RAP PUBLICATION 2013/08

ADVANCEMENT OF PESTICIDE REGULATORY MANAGEMENT IN ASIA

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FOREWORD

For the past 30 years, FAO has assisted countries in the Asia and Pacific region in establishing pesticide legislation and regulations, and in managing these products in accordance with the *Code of Conduct on the Distribution and Use of Pesticides* and other international conventions and treaties. With the advance of globalization and the free movement of goods and services, it has became more and more important to harmonize pesticide regulatory management in order to stay competitive in the international marketplace. Harmonization would enable countries to work together more closely, share resources, lower the costs of pesticide registration, and coordinate implementation of international conventions. The ultimate goal of pesticide regulatory harmonization is reducing duplication of efforts and streamlining review processes. This would increased the efficiency of regulatory agencies and reduce the cost of data submission.

While international norms and standards have been laid down in various treaties, conventions and guidelines, national governments need to adjust their laws and regulations accordingly to make them more uniform and mutually compatible. This would improve trade and provide better protection for the population and the environment against poor quality and highly hazardous pesticides. To assist countries in the Asia-Pacific region in these efforts, FAO implemented from 2009 to 2011 a project titled *Assisting countries in Southeast Asia towards achieving pesticide regulatory harmonization* under its Technical Cooperation Programme (TCP). Seven countries participated in this project, and they agreed on five regional guidelines for harmonizing various aspects of pesticide management that established common standards for registration requirements and practices.

As a follow-up one year after the end of the TCP project, an APPPC Regional Workshop on *Enhancement of Regional Collaboration in Pesticides Regulatory Management* was held from 26-30 November 2012 in Chiang Mai, Thailand. It was attended by 20 participants from 16 Asian countries who reviewed their national pesticide regulatory management systems in relation to the 2010 *Code of Conduct Guidelines for Registration of Pesticides* and the five regional harmonization guidelines that were developed in 2011 for Southeast Asia. The workshop also wanted to show a way forward and give new impulses toward greater collaboration, work sharing and information exchanges that could serve as a model for elsewhere.

This publication contains documents from this workshop which could help countries to prioritize their harmonization efforts and to make the international and regional guidelines more operational. It is hoped that they will serve as a reference and encouragement for all participating countries to further enhance their pesticide registration and management schemes to make them more effective, efficient and transparent. This will not only safeguard against adverse effects of pesticides to human health and the environment, but will also promote food security, food safety and the intensification of sustainable crop production for meeting the challenges of the future.

Hiroyuki Konuma
Assistant Director-General and
Regional Representative for Asia and the Pacific
Food and Agriculture Organization of the United Nations

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LIST OF ACRONYMS

a.i.	active ingredient
AC	Agricultural chemicals
APPPC	Asia and Pacific Plant Protection Commission
ASEAN	Association of Southeast Asian Nations
AVA	Agri-Food and Veterinary Authority
BCA	Biological Control Agent
BPCA	Biochemical pest control agents
BPI	Bureau of Plant Industry
BPH	Brown Plant Hopper
CAS	Chemical Abstracts Service
CWC	Chemical Weapons Convention
DADO	District Agricultural Development Officer
DNA	Designated National Authority
DOA	Department of Agriculture
ETL	Economic Threshold Level
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FFS	Farmer Field School
FPA	Fertilizer and Pesticide Authority
GAP	Good agricultural practices
GDP	Gross Domestic Product
GHS	Globally harmonized system
GIZ	German International Cooperation (formerly GTZ)
GLP	Good laboratory practice
HHP	Highly hazardous pesticides
ICAMA	Institute for the Control of Agrochemicals, Ministry of Agriculture
IPM	Integrated Pest Management
LCD	Liquid Crystal Display
LD	Lethal Dose
MAFF	Ministry of Agriculture, Forestry and Fisheries
MOA	Ministry of Agriculture
MOE	Ministry of Environment
MOH	Ministry of Health
MOPH	Ministry of Public Health
MPCA	Microbial pest control agent
MRL	Maximum residue limits
MSDS	Material safety data sheet
NA	Not available
NAFTA	North American Free Trade Association
ND	Not detected
NGO	Non-governmental organization
NPC	National Project Coordinator
NPPO	National Plant Protection Organization

OC	Organochlorine (pesticides)
OECD	Organisation for Economic Co-operation and Development
OP	Organophosphate (pesticides)
OPR	Office of Pesticide Registrar
PCD	Pesticide Control Division
PCO	Pest Control Operator
PIC	Prior Informed Consent (Rotterdam Convention)
PHI	Pre-harvest interval
PMC	Project management committee
POP	Persistent organic pollutants (Stockholm Convention)
PPD	Plant Protection Department
PPQS	Directorate of Plant Protection, Quarantine and Storage
PPW	Plant Protection Wing (Bangladesh)
PRB	Pesticide Registration Board
PRG	Plant Growth Regulator
PRMD	Pesticide Registration and Management Division
QC	Quality control
RB	Risk-benefit
SAICM	Strategic Approach to International Chemicals Management
SIAC	State Administration for Industry and Commerce
SOP	Standard Operating Procedure
TCP	Technical Cooperation Programme
TG	Technical grade
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNEP	United Nations Environmental Programme
USD	United States dollar
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction

1.1 PESTICIDE REGULATORY HARMONIZATION IN SOUTHEAST ASIA

by Piao Yongfan

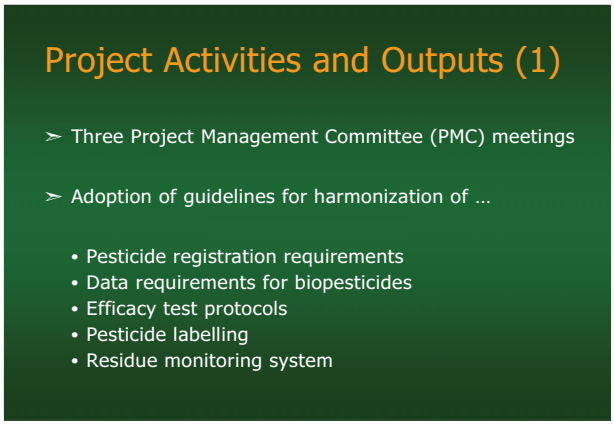
Since 1982, FAO has played an important role in assisting countries in the Asia and Pacific region to establish pesticide legislation and regulations, and to manage these products in accordance with the *International Code of Conduct on the Distribution and Use of Pesticides* and other international conventions and treaties. These agreements encourage pesticide regulatory harmonization through greater collaboration and information exchange.

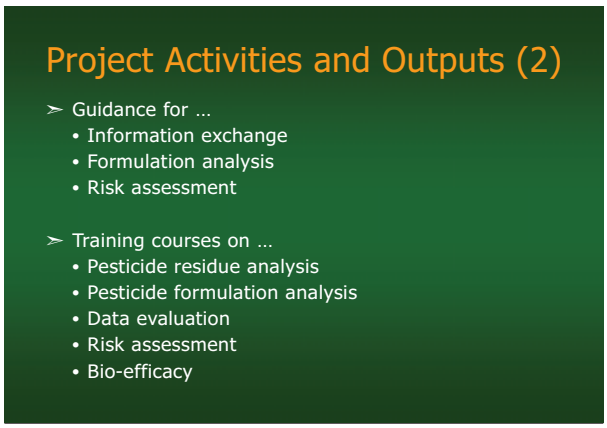
With the advance of globalization, it would be important for the countries in the Asia-Pacific region to harmonize their pesticide regulatory management in order to stay competitive in the international marketplace, improve trade and protect their populations and the environment against poor quality and highly hazardous pesticides. With regulatory harmonization, countries would be able to work together more closely, share resources, lower the costs of pesticide registration, and coordinate implementation of a number of international conventions related to pesticides such as the Rotterdam, Stockholm or Basel Conventions. For these reasons, other regions such as the European Union and NAFTA have already harmonized their pesticide regulatory management.

Harmonized pesticide management in the Asia-Pacific region would allow for the application of the same requirements and quality standards in pesticide registration and post-registration monitoring. It would also be a way of helping lesser developed countries to strengthen their pesticide management and learn from their neighbours.

In January 2002, FAO sponsored a workshop on pesticide regulatory harmonization for Southeast Asian countries. A follow-up meeting in Kuala Lumpur in August 2003 discussed the scope and approach of strengthening pesticide management among these countries. In July 2005, a regional workshop was held in Bangkok on the *Implementation, Monitoring and Observance of the International Code of Conduct on the Distribution and Use of Pesticides* for the purpose of strengthening pesticide management and to share information about regulatory processes among the countries.

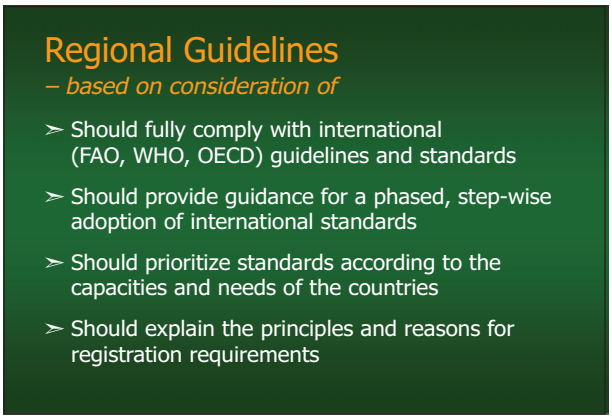
To support these efforts, FAO agreed in 2009 to implement a project under its technical cooperation programme (TCP) to assist seven participating countries in Southeast Asia towards achieving greater pesticide regulatory harmonization. The purpose of the project was to review regulatory processes, prepare guidelines for harmonization, strengthen information exchange, train pesticide regulatory officers and plan sustainable future activities. The implementation of the project took place in 2010 and 2011.

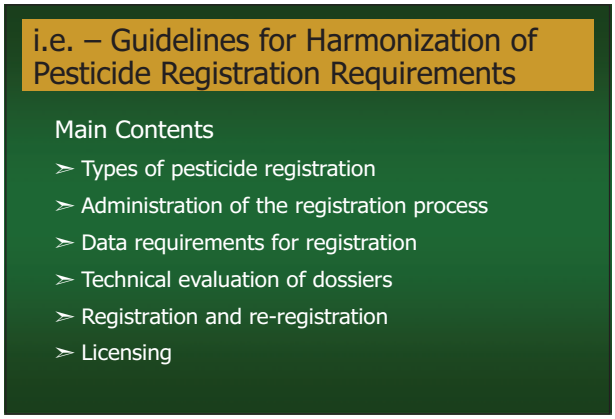


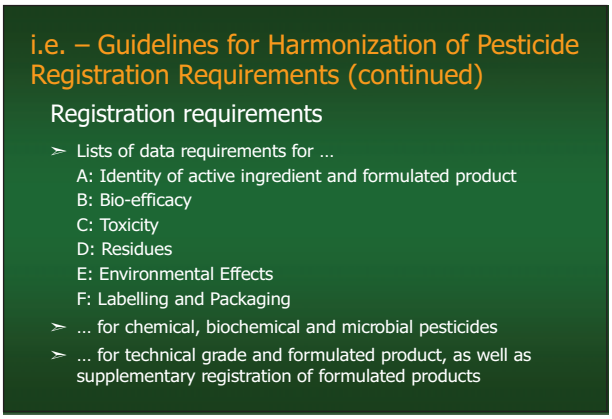


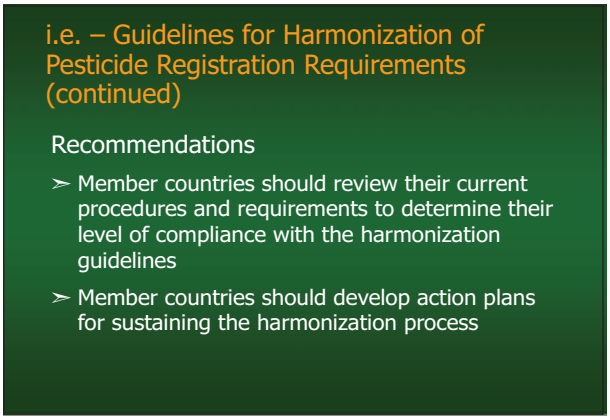
The project adopted a set of five guidelines on the (1) harmonization of pesticide registration; (2) harmonization of registration requirements for biopesticide; (3) harmonization of pesticide labelling; (4) harmonization of monitoring pesticide residues in agriculture products; and (5) updated guidelines for the preparation of bio-efficacy test protocols. An internet-based system for information exchange on pesticide matters was recommended for implementation. The project also organized training courses on pesticide formulation and residue analysis, bio-efficacy evaluation and risk assessment

The regional guidelines comply with international guidelines and standards and provide guidance for a phased, step-wise adoption by the participating countries. They would be implemented in the coming years dependent on the capacities and needs of a country. The member countries agreed to review their regulatory processes in view of the new guidelines and make detailed action plans for adjusting their country's pesticide management in line with the harmonized standards. To assist in this process, check lists for guideline parameters that require harmonization and a list of activities, targets and indicators were produced.









