by National Office of Intellectual Property (if any)

Documents for Pesticide Registration Registration for pesticide field trial

For changing in Scope, dosage, using method

- Application form for pesticide field trial
- Copy of certificate for pesticide registration
- Draft label

Documents for Pesticide Registration Registration for pesticide field trial

For changing in Forms, contents of a.i.

- Application form for pesticide field trial
- Copy of certificate for pesticide registration
- Draft label
- Technical data (Vietnamese or English)

LABELLING

- Following the FAO Guidelines on Good labelling Practice of Pesticide
- The pesticide products should be classified according to the WHO classification of pesticides
- The GHS label has not been used

Guidelines on Good Labelling Practice for Pesticides

Information appearing on the label:

- **Company name** (and correct logo, if applicable)
- **Product name** (and logo, if applicable)
- **Product type**, e.g. herbicide, insecticide
- **Formulation type**, e.g. EC, WP, SC
- **Active ingredient**, common name and content
- **Statement of use**
- **Net content of pack**
- **Instruction to read safety advice** before opening pack
- **All trade marks** correctly acknowledged
- **Name, address and telephone number of manufacturer, distributor, agent and/or registrant**
- **Telephone number** for emergency response
- **Label code**
- **Storage stability**, e.g. expiry date
- **Registration number**
- **Registration for batch number and manufacture date**

- **Safety Precautions**
 - Any locally required additional precautions
 - "Keep locked up and out of reach of children" warning
 - Safety pictograms
- **Instructions for use:**
 - "Use only as directed" statement
 - Pests controlled
 - Approved uses
 - Method of application
 - Application rates
 - Timing and frequency of application
 - Pre-harvest intervals
 - Re-entry periods



Actual Status – Importation

- The pesticides in list of permitted are imported with customs formalities
- The PPD grant to import:
 - Pesticides are not include in list of permitted use in Viet Nam
 - Restricted pesticides
 - Methyl Bromide is following Montreal Protocol

Table 4. Quantity of Imported Pesticides in Viet Nam

Year	Quantities (tonnes of F.P.)	Rate of Pesticide Groups (%)				Values (USD mills)
		I	F	H	Others	
2010	72 560	25.7	27.5	38.8	8.0	503.63
2011	85 084	27.0	22.6	44.7	5.7	597.00

(Data source of Customs Head Department)

ROTTERDAM CONVENTION

- PPD has been appointed to be a DNA for Pesticide
- Implementation of Rotterdam Convention include:
 - Notification of Final Regulation Action to ban or severely restrict a chemical (Annex 5)
 - **Import response to Annex II: 33 (2011-2012)**
 - Acknowledging Export Notification
 - Participate in Rotterdam Convention meeting

MONTREAL PROTOCOL

- PPD control import of methyl bromide by setting quota for each importer base on past record
- The using of methyl bromide for non-QPS is zero in 2015

QUALITY CONTROL OF PESTICIDES

- The imported pesticides have to control for quality
- The quality of pesticides shall be the same as it is claimed at registration
- There are 5 Laboratories for pesticide quality analysis and all meet ISO 17025 certificates: 02 Labs belong to PPD and 03 labs in Ministry of Science (GC, LC, GC/MS...)

MRLs FOR PESTICIDES

- The Ministry of Health approve the list of MRLs for pesticides.
- To accept Codex MRLs
- Viet Nam has not been established the MRLs for pesticides on crops yet
- There are 5 Laboratories for pesticide residue analysis and all meet ISO 17025 certificates: 02 Labs belong to PPD and 03 labs in Ministry of Science (GC/MS, GC/MS/MS, LC/MS, LC/MS/MS...)

INFORMATION EXCHANGE

- Website: www.pd.gov.vn
 - Update list of approved (permitted, restricted and banned to use)
 - Information concern pesticide management (Rule/regulation, Guidelines, Label...)
- Pesticide databases have not established for information exchange with Asean members country

Infrastructure and Human Capacities for Pesticide Regulatory Management

- Personnel for pesticide registration: 8 persons
- Personnel for pesticide monitoring and enforcement: 558 persons
- Personnel for formulation quality control and pesticide residue: 70 persons
- Number of trained toxicologists for toxicology dossier evaluation: 02 persons

General Assessment of Status of Pesticide Regulatory Management

- Assessment of progress and achievement towards harmonization
 - Translated and printed the guidelines into vietnamese
 - Benefit documents for set up the technical requirement
 - Have good experience exchange between registration agencies
- Constrains and difficulties
 - Put guideline under project for adoption by the pesticide regulatory should be need long time
 - Capacities is not enough (infrastructure, manpower)

General Assessment of Status of Pesticide Regulatory Management

- Recommendations and suggestion
 - Need assistance for training toxicology, risk assessment...
 - Continue Experience exchange between registration agencies
- Short and long term targets and workplan
 - Set up the supplementary under Pesticide law in line with the project guidelines
 - Building up the capacity of manpower to speed up the process of critical and accurate evaluation of data dossier for registration

3.17 SUMMARY AND CONCLUSIONS

The country reports presented at the Chiang Mai workshop showed that all countries have conducted activities to strengthen their pesticide management system, and many were in the process or revising their national legislation in line with international standards and developments.