The project results and guidelines were summarized and compiled in a publication titled *Guidance for harmonizing pesticide regulatory management in Southeast Asia* (RAP Publication 2012/13, also available online at the IPPC/APPPC website[1]). The document may serve as a reference manual to the countries in their efforts to strengthen and harmonize their pesticide management.

While these guidelines were an important step forward, putting them into practice requires further consultations and cooperation. It was found that the check lists and registration data requirements were not fully consistent and needed further adjustments and clarifications which would best be done after the countries have started working with them. For this reason, further consultations and sharing of experience are necessary until a practical and transparent regional harmonized regulatory system will emerge.

[1] http://www.apppc.org/index.php?id=1110802&tx_publication_pi1[showUid]=2184813&frompage=1110817&type=publication&subtype= &L=0#item

The APPPC Standing Committee on Pesticides Management also provides a regional platform for countries to collaborate on pesticide regulatory harmonization. The action plans prepared by the TCP countries supplement the implementation plan of the APPPC Standing Committee on pesticide management. The achievements and experiences among the Southeast Asian TCP countries may therefore serve as a starting point for a wider regional harmonization and a closer cooperation with more advanced countries in the Asia-Pacific region.

Self-Assessment

- A checklist was developed to assess the level of compliance with the harmonization guidelines
- Each country developed a work plan for the imediate follow-up steps, incl. translation of the guidelines *(Lao PDR and Viet Nam-funded)*
- Each country was asked to carry out a self-assessment and develop an action plans for short-, medium- and long term periods

For these reasons, it was decided to convene a workshop one year after the end of the TCP project from 26 to 30 November 2012 in Chiang Mai, Thailand. The workshop brought together the National Project Coordinators of the Southeast Asian TCP countries, i.e. Cambodia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand and Viet Nam as well as from other ASEAN countries which did not join the TCP project (Indonesia and Singapore); furthermore, persons responsible for pesticide management in Bangladesh, China, Korea, DPR, Japan, Nepal, Pakistan and Sri Lanka were invited. For the issues related to the registration of biological pest control agents, a resource person from the GIZ programme "ASEAN BIOCONTROL (ABC)" kindly provided technical support during the meeting.

Goal and objectives of the workshop

The overall goal of the workshop was to build on the achievements of the recent TCP project and to further advance the harmonization process of pesticide management in Southeast Asia by making it more operational and transparent. This would strengthen the regulatory capacities of the countries and serve as a model for other countries to join the harmonization process.

In particular, the workshop aimed at achieving the following objectives:

- Review the regulatory harmonization progress in the TCP member countries one year after the end of the project and identify successes, difficulties and new issues that have emerged.
- Inform other countries in the region of the sub-regional developments and invite their support and suggestions.
- Identify the similarities and differences between the sub-regional pesticide management standards and the other pesticide management systems in the region.
- Share the outcomes of each country's self assessment exercises and compile the results in a system that allows assessing the level of regulatory harmonization in the following areas: (1) legislation and regulation; (2) minimum registration data requirements; (3) technical evaluation of registration data; (4) registration and licensing; and (5) post-registration monitoring.
- Consolidate the recommended data requirements for different types of registration (provisional, proprietary, supplementary and re-registration) for chemical, microbial and biochemical pesticides and produce an easy to use summary table of the requirements. (taking into account new draft guidelines on microbial pesticides).
- Update and prioritize the targets and indicators for regulatory harmonization and set short-, mid- and long term goals.
- Review and share the country action plans to achieve greater regulatory harmonization and identify constraints and opportunities for regional collaboration.
- Review the status of implementation of international conventions, including the observance of the Code of Conduct.

- Utilize the APPPC website for information sharing, including posting of an updated list of banned and restricted pesticides in the region.
- Encourage closer cooperation among National Project Coordinators and recommend next steps in the harmonization process.

Scope of the workshop

The workshop focused on the harmonization of the following aspects of pesticide management:

- Legislation and regulations (types of registration, data protection period)
- Registration data requirements (provisional, proprietary, supplementary and re-registration for chemical, biochemical and microbial pest control agents)
- Evaluation of registration data (risk assessment, bio-efficacy, ecotoxicology, formulation analysis)
- Registration and licensing (labelling, length of registration validity, banned or restricted pesticides)
- Post-registration monitoring (enforcement, residue monitoring, information exchange)

In addition, the workshop covered implementation, monitoring and observance of the Code of Conduct and other international conventions related to pesticide management (Rotterdam, Stockholm, Basel).

Outputs

The workshop was expected to produce the following outputs:

- Compilation of self-assessment results into matrixes for different categories showing the level of harmonisation in the individual countries;
- Consolidated summary tables of data requirements for different types of registration (provisional, proprietary, supplementary and re-registration) for chemical, microbial and biochemical pesticides;
- Revised targets and indicators for the short-, mid- and long-term harmonization goals;
- Updated country action plans for harmonizing the pesticide regulatory processes towards the short-, mid- and long term targets;
- Updated regional database lists of banned and restricted products;
- Posting of relevant information on the APPPC website for information sharing;
- Identified needs, priorities and emerging issues at country level regarding the harmonization of pesticide regulatory matters;
- Recommendations for follow-up actions and for other countries to join the harmonization efforts;
- Identified mechanisms for coordination and exchange of information among the countries in the region;
- Proceedings of the workshop.

1.2 HIGHLIGHTS OF QUESTIONNAIRE RESPONSES ON PESTICIDE REGULATORY HARMONIZATION

by Gerd Walter-Echols and Piao Yongfan

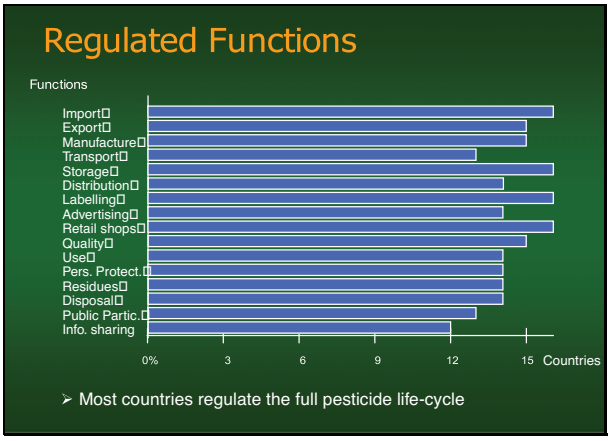
In preparation for the Chiang Mai workshop in November 2012, questionnaires were distributed to the participants to assess the status of pesticide regulatory management in their respective countries in relation to the 2010 *Code of Conduct Guidelines for Registration of Pesticides*. A supplementary questionnaire to the seven ASEAN/TCP countries aimed to assist in the self-assessment of their progress toward regional harmonization and to identify constraints with implementing the recommendations. The full compilation of the questionnaire responses are given in Annex 1. The main results were:

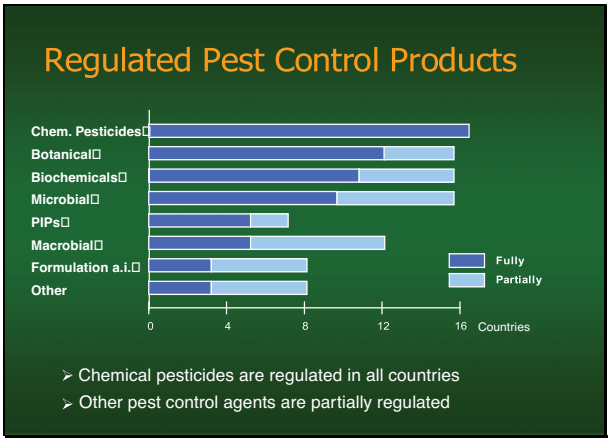
Pesticide legislation and regulations

The new Code of Conduct registration guidelines promote the uniform management of all pesticides in all sectors by a single national authority. This would optimize the use of limited resources available in most countries.

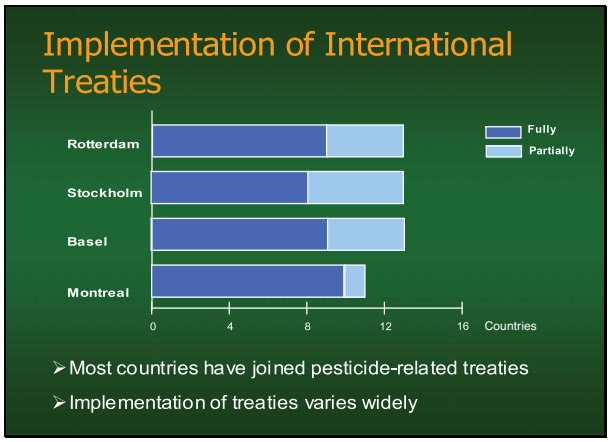
The survey showed that this was not the case in many countries. All countries regulated agricultural pesticides; however, the regulation of pesticides used in other sectors varied greatly from country to country and was often in the hands of different authorities. It therefore appears that some countries also need to harmonize pesticide regulatory management within their own borders.

Most national authorities regulated all functions in the life-cycle of pesticides from import or manufacture to application or disposal. With regard to the types of pesticides, only chemical pesticides were regulated in all countries. Of other pest control products, botanical and biochemical pesticides were already widely regulated. Microbial biocontrol agents were fully regulated in more than two-third of the countries. Fewer than one-third of the countries regulated macrobials (e.g. natural enemies), plant incorporated protectants (PIP), non-pesticide active ingredients and other substances.

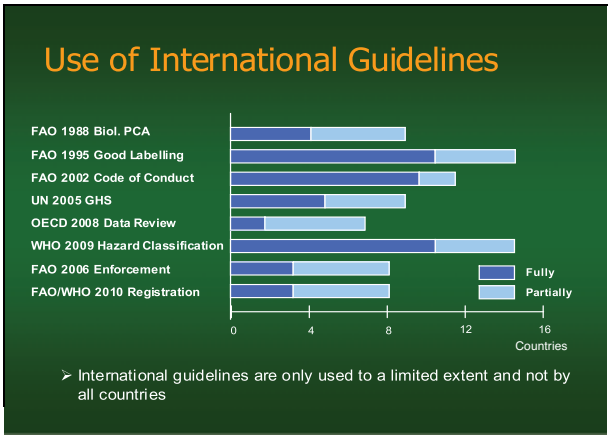




With regard to international treaties, all countries had signed the Montreal Protocol, one country still needed to join the Basel Convention and two the Stockholm Convention. Four countries had not yet ratified the Rotterdam Convention. However, not all treaties that were signed are already fully implemented; the survey showed that about half the countries need further efforts or assistance to comply with all provisions of the treaties.



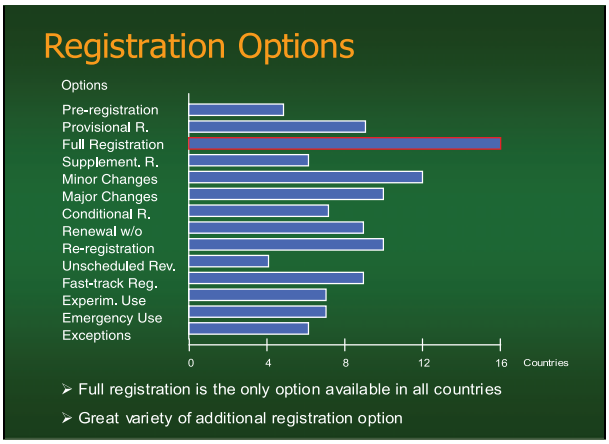
Of the many international guidelines that exist on various aspects of pesticide regulatory management, the most widely followed guidelines were the FAO *guideline on good labelling practice for pesticides* and the WHO *recommended classification of pesticides by hazard*. Least known among the countries were the OECD guidelines and the 2010 FAO *Guidance on Pest and Pesticide Management Policy Development*. Therefore, regional harmonization could be further strengthened by a more extensive use of all available international guidelines.



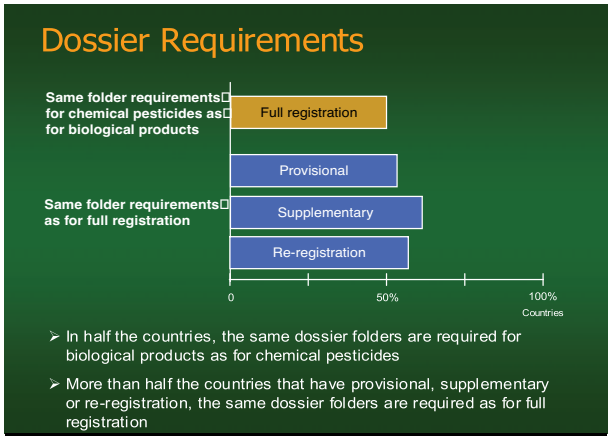
Pesticide registration application and data requirements

The Code of Conduct registration guidelines promote a transparent registration process and data requirements specific to the pest control agent. Also, stakeholders should participate in the process wherever possible.

The survey showed that most countries followed the recommended registration steps. With regard to the types of registrations issued, only the regular, full registration was uniformly granted in all countries. In addition, there were many other registration options which differed from country to country. From these results it would seem fitting that harmonization efforts should primarily focus on the full registration. The harmonization of preliminary or supplementary registrations as recommended in the TCP guidelines may be premature since not all countries issue such registrations.



With regard to dossier requirements, survey results showed that half the countries did not distinguish between chemical and biological products and required the same set of information. Considering the distinctly different characteristics between chemical and other pest control agents, it would be more appropriate to have specific registration requirements for different groups.



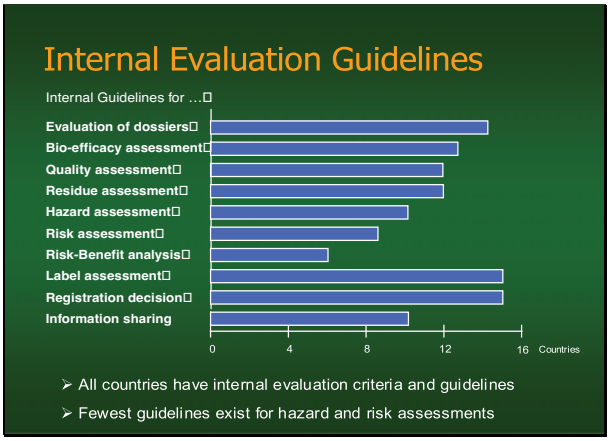
Slightly more than half the countries that had provisional, supplementary or re-registration options required the same dossier folder data as for full registration. Other countries had reduced data requirements for their more limited types of registration.

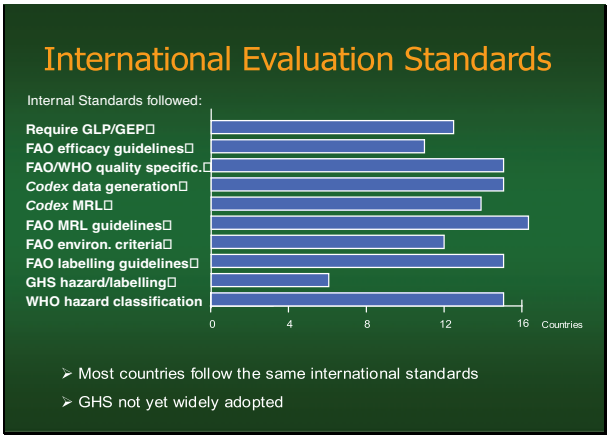
To promote regional harmonization, countries may want to issue the same types of registrations and request registration data specific to the type of pest control agent and registration.

Technical evaluation of application dossiers

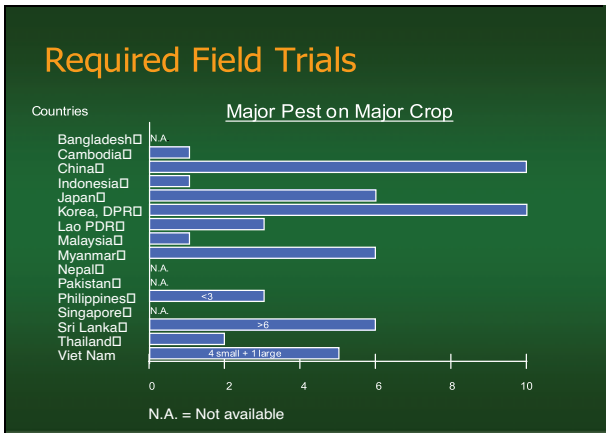
The Code of Conduct recommends that the evaluations of the application dossiers are based on sound and published criteria and guidance documents. For acceptance and quality of data, common international standards should be used.

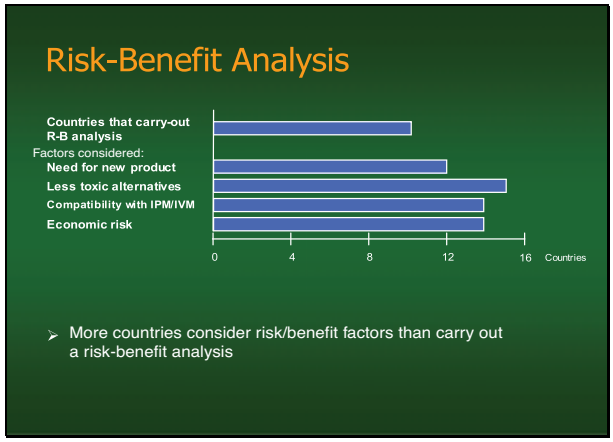
The survey results showed that that there was already a high degree of similarities in the general procedures for the evaluation of dossiers and most countries followed international standards. Almost all countries had internal guidelines and they verified analytical methods and test protocols. There was also a high degree of harmonization with regard to pesticide quality and label information.





All survey countries accepted WHO efficacy assessments and evaluations for public health pesticides; however, they generally did not accept such external assessments for agricultural pesticides. Only three countries accepted field trials from other countries while the majority required local efficacy trials. There were substantial differences in the number of required field trials and growing seasons, which ranged from 1-10 trials to be carried out over one to more than three seasons.





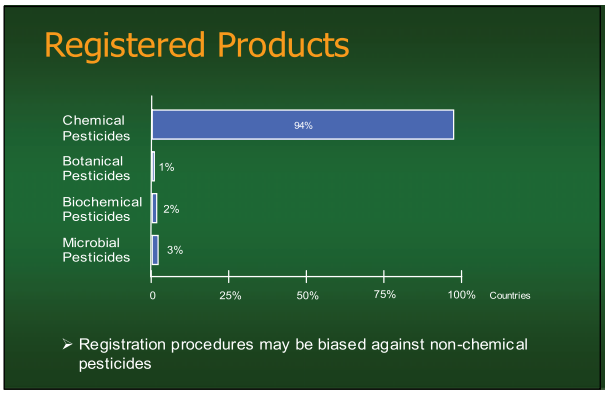
Almost all countries required pesticides to conform to FAO/WHO specifications and they used maximum residue limits (MRL) defined by the *Codex Alimentarius*. Even though most countries required health and environmental studies, many lacked internal guidelines and decision-making criteria for the evaluation of health and environmental risks. While economic risk and less toxic alternatives were considered, formal risk-benefit analyses still need to be conducted in a number of countries.

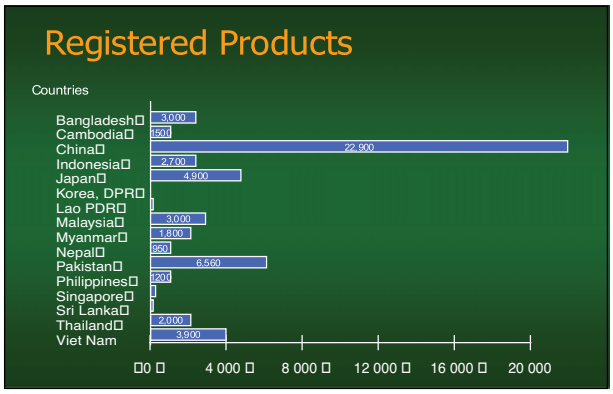
Pesticide registration and licensing

The decision to register a pesticide product should be taken by well qualified experts based on legally defined and well established criteria. It is recommended that this is done by an independent Pesticide Board consisting of experts from agriculture, health and environment. It is also important that a registration can be cancelled if new information warrants such action.

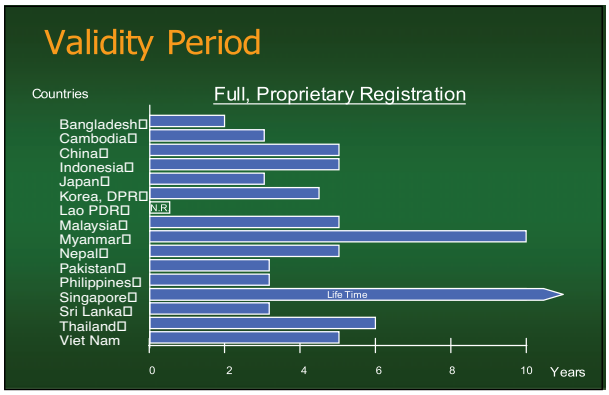
The survey showed that all countries had legally defined criteria for accepting or rejecting a registration application, and there were provisions to cancel or restrict a valid registration if new evidence indicated previously unknown risks. In most countries, the registration decision was taken by the responsible national regulatory agency, and only in about a third of the cases by an independent pesticide board or similar committee.

It was found that about 99 percent of all registered products were chemical pesticides. The total number of pesticides registered in a country ranged widely from 73 to more than 20 000 products, with an average of about 3 300. The low numbers of registered biological pest control agents was surprising and may be partially due to unreasonable or inappropriate registration requirements.

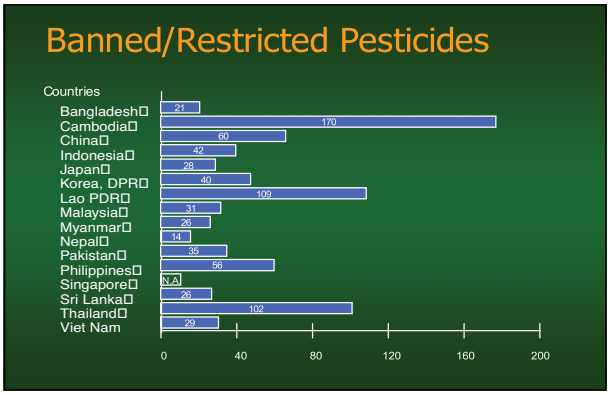




The validity period for the regular, full registrations ranged widely from two years to unlimited, but generally it was between 4 and 6 years. After expiration, some countries allow a simple renewal, while others require a full new registration procedure. Half the countries issue provisional or conditional registrations which are normally valid for one year.