Many of the reports contained remarkable and outstanding examples for (1) registration set-up and interdepartmental cooperation; (2) use of information technologies to increase transparency and information sharing; (3) efforts to reduce the number of pesticide registrations; (4) monitoring health and environmental incidences; (5) selecting pesticides for review; and (6) strengthening the implementation of international conventions.

For example, Bangladesh reported that it had recently increased the number of required efficacy trials, while in Cambodia; a new law on the management of pesticides came into effect in 2012. In China, the second amendment to the regulations on pesticide management is expected to be passed in 2013 and all registration information is publicly available through a well developed website. Indonesia has issued new guidelines and requirements for pesticide registration, including new tests on side effects on natural enemies in rice. Japan is undergoing a reform of the registration system with the active involvement of various stakeholders, while the government of Korea, DPR is recognizing the necessity of international cooperation for improving the national pesticide management and intensifying its material and technical foundation. Lao PDR has introduced new regulations for controlling pesticides in 2010 and has ratified the Rotterdam and Basel Conventions, while in Malaysia, new advertisement and pest control operator rules will come into effect in 2013. Myanmar, Nepal and Pakistan have taken steps to ban or restrict various hazardous pesticides. The Philippines have facilitated the import and export of pesticides through an online National Single Window (NSW), while Singapore has increased its farm and produce surveillance. In Sri Lanka and Thailand, new registration procedures and requirements were introduced, and the countries are in the process of issuing new regulations or amending existing ones. In Viet Nam, a new pesticide law is expected to be submitted to the parliament in 2013.

All countries share a common concern for human health, food safety and environmental protection and they generally follow the same principles and procedures of pesticide management. Thus there is already a high degree of harmonization which can be subdivided into the following categories:

Harmonization of norms

International safety and quality standards are accepted by all countries. Many international conventions and treaties such as the Stockholm, Rotterdam, Basel or chemical weapons conventions, the Montreal Protocol, or the *Strategic Approach to International Chemicals Management* (SAICM) provide world-wide standards that are followed by all nations and were largely reflected in the lists of banned or severely restricted pesticides. In addition, many countries have further safety concerns that have led to restrictive regulatory actions in one or more countries. If scientifically justified, these concerns should also be gradually harmonized as they would apply to all countries.

The *Codex Alimentarius* provides a widely accepted international standard for residue limits in food (MRL) that are adhered to by most countries, even though some countries have also established their own MRL according to local needs and practices.

All countries also accept the same quality standards of chemical pesticides as expressed in the FAO specifications, and apply the same analytical methods for formulation and residue determination. As more international norms are being developed, countries will have to continue to adjust their registration processes after adopting the new standards.

Harmonization of registration requirements

Even though all countries have their own registration requirements, there is a general consensus about the type of data and studies that need to be submitted with the application. Guidelines developed by FAO and OECD provide widely used standards, particularly for testing protocols and label information. Some

countries have already started implementing the GHS label format. In addition, the FAO-TCP project has identified minimum data requirements which have been agreed upon by Southeast Asian countries. For biological pest control agents, an ASEAN-GIZ initiative has been launched to develop registration requirements for these products.

Even though substantial variations exist on the number of field trials and type of residue studies, countries in Asia are moving steadily toward a common registration application standard.

Harmonization of procedures

The Code of Conduct and various registration guidelines have publicized good registration practices that are accepted world-wide. To implement these practices, international and local training was offered to the registration staff so that all countries would follow the same principles.

While procedures are largely internal matters that would not affect other countries, their harmonization provides confidence and transparency in the registration process. Countries do not need to develop their own procedures since they can count on the experiences with successful practices. However, while some items are already uniformly implemented, others differ considerably as determined by available resources and trained staff. Major differences still exist with regard to the decision making process, number of registration options, validity periods and re-registration/renewal procedures.

Harmonization of international cooperation

While most of the reported harmonization efforts were internal affairs, a few dealt with international cooperation and work sharing. Some countries actively participated in norm-setting and standardization activities, and several published registration information for use by stakeholders and other countries. While no country was yet ready to accept evaluation reports and registrations from other countries, a few considered the registration status in other countries to facilitate their own registration process and reduce their work load.

International efforts to combat illegal trade or counterfeit products, however, have not yet been harmonized.