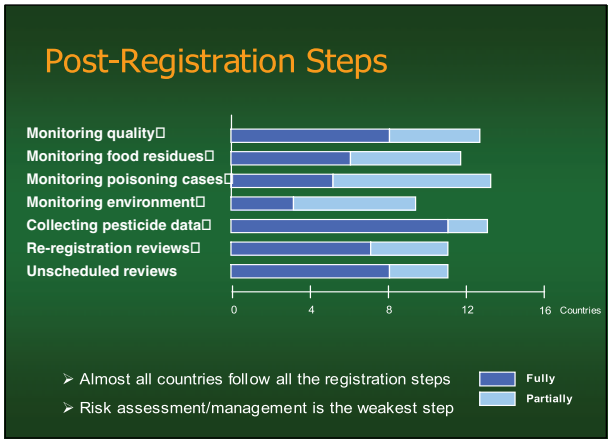
Even though international conventions provide guidance for banning or restricting the use of hazardous pesticides, the total number of such products ranged widely from 14 to 170 per country. The number of banned or restricted highly toxic pesticides ranged from 3 to 46, while this number for persistent organic pollutants (POP) ranged from 0 to 15. Since almost all countries had joined the international treaties and conventions, one would have expected that the same pesticides were banned and restricted in most countries. Presently, many countries still register pesticides that are already banned by their neighbours.

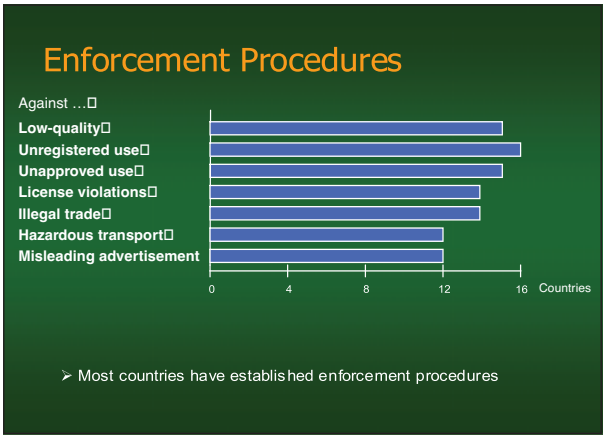


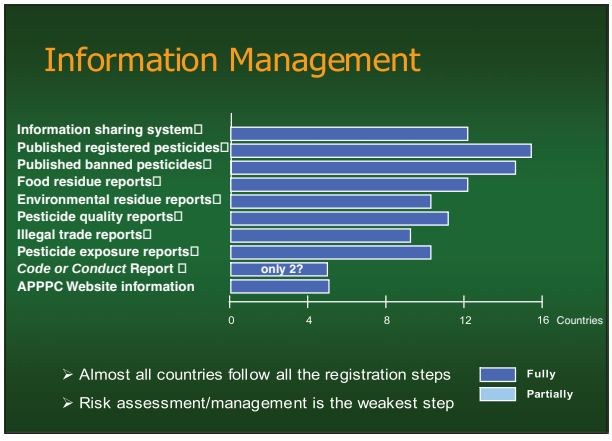
Post-registration activities

The Code of Conduct recommends that all registration decisions and assessments are properly documented and stored for future reference. Furthermore, the national authorities are called to monitor pesticide use, efficacy, safety and environmental effects to verify the assessments that lead to the registration. This would allow for corrective action to be taken if a product fails to perform as expected.

The survey showed that fewer than two-third of the countries fully archived all registration documents and correspondence. About half the countries monitored the quality of pesticides and collected pesticide use data, but the monitoring of residues in food, poisoning cases of humans and livestock, or adverse effects on the environment were still weak or only partially implemented in many countries. The survey also showed that half the agencies had no or only incomplete information about the types and amounts of pesticides used in their country. Consequently, many countries lack the necessary monitoring results to take corrective actions.







Most countries had procedures to enforce the registration provisions, but the number of enforcement staff was often inadequate, with only 1-2 officers in four countries.

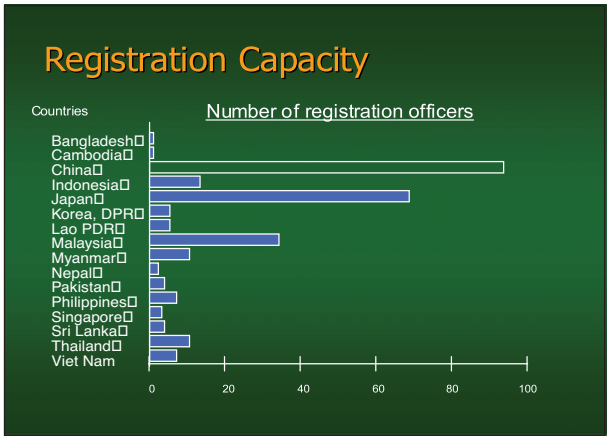
The majority of countries had regulations or guidelines for information sharing, and almost all had published lists on registered and banned/restricted pesticides. However, a number of countries had no reports on residues, quality, illegal trade or poisoning cases, and only a few had issued reports on the implementation of the Code of Conduct or used the APPPC website for information exchange.

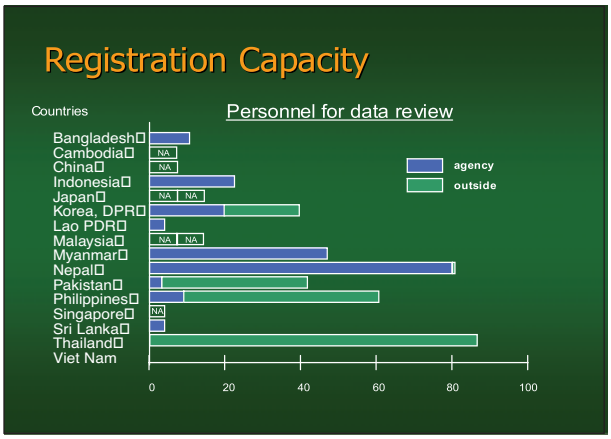
Infrastructure

To carry out its tasks, the responsible authorities need to be sufficiently equipped and have an adequate number of qualified staff.

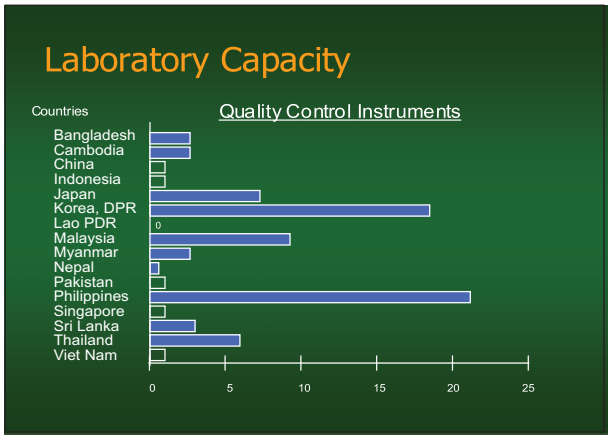
The survey showed that the number of registration officers varied greatly from 1 to about 70 per country. Three countries had only 1-2 officers who would have had to process more than 500 or 1 000 registrations in a year. Likewise, the inadequate number of enforcement officers made it unlikely that registration conditions were enforced.

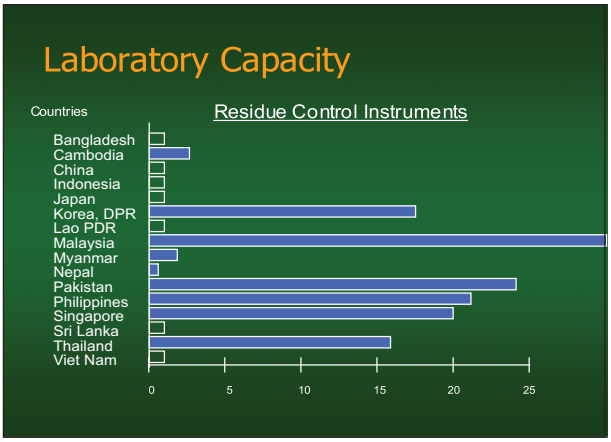
Seven countries involved specialists from outside the agency, most often pesticide chemists and toxicologists, in the review of dossiers. However, the majority of countries engaged no outside experts even when the agency had only limited staff.





Almost all countries had quality control and residue analysis laboratories, and some of these were internationally accredited in seven countries. Seven countries also had toxicology laboratories. However, the majority of the countries had only limited instrumentation and staff that were not enough to carry out routine, post-registration investigations.

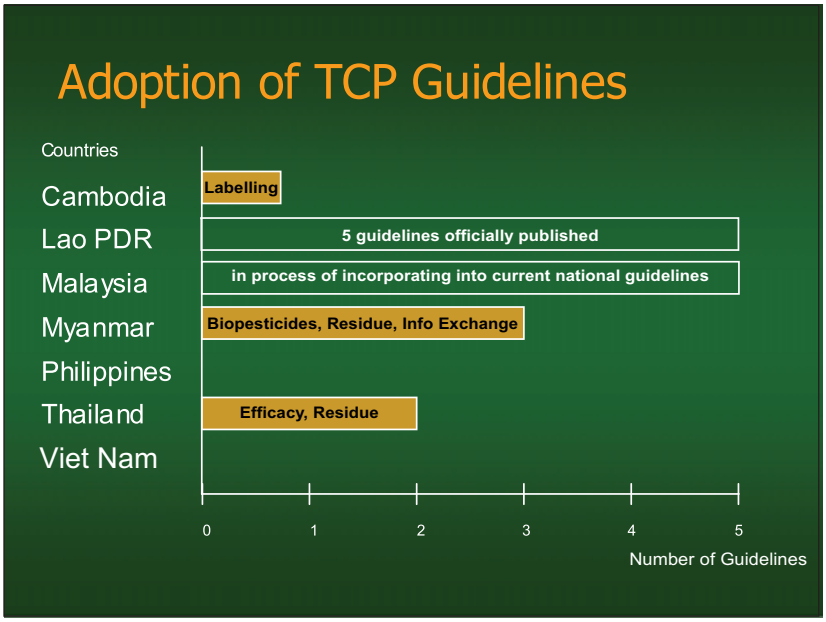




Many countries cited the lack of qualified personnel and insufficient laboratory capacity as the most serious constraints for their regulatory pesticide management.

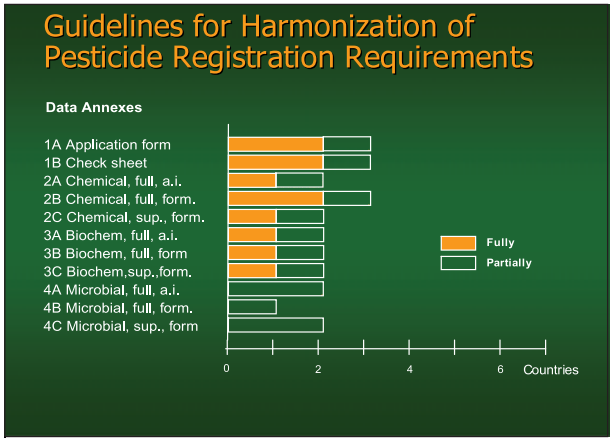
ASEAN-TCP Supplementary Survey

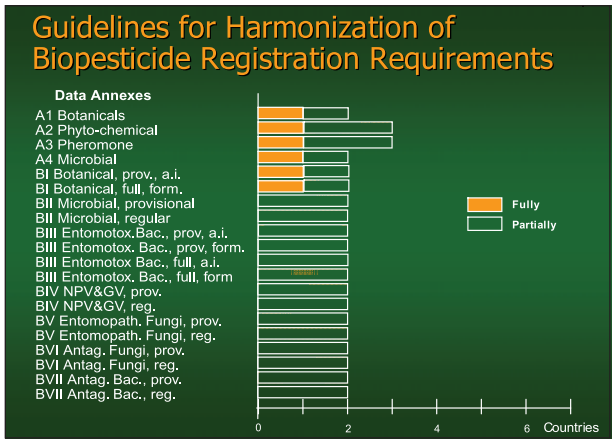
At the final Project Management Committee (PMC) meeting of the TCP project it was recommended that the guidelines should be translated, adopted and officially published by the member countries to give them legal status.

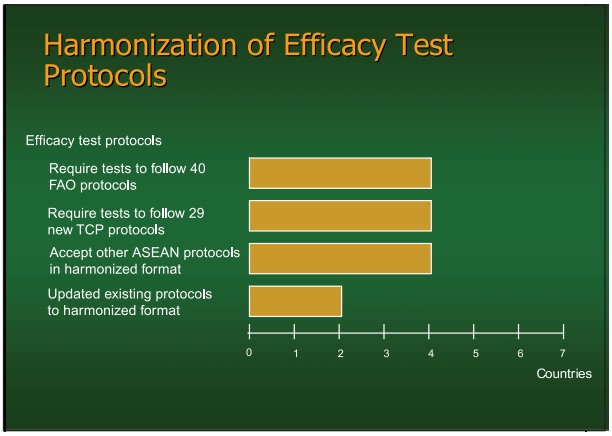


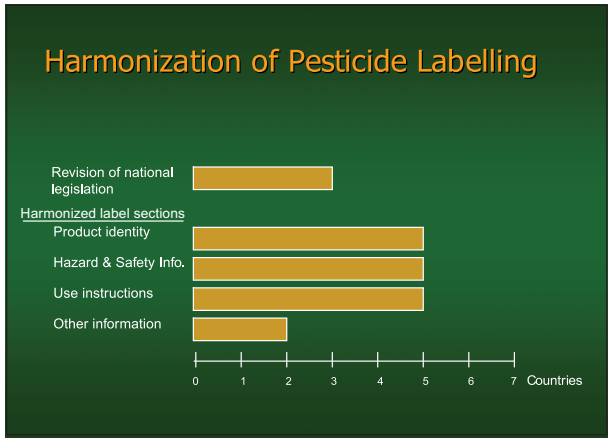
It was found that most TCP countries have not yet implemented these recommendations. Four countries translated some or all guidelines, and only three countries adopted selected guidelines. Lao PDP reportedly officially published all guidelines.

No country had adopted the *Guidelines for Harmonization of Pesticide Registration Requirements*, but two countries had used its annexes. The *Guidelines for Harmonization of Biopesticide Registration Requirements* were only adopted by Myanmar; three countries reported to have used some of the annexes to harmonize their registration data requirements.

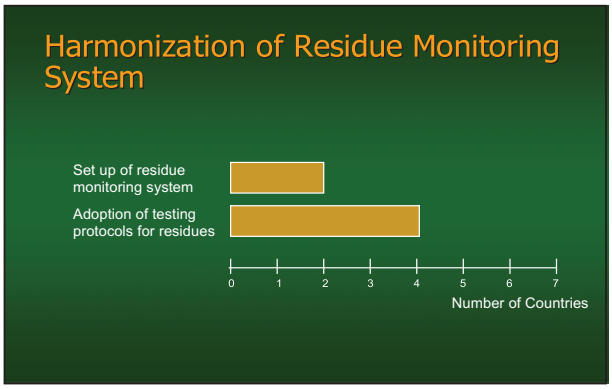


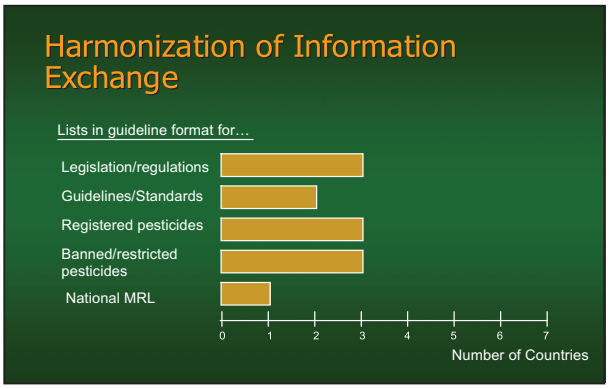






Of the other TCP project guidelines, parts of the *Guidelines for the Preparation of Efficacy Test Protocols* were implemented by 4 countries, while parts of the *Guidelines for the Harmonization of Pesticide Labelling* were used by 5 countries. Four countries have adopted parts of the *Guidelines for Pesticide Residue Monitoring System*, and three countries reportedly followed some of the recommendations for information exchange on pesticide regulatory matters.



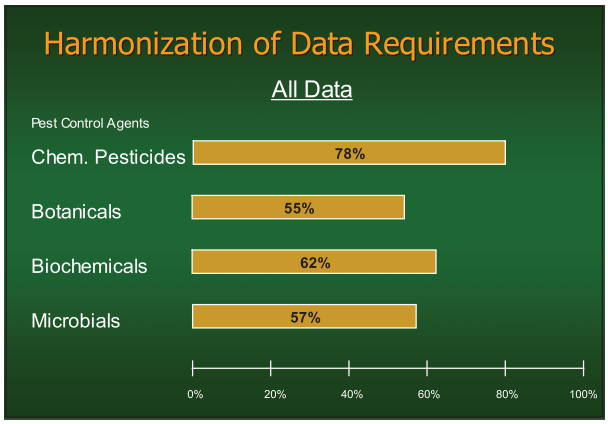


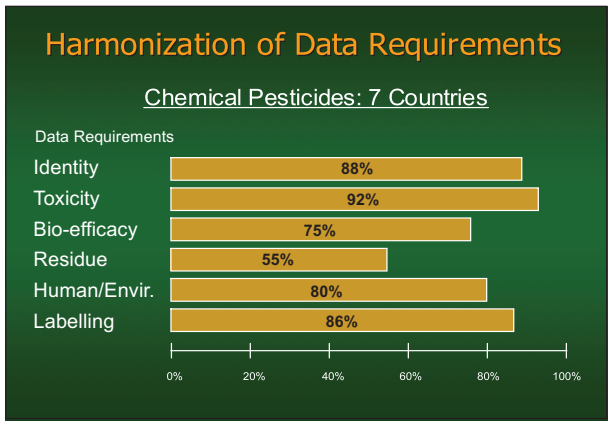
Thus the guidelines developed and adopted by the TCP project have not yet become a common regional standard. However, even though their official adoption has been slow, parts of the guidelines have been used to harmonize regulations and procedure in the region.

Considering the complicated legal requirements and procedures for official adoption, the recommendation of the PMC meeting may have been unrealistic. For some guidelines, particularly the *Guidelines for Harmonization of Biopesticide Registration Requirements,* an official adoption may even have been premature since more consultations and clarifications are needed. With others, new international standards could soon require changes in the guidelines.

The regional survey showed that it may have been unnecessary and confusing to provide different lists of data requirements for pure and formulated substances and different types of registration options. It would be sufficient to focus on the harmonization of data requirements for the regular, full registration of formulated products.

Despite the slow adoption of the TCP guidelines, the supplementary survey of the actual registration data required by the different countries showed that there is already a high degree of harmonization. The data requirements for the registration of chemical pesticides were already 78 percent harmonized, while those for botanical, biochemical and microbial pest control agents were from 62–67 percent identical. For chemical pesticides, the lowest level of harmonization was for residue, bio-efficacy and human and environmental data, while the data for identity, toxicity and labelling data were already around 90 percent the same in all countries.





The supplementary survey results showed that each country implemented the TCP project results differently. Regional regulatory harmonization may not require the official adoption of the project guidelines but can be achieved through adjustments of internal operational procedures and evaluation standards. The survey identified which data requirements are already harmonized and which require further action. Efforts can now focus on the few items that are still different. While regional harmonization is desirable for some registration requirements and procedures, there are many other registration functions that are country-specific and need not to be harmonized.

Conclusions

- Pesticide registration is carried out in all countries, and to a large extent, the same steps, procedures and standards are applied.
- Some steps of pesticide registration are very resource-intensive, and some countries lack the required resources for full implementation.
- There are plenty of international and regional guidelines, but their adoption and implementation is slow and varies greatly.
- The field of pesticide management is still developing and new guidelines are written and old guidelines updated.

To further strengthen pesticide regulatory management, more education is needed about global developments, new technologies and new guidelines. It could also be strengthened through a greater use of available recourses and through minimizing duplications through greater cooperation, particularly on regional level.

Harmonization could aim at…

- agreeing on the lowest level of common technical requirements that should be applied in all countries (e.g. minimum data requirements); or
- agreeing on longer-term targets for pesticide management, but each country would have to find its own way (e.g. guidelines and treaties); or
- agreeing on a step-wise path toward more cooperation and sharing of resources.

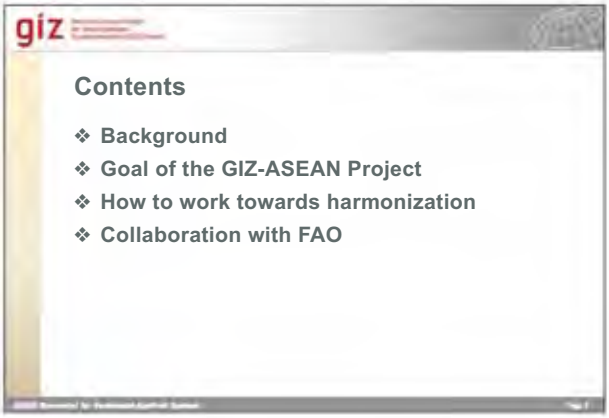
More discussions and clarification may be required with regard to the kind and degree of harmonization desired. While it is important that a country finds the right balance between too little and too much regulation, it is also necessary to find the right balance between too little and too much harmonization. Without harmonization there would be much duplication of efforts and high costs for the industry and governments, while one unified registration for an entire region would make more efficient use of government resources, would ensure more qualified data assessment, lower costs and more resources would be available for country-specific tasks of pesticide management.

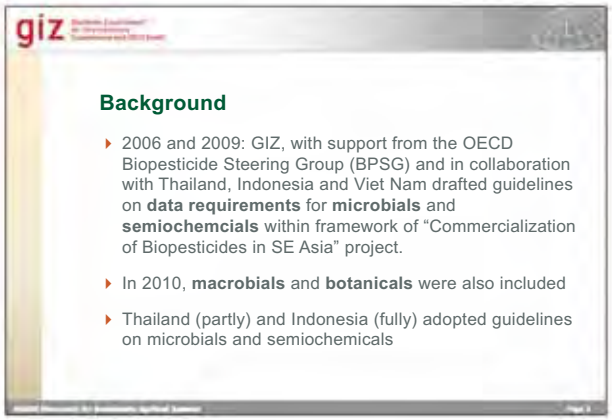
1.3. HARMONIZATION GOALS AND APPROACHES OF THE GIZ-ASEAN PROJECT WITH REGARD TO BIOCONTROL AGENTS

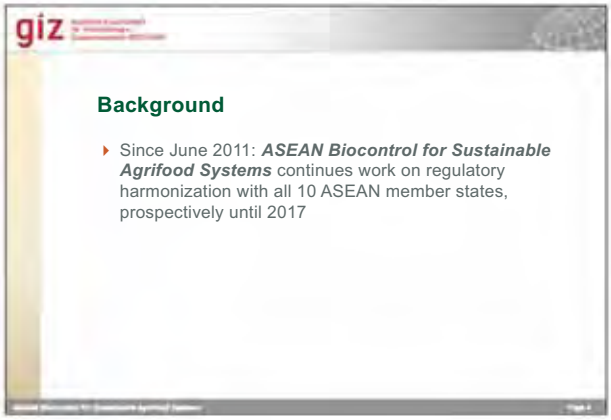
by Thomas Jäckel

ASEAN Biocontrol aims to develop selected regionally coordinated policies and strategies for sustainable agriculture, and the food sector. Agrifood systems will be advanced by promoting sustainable inputs and their management through the promotion of biocontrol agents and sustainable crop management practices. The use, trade and registration of sustainable agricultural inputs, such as pesticides and fertilizers is also encouraged under the project. Sustainable agrifood systems must also be profitable for supply chain actors, such as farmers, processors, traders, and input suppliers.

ASEAN Biocontrol works primarily on a regional level, and in some cases with individual ASEAN member states. Focus is primarily given to the more agrarian ASEAN nations. The project will support ASEAN Member-States by providing advice through (inter)national experts, and the facilitation of pilots implementation. Enhancing regional communication, it will establish a platform for wider policy dialogue between the public, private and civil society sectors, as well as harmonizing registration requirements







Goal of the GIZ-ASEAN Project

- Objective of first phase (2011–2013)

"*Guidelines for the registration, trade and use of biological plant protection products are jointly agreed upon between ASEAN Members*"

How to work towards harmonization

ASEAN Guidelines on Registration, Trade and Use of BCA

How to achieve?

- ✓ Training/information input
- ✓ Work meetings with ASEAN Member States in the **Regional BCA Expert Groups** on **Regulation** and **Application**
- ✓ Focus on government, regulatory departments, etc.
- ✓ Supporting research (application protocols)

How to work towards harmonization

ASEAN Experts of the 'Regional BCA Expert Groups' (Nov 12)

Country	Regulation	Application
Brunei	Ms Suzannie Lim	Ms Siti Amaniah Haji Awg Besar
Indonesia	Ms Yulia Purwanti	Dr Dwi Iswari
Lao PDR	Mrs Yatkeo Phoumidalyvanh	Mr Phoukaothong Sikaisone
Malaysia	Mr Ismail Iberahim	Ms Aishah Jafar
Philippines	Ms Rosemarie Villas Calibo	Dr Bonifacio F. Cayabyab
Thailand	Dr Supanon Sirichuaychoo	Dr Amporn Winotai
Viet Nam	Ms Tran Thi Phuong Hoa	Mrs Nhung Nguyen Thi
Singapore	Ms Bee Leng Low	–
Cambodia	Ms Bunry Rinda	Dr Sophea Kean

How to work towards harmonization

Regional Expert Group meetings for guideline development

2013

Three work meetings of BCA Expert Groups

Last meeting: Wrap up by committee formed by Regional BCA Regulation & Application Groups

Regional Expert Group Meetings 2013
Topics 'Regulation'

1st WM	2nd WM	3rd WM	Wrap Up
Feb 4th wk	May 4th wk	Jul 4th wk	Oct 4th wk
• Harmonization • Microbials • Reg. procedures • Trade	• Botanicals • Macrobials • Trade	• Semiochemicals • Trade • Harmonization • Plan for wrap up	Wrap Up

Each session about 3 days

How to work towards harmonization

In context of **ASEAN** and **regulatory management**, the **development of guidelines** (recommendations) that are **tailored to the needs** of MS

- ➢ Minimum data requirements that provide for the **safety** and **effectiveness** of BCA, for all categories (Sources: FAO, OECD, EU, etc.)
  - Microbials
  - Macrobials
  - Semiochemicals
  - Natural Products (incl. botanicals)
- ➢ Clear registration and post-registration procedures
- ➢ Recommendations on import/export of BCA to help facilitate trade within ASEAN
- ➢ Work on special topics that currently constitute obstacles to registration
- ➢ National adoption/implementation at the discretion of MS

Collaboration with FAO

- ASEAN Biocontrol seeks to join forces with FAO on regulatory harmonization in the region
- ASEAN Biocontrol offers the project's platform to further elaborate on (complement, explain, clarify, condense, simplify) the currently available FAO guidelines on biopesticides:
  - ASEAN Regional BCA Expert Group on Regulation as **work and discussion platform** in 2013 and beyond (some ASEAN MS will also establish National Expert Groups)
  - Reach out to Asia-Pacific-Plant-Protection-Commission network to discuss future activities

Collaboration with FAO

Current Guidelines on biopesticides of FAO:

Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia

- Tremendous effort to harmonize pesticide regulation in the region
- Very useful (simplified) data requirements for **harmonized registration** of microbials, botanicals and semiochemicals
- Helpful instructions on analytical and testing procedures

- Important points that need to be addressed with regard to regulatory harmonization of BCA will be **further discussed in Session 7**

2. Regional status of pesticide regulatory management

The participants of the Chiang Mai workshop reviewed the questionnaire survey results and made corrections where needed. For some questions, additional surveys were conducted and issues of common interest were discussed in two groups, one consisting of the coordinators of the seven TCP-pesticide project countries (ASEAN) (Group 2), and another group of the non-TCP Asian countries (Group 1). In the following units, the relevant international and regional recommendations are given, followed by the results from the workshop group sessions and a concluding summary.

2.1 STATUS OF HARMONIZATION OF LEGISLATION AND REGULATIONS

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

- The increasing complexity of evaluation and assessment of pesticides and their management requires substantial resources and adequate national infrastructure, which includes well-trained personnel in the various fields of pesticide management. The guidelines therefore promote the establishment of a single national authority for registration of all pesticides to optimize the use of limited resources available in most countries.
- This would not only make better use of often limited human and financial resources in many countries, but would also reduce the cost of operating the scheme, ensure more efficient use of combined expertise and experience and facilitate close collaboration between stakeholders. Furthermore, it may reduce the cost of registration to the applicant and hence the cost of pesticides to the user. Finally, since many pesticides may be used in different sectors (e.g. in agriculture and in public health), separate registration schemes could result in inconsistencies regarding authorized uses of a pesticide product.
- Increasingly, pesticide registration is carried out by independent statutory bodies, which may be accountable to various ministries simultaneously. This tends to provide more independence in decision making. Other pesticide regulatory tasks (e.g. licensing, inspection, enforcement) may be under one or more other government ministries.
- The pesticide board is the ... legally appointed body that takes the final decision on the application for registration of a pesticide. It should consist of highly qualified independent experts who together cover all the relevant fields of pesticide evaluation and management. Members could be drawn from government, academia or may be independent experts, and should cover at least the sectors of agriculture, health and environment.
- The responsible authority serves as the secretariat to the pesticide board. It deals with all matters related to the implementation of the pesticide registration scheme.

Definitions given by the Code of Conduct:

Pesticide

Pesticide means any substance, or mixture of substances, or micro-organisms including viruses, intended for repelling, destroying or controlling any pest, including vectors of human or animal disease, nuisance pests, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products or animal feeding stuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as insect or plant growth regulators; defoliants; desiccants; agents for setting, thinning or preventing the premature fall of fruit; and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term also includes pesticide synergists and safeners, where they are integral to the satisfactory performance of the pesticide.

Biological Pest Control Agent

Biological pest control agents are naturally occurring or genetically modified agents that are distinguished from conventional chemical pesticides by their unique modes of action, low use volume, and target species specificity. There are two major categories of biological pest control agents: the biochemical pest control agents and the microbial pest control agents.

[Source: 1988 FAO Guidelines on the Registration of Biological Pest Control Agents]

Regional recommendations

Regional guidelines for Harmonization of Pesticide Registration Requirements

- Member countries should review their current procedures and requirements to determine their level of compliance with the harmonization guidelines
- (No recommendations with regard to organization of pesticide registration, other than registration and technical committees)

Issues

- All countries register pesticides, but sometimes registration is limited to pesticides of certain sectors.
- Pesticides of all sectors should be regulated under the same standards of efficacy and safety.
- Besides pesticides, many national responsible authorities also regulate other pest control agents which need different data requirements and assessment procedures.

Workshop results

Responses to survey questions

Group 1	**Bangladesh**	**China**	**Indonesia**	**Japan**	**Korea, DPR**	**Nepal**	**Pakistan**	**Singapore**	**Sri Lanka**
How many agencies in your country regulate pesticides? (agriculture, public health, livestock, fisheries, forestry, household, industrial, etc.)	1	1	1	3	3	1	7	2	1
How many sets of legislations are there that regulate the above types of pesticides (by sector)?	1	1	1	2	3	1	7	3	1
Does your agency follow the same definition for pesticides as the Code of Conduct?	N	N	Y	N	Y	N	N	N	Y

B: Public health included under agriculture. No legislation for other sectors.

Group 2: TCP-pesticide project countries (ASEAN)	**Cambodia**	**Lao PDR**	**Malaysia**	**Myanmar**	**Philippines**	**Thailand**	**Viet Nam**
How many agencies in your country regulate pesticides? (agriculture, public health, livestock, fisheries, forestry, household, industrial, etc.)	1	1	1	1	3	5y	5
Pesticide board	N	N	1	1	FPA	1	N
Committees	1	1	1	1	6	5	5
How many sets of legislations are there that regulate the above types of pesticides (by sector)?	1	1	1	1	3	1	3
Does your agency follow the same definition for pesticides as the Code of Conduct? – old definition	Y	Y	N	Y	Y	Y	Y

Conclusions:

- 9 countries have a single agency regulation pesticides
- 7 countries had multiple agencies regulating pesticides, with as many as 5–7 agencies
- 10 countries had a single set of legislation, while 6 countries had multiple regulations; the maximum number was 7 different sets of regulations
- The Code of Conduct definition of pesticides was followed in 9 of the 16 countries.

Workshop discussions

Question 1:

"Should there be a single agency or multiple agencies for agriculture, public health, forestry and livestock products? Discuss advantages and disadvantages."

Group 1

Single Agency Departments within a Ministry Single agency only handling registration of all pesticides covering all sectors	
Advantage	**Disadvantage**
• Bangladesh, Cambodia, Sri Lanka • Seamless decision making • Cost effective – less cost • More consistent policy • Integrated oversight • Information sharing e.g. toxicology data • Training	• Slow decision making – many procedures • Under limited resources climax - > may create inefficiency
Multiple Agencies Be aware: Requires a common mechanism for communication, coordination and cooperation.	
Advantage	**Disadvantage**
• Different agencies looking at registration for the different sectors • For effective safety assessment pertaining to the different sector/area • Faster decision making • More specialised training pertaining to the different sector/areas	• Lack of consistent policy • Lack of oversight • Lack of communication, coordination & cooperation

Group 2 TCP-pesticide project countries (ASEAN)

	Advantages	**Disadvantages**
Single agency	• Board comprise of multiple agencies • Single window • Standardized application system • 1 standard • Only one Pesticide Act • Easy to facilitate registrant	• Difficult to get all members at every meetings • Overcome by a multi-agency technical committee
Multiple agencies	• Different registration committees in different agencies • More focused in evaluation in each agency • Involved different risks in different fields	• Difficult for registrant to registration 1 product • Different agency for different use category • Different rules and regulations to follow • Different standards e.g. different test requirement for different registration, even though same pesticides and same target

Question 2:

"Which pesticides and pest control agents should be regulated by the agency for agricultural pesticide registration, and which agents should be except from registration or regulated differently?"

Group 1

Pesticide or Pest Control Agent	Mark which should be regulated
Chemical Pesticides	Y
Botanical Pesticides (Phytochemicals)	
Direct toxins (e.g. Pyrethrum, Neem/Azadirachtin, Rotenone, Nicotine)	Y
Other plant products (e.g. oils)	Y
Biochemical Pest Control Agents (BPCA)	
Semiochemicals	Y
Hormones	Y
Nat. Plant regulators and insect growth regulators	Y
Enzymes	Y
Microbial Pest Control Agents (MPCA)	
Viruses (e.g. NPV/GV)	Y
Entomotoxic bacteria (e.g. Bt., Bacillus subtilis)	Y
Antagonistic bacteria	Y
Entomopathogenic fungi (e.g. Beauveria bassiana, Metarhizium)	Y
Antagonistic fungi (e.g. *Chaetomium cupreum, Trichoderma)*	Y
Parasitic protozoan (e.g. *Sarcocystis singaporensis*	Y
Entomopathogenic nematode (EPN, e.g. *Steinernema*)	Y
Plant Incorporated Protectants (PIP)	
Bt. in corn, cotton, etc.	Mixed opionions
Macrobial pest control organisms (BCA)	
Invertebrate biocontrol agents (IBCA)	
• Predators	Y/N
• Parasitoides	Y/N
Minerals	Y

Conclusions:

- There is a general consensus that chemical pesticides, botanical products, minerals, biochemical and microbial pest control agents should be registered;
- Different opinions exist with regard to the registration of PIPs and invertebrate pest control organisms.

SUMMARY

Legislation

All countries in the region have legal arrangements for pesticide registration. In ten countries there is a single legislation covering all uses. The other six countries have separate laws for different sectors, particularly for pesticides used for public health or veterinary purposes. To what extent the different legislations are harmonized and apply the same standards and regulations was not determined. All pesticide registration authorities that participated in the survey registered agricultural pesticide and most of them also those for forestry and public health. However, more than half the national authorities did not deal with pesticides used with livestock and fisheries. While there are advantages and disadvantages for single and multiple registration authorities, a single authority would be more cost effective and consistent with regard to safety policies and standards. However, its establishment may not always be politically feasible.

The legislations and regulations generally cover all functions in the pesticide life cycle. All 16 countries in the survey regulated import, storage, labelling, packaging and retail; a few countries did not regulate transport, information sharing and public participation in the regulatory process.

Special legislation or regulations exist in almost all countries for highly toxic products, persistent organic pollutants and methyl-bromide. These are in line with international treaties and conventions which most countries in the region have ratified.

Regulated products

There are considerable differences in the region with regard to the classes of pest control agents that require registration. Apparently, not all countries define pesticides the same way. The Code of Conduct definitions for pesticides and biological pest control agents are followed by nine countries.

The legislations in all countries regulate chemical pesticides, and also botanicals (except for Cambodia), biochemical and microbials. However, the registration of non-chemical pest control agents is only partially implemented in some countries. Main differences exist with regard to plant incorporated protectants (PIP), certain non-pesticide active ingredients in formulations and other chemical agents used in agriculture which are only regulated in fewer than half the countries. Invertebrate biocontrol agents are also regulated by the national authority in 12 countries, even though their control would be more related to quarantine regulations rather than pesticide registration.

For regional harmonization it would be desirable if countries would encourage more the use of non-chemical pest control agents and follow the same procedures.

Registration procedure

All countries follow more or less the same registration procedure from application to final publication of the registration decision, but the level of implementation varies greatly. In Lao PDR and Nepal, most of the steps are not yet fully implemented. Online submission of the registration application is only accepted in Singapore. The protection of confidential business information and proprietary data is guarantied in most countries; however, the length of the protection period varies widely from 2 years to unlimited. Only six countries make non-protected data available to the public; ten countries share health and safety data.

2.2 STATUS OF HARMONIZATION OF MINIMUM DATA REQUIREMENTS

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

- The guidelines promote harmonized pesticide registration requirements, procedures and evaluation criteria.
- Separate, in-depth technical registration data requirement guidelines have been developed by FAO, WHO, OECD
- Governments should design procedures suited to their own specific requirements and need not necessarily adopt all the elements of a comprehensive regulatory scheme as operated in countries with extensive resources.
- Countries should carefully consider pesticides by a case-by-case basis to determine what specific data requirements apply to the product in question.
- Many countries apply a tiered or step-wise approach when a limited data set is required in a first submission, and additional data may be requested if necessary.
- Data requirements may differ depending on various aspects, among them:
  - the nature of the pesticide (synthetic chemical pesticides, microbial pesticides, etc.);
  - the intended use pattern (e.g. agricultural pesticides for field use, pesticides used in greenhouses, vector control pesticides, domestic use pesticides, wood preservatives);
  - whether the product is an active ingredient or a formulation;
  - whether the product is based on a new active ingredient or a generic one;
  - whether the product will be used on a large scale or be of minor use;
  - whether the product is (closely related to) a recognized low-risk pesticide.

Regional recommendations

The following guidelines were adopted by the project for implementation in the countries:

Regional guidelines for harmonization of pesticide registration requirements

The nine annexes of the guidelines provide all the recommended data requirements for proprietary and supplementary registrations of the technical concentrate and the formulated product. They are given for chemical, biochemical and microbial pesticides.

Regional guidelines for data requirements for the registration of biopesticides

The guidelines contain 20 annexes with minimum data requirements for concentrated and formulated phytochemicals, pheromones and various types of microbial pest control agents. Some of the list overlap with the requirements given in the above guideline.

Issues

- How can one harmonize data requirements, when they should be considered on a case-by-case basis and should differ depending on various aspects?
- Regular registration is the only option available in all countries; it is therefore the only option that needs to be harmonized.
- Should there be separate lists for active substance and formulated product?
- How many lists of minimum data requirements are useful?
- There are strong similarities between the different lists of requirements so that they could be simplified and unified.

Workshop results

Responses to survey questions

Group 1: Non-TCP Asian countries **"For which products do you have a systematic, tiered procedure of data requirements?"**	**Bangladesh**	**China**	**Indonesia**	**Japan**	**Korea, DPR**	**Nepal**	**Pakistan**	**Singapore**	**Sri Lanka**
Chemical Pesticides	**Y**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**
Botanicals	**N**	**N**	**Y**	**N**	**Y**	**N**	**N**	**Y**	**Y**
Biochemicals	**Y**	**N**	**Y**	**N**	**N**		**N**	**Y**	**Y**
Microbials	**Y**	**N**	**Y**	**Y**	**N**	**N**	**N**	**Y**	**Y**

Japan: waivers may have the effect

Group 2: TCP-pesticide project countries (ASEAN) **"For which products do you have a systematic, tiered procedure of data requirements?"**	**Cambodia**	**Malaysia**	**Myanmar**	**Lao PDR**	**Philippines**	**Thailand**	**Viet Nam**
Chemical Pesticides	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Botanicals		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Biochemicals	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Microbials	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**

Workshop discussions

Group 1:

> "What aspects of data requirements should be harmonized and which need to be decided on a case-by-case or country-by-country basis?"

HARMONIZE	NOT HARMONIZE
MRL	Local or foreign field trials
Identity product	Waiting period PHI
Efficacy protocols	Studies (residues, …
Toxicology Protocols	Environmental impact
Residue protocols	(Fish) toxicity studies
Method of chemical formulation analysis	
Label content	

Group 2: TCP-pesticide project countries (ASEAN)

> "The harmonized guidelines contained 29 different lists of data requirements? Were they clear or confusing? Which were more useful than others? Are there patterns that would allow reducing the number of lists or simplifying them?"

Having 29 different lists was confusing. It would be better to emphasize on a few common lists which would be applicable to all. Basically, all countries have different systems, but all have full registration for formulated products. They need more capacity building on evaluation and data requirements for biocontrol agents as not all countries have registration or much experience in this field.

> "For which registration options should there be separate harmonized data requirement lists (active substance/formulated product, provisional/proprietary/supplementary/re-registration)?"

There is a need to have clear definitions for all types of registration as some countries have a different interpretation of regular, proprietary registration.

SUMMARY

Use of international guidelines

To promote harmonization, technical registration data requirement guidelines have been published by FAO, WHO and OECD. The countries in the region have applied them to variable degrees. Particularly the more recent publications are not yet widely implemented and more time may be needed to incorporate the recommendations into local legislations and regulations. For example, the *Globally harmonized system of classification and labelling of chemicals* (GHS) has only been fully adopted in four countries. Also, the OECD *Guidance Documents for Pesticide Registration* which are a good source of registration data requirements are only reflected in the legislation and regulations of a few countries.

Use of TCP guidelines

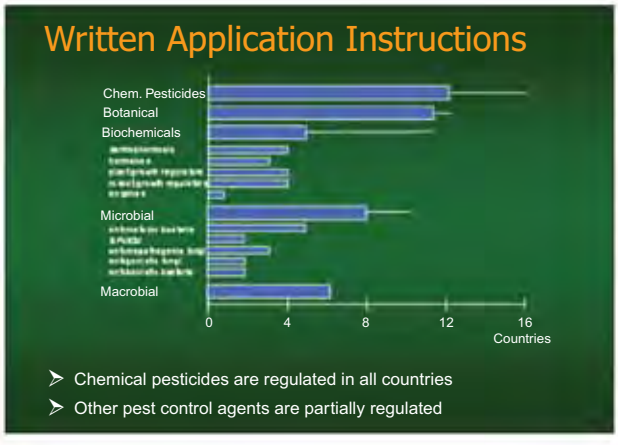
The registration requirements in the regional guidelines for Southeast Asia have only been partially used so far by 3 countries. One reason for the low rate of adoption may have been the large number of 29 different data lists in the two guidelines for pesticides and biopesticides. These were apparently too confusing for practical work. There were separate data list for active ingredients and formulated products, as well as for preliminary, supplementary and full registration for chemical pesticides and eight types or biological pest control agents. The workshop participants recognized that it would be better to focus the harmonization efforts on a few lists which are applicable to all countries, such as the data requirements for a regular, full registration of formulated products.

Folder requirements

All national authorities follow the same system of dossier folders for registration applications, i.e. (1) identity and properties of the product, (2) toxicity data, (3) bio-efficacy data, (4) residue data, (5) human and environmental fate and effect data, as well as (6) labelling, packaging and storage data. The specific data in the folders should depend on the type of pest control agent and registration. Some countries have special application options for concentrated active substances while the registration of the finished, formulated product is generally the norm.

About half the countries have the same folder requirements for chemical pesticides as for biological pest control agents, and they also require the same data for provisional, supplementary or re-registration as for a full registration. Such similarities would indicate that the data requirements have not been differentiated according to the group of pest control agents and type of registration and different strategies and approaches are applied in different countries. For the purpose of regional harmonization it would be desirable if all countries would follow the same general concept.

About half the countries reported that they apply a tiered, step-wise approach to data submission under which additional data may be requested if those are needed after the review of the initial, minimum requirements.



Registration application

Registration authorities should provide comprehensive and clear instructions to the applicants with regard to procedures and data requirements. The survey showed that written instructions exist mostly for chemical and botanical pesticides, while only few countries have them also for microbial and biochemical pest control agents. This shows that many national authorities are not yet fully prepared to register biological pest control agents.

2.3 DEVELOPMENT OF A UNIFIED SYSTEM OF MINIMUM DATA REQUIREMENTS
(chemical pesticides)

Regional recommendations

Regional guidelines for harmonization of pesticide registration requirements

Three data requirement lists*:*

- Requirements for the proprietary registration of active substances
- Requirements for the proprietary registration of formulated products
- Requirements for the supplementary registration of formulated products

Survey results

- Half the countries do not register active substances
- 7 countries do not have a provisional registration
- 10 countries do not have a supplementary registration
- Some botanical pesticides may be registered like chemical pesticides (FAO guideline)

Issues

- The harmonized data requirement lists were only partially adopted by a few countries.
- For the proprietary registration of chemical pesticides, 78 percent of the recommended data are already harmonized in the TCP-pesticide project countries (ASEAN).
- The lowest harmonization rate is for residue data.
- The harmonization rate could be increased if the number of required data were decreased.
- Can the lists be simplified considering that …
  - normally, the formulated product is registered
  - many countries do not have a provisional, supplementary or re-registration option

Workshop results

Discussion:

Identify in the following table the minimum, basic (Tier I) data that should be required by all countries, including those with limited resources and assessment capacities.

Explanation:

The following table indicates which group chose a respective data requirement (1 = group 1; 2 = group 2). Data requirements that were agreed by both groups are highlighted.

A. Identity

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
Active Ingredient (AI)			
A.1.	**Chemical identity**		
	1.1. Chemical Abstract Services Number (if any)	1/2	
	1.2. Common name (proposed or accepted by ISO and synonyms)	1/2	
	1.3. Structural formula	1/2	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC)	1/2	
	1.5. Empirical formula and molecular weight	1/2	
	1.6. Specification together with method of analysis of active ingredient	1/2	
A.2.	**Physical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour, odour)	1/2	
	2.2. Melting/decomposition/boiling point	1/2	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20–25 ºC), but only when above 10-3 Pascal)	1/2	

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20–25 °C)	1/2	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	1/2	
	2.6. Density (for liquids only)	1/2	
	2.7. Hydrolysis rate under stated relevant conditions	1/2	
	2.8. Photolysis under stated relevant conditions	1/2	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	1/2	
A.3.	**Technical grade active Ingredient**		
	3.1. Source; name and address of manufacturer and addresses where manufactured	1/2	
	3.2. Appearance (physical state, colour and odour)	1/2	
	3.3. The minimum (and maximum) active ingredient content in g/kg	1/2	
	3.4. Identity and amount of isomers, impurities and other by-products	1/2	
	3.5. Analytical test report of impurity profile	1/2	
	3.6. Analytical test report of specifications	1/2	
	3.7. Process of manufacturer	1/2	
	3.8. Shelf life	2	1
	3.9. Specification together with methods of analysis (and physicochemical properties)	1/2	
A.4.	**Material Safety Data Sheet (MSDS)**		
	4.1. Physical data (melting point, boiling point, flash point, etc.)	1/2	
	4.2. Chemical toxicity	1/2	
	4.3. Health effects	1/2	
	4.4. First aid	1/2	
	4.5. Reactivity	1/2	
	4.6. Storage	1/2	
	4.7. Disposal	1/2	
	4.8. Protective equipments	1/2	
	4.9. Spill-handling procedure	1/2	
	4.10. Label including hazard symbol	1/2	
Formulated product			
A.5.	**Product identity**		
	5.1. Formulator's name and address	1/2	
	5.2. Distinguishing name (proprietary name)	1/2	
	5.3. Use category (herbicide, insecticide, etc.)	1	
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	1/2	
	5.4. Confidential statement of formula (this statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material)	1/2	
A.6.	**Composition of product**		
	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	1/2	
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g., technical grade, adjuvants and inert components	1/2	
	6.3. Water/other solvent content (where relevant)	1/2	
	6.4. Specification together with method of analysis	1/2	
	6.5. Analytical test report	1/2	
A.7.			
	7.1. Appearance (physical state, color, odor)	1/2	
	7.2. Storage stability (in respect to composition and physical properties related to use)	1/2	
	7.3. Density (for liquids only)	1/2	
	7.4. Flammability: liquids – flash-point; solids – a statement must be made as to whether the product is flammable	1/2	
	7.5. Acidity (where relevant)	1/2	
	7.6. Alkalinity (where relevant)	1/2	
	7.7. Other properties may in certain cases need evaluation	2	1

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
A.8.	**Physical Properties of the Formulated Product Related to Use**		
	8.1. Wettability (for dispersible powders)	1/2	
	8.2. Persistent foam (for formulations applied in water)	1/2	
	8.3. Suspendibility (for dispersible powders and suspension concentrates)	1/2	
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	1/2	
	8.5. Dry sieve test (for granules, dusts)	1/2	
	8.6. Emulsion stability (for emulsifiable concentrates)	1/2	
	8.7. Corrosiveness (when necessary)	1/2	
	8.8. Known incompatibilities with other products, e.g. fertilizers	1/2	
	8.9. Specification together with method of analysis	1/2	
	8.10. Analytical test report	1/2	
	8.11. Shelf life	1/2	

B. Toxicity Data

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
B.1.	**Acute Toxicity tests**		
	1.1. Acute oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	1/2	
	1.2. Acute dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	1/2	
	1.3. Acute inhalation toxicity (LC_{50} in mg/l)	1/2	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	1/2	
	2.2. Eye irritation	1/2	
B.3.	**Allergy/sensitization test**	1/2	
B.4.	**Sub-chronic toxicity tests in (minimum of oral test of 90 days duration in rats)**	1/2	
B.5.	**Reproduction Effects studies (minimum of two generations in rats)**	1/2	
B.6.	**Teratogenicity studies (in two species, one in rats and other in non-rodents)**	1/2	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	1/2	
B.8.	**Mutagenicity studies (minimum of Ames test and in vivo micronucleus test)**	1/2	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats**	1/2	
B.10.	**Medical Data/Poisoning symptoms/Antidote**	1/2	

C. Bio-efficacy Data and Pest information

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
C.1.	**Bio-efficacy and Pest information**		
	1.1. Pest (Common/Scientific Name)	1/2	
	1.2. Dosage/rate of application	1/2	
	1.3. No. of applications	1/2	
	1.4. Application Method (e.g. dusting/spraying (high volume/low volume/ ultra low volume, etc.)/Appliances	1/2	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	1/2	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	1/2	
	2.3. Pre-harvest intervals	1/2	
C.3.	**Field trials planning/design (location/climatic data/statistical design/plot size/ controls/replications)**	1/2	
C.4.	**Pesticide/MCPA evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	1/2	
C.5.	**Method of Sampling**	1/2	
C.6.	**Recording field data**	1/2	
C.7.	**Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence**	1/2	

D. Residue Data

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
D.1.	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	1/2	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)		2
	1.3. Crop groupings		2
	1.1. Use of radio labelling material (C-14, P-32, S-35)	1	2
	1.1. Dosage rate (at least equal to intended use)	1/2	
	1.2. Identification & characterization of residues	1/2	
	1.3. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	1	2
D.2.	**Farm Animal Metabolism**		
	2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken	1/2	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	1/2	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed	1/2	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	1/2	
	2.5. Parental compounds should be used	2	
D.3.	**Farm Animal Feeding Studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	1	2
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs	1	2
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	1/2	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X)) and control group)	Y/1 (3) Thailand, Cambodia, Philippines	2
	3.5. Material used: usually parent compound	2	
D.4.			
	4.1. Data on transfer of residues into processed commodities		1/2
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup), Peas and beans (without pods), Oil seeds (meal, oil), Olive (virgin oil), Tea (brewed)		1/2
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	?	2
	4.4. Glasshouse trials (protected crops)	?	2
	4.5. Post-harvest treatment studies (wheat, potato)	?	2
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	?	2
	4.7. Decline Studies (4 sampling intervals, i.e., five samples) Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	?/2	
	4.8. Extrapolation studies ±25% rule for comparing GAPs	?/2	
D.5.	**Analytical Methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	1/2	
	5.2. Analytical standards/reference chemicals	1/2	

E. Human Health Exposure/Environmental Data

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
E.1.	**Human Health Exposure Effects**		
	Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring)	2	1
	Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring)		1/2
E.2.	**Evaluation of Environmental Fate & Effects**		
	3.1. Data on translocation of pesticides in soil and water	1/2	
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	1/2	
	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators, etc.)	1/2	
	3.3. Primary data on aquatic toxicity (e.g. fish and other aquatic animals)	1/2	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	1	2
	2.4. Primary data on phytotoxicity effects	1/2	
	3.4. Primary data on persistence/translocation in plants	1/2	
	2.6. Primary data on treatment of effluents & disposal	1	2
E.4.	**Monitoring of environmental effects**		
	4.1. Monitoring of substantial change in use/application pattern		1/2
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)		1/2
	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate		1/2
E.5.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence/resistance)**		1/2

F. Labelling/Packaging/Storage Data

Sl. No.	Data Parameters for regular (proprietary) registration	Minimum	Later as necessary
F.1.	**Labelling**		
	1.1. Chemical name/Common name of MCPA	1/2	
	1.2. Product name	1/2	
	1.3. Formulation/contents of the product	1/2	
	1.4. Quantity (Wt/Vol.)	1/2	
	1.5. Registration Number/date of registration/date of expiry and or/import permit number/date of issue, where applicable	1/2	
	1.6. Manufacture Licensing Number/date of issue	1/2	
	1.6.1. Batch Number	1/2	
	1.6.2. Manufacturing date	1/2	
	1.6.3. Date of expiry of product	1/2	
	1.7. Precautions & Directions for use	1/2	
	1.8. Warning phrases & Symbols	1/2	
	1.9. Storage conditions	1/2	
	1.10. Recommended crop/commodity	1/2	
	1.11. Pre-harvest intervals	1/2	
	1.12. Restrictions, if any	1/2	
	1.13. Signs/symptoms of pesticide poisoning & treatment	1/2	
F.2.	**Packaging**		
	2.1. Specification of primary package	1/2	
	2.2. Specification of secondary package	1/2	
	2.3. Specification of bulk package for transport	1/2	
F.3.	**Storage tests (Shelf life)**	?/2	

Conclusions:

The following consensus was achieved with regard to the recommended minimum registration data requirements for chemical pesticides (numbers indicate the number of data items):

Folder		Consensus		More discussions required
		Required	Later as necessary	
A	Identity	59	0	3
B	Toxicity	13	0	0
C	Bio-efficacy	12	0	0
D	Residue	10	2	16
E	Health/Environment	6	5	3
F	Labelling/Storage	19	0	1
	Total (149)	119	7	23
	Percent of total	80%	5%	15%

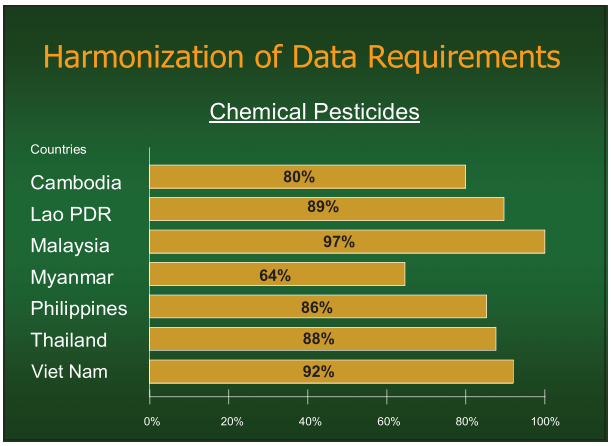
SUMMARY

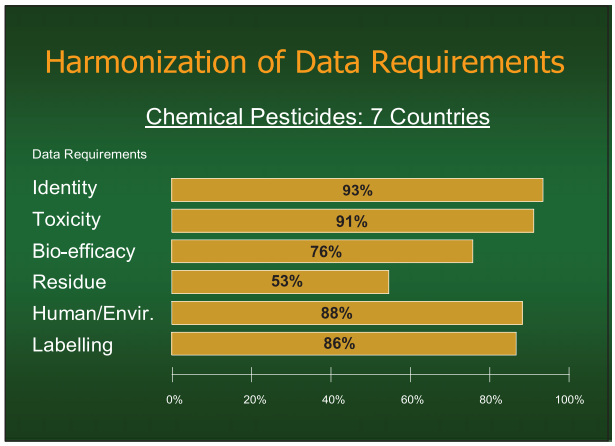
The workshop succeeded in further enhancing the harmonization efforts for the minimum data requirements for chemical pesticides and developed a new, shorter list that was agreed upon by all delegates. Out of the original list of 149 data requirements given in the TCP guidelines, the workshop delegates agreed on 119 items (80%) as basic, minimum requirements and seven items (5%) that may be added later as required. The two working groups had different opinions about 23 items. There was almost complete agreement with regard to the folders *Identity, Toxicity, Bio-efficacy* and *Labelling*, while the opinions for the requirements for *Residue data* and *Human health exposure/Environmental data* differed. More regional discussions are required about those items and they may be added later to the minimum data requirements as the harmonization efforts progress.

Based on this new list, the level of harmonization of data requirement in Southeast Asia ranged from 64 percent (Myanmar) to 97 percent (Malaysia). Some countries that reported to have fully or partially adopted the regional guidelines had 64 percent to 89 percent of their registration data match with the list of minimum data requirements.

With regard to individual folders, the folders *Identity, Toxicity* and *Labelling* were already harmonized to 86–93 percent. Least harmonized was the folders *residue data* (53%) which still needs more clarifications with regard to the minimum requirements. Even though there is a consensus about bio-efficacy data, its level of harmonization was only 76 percent.

Folder	Harmonization of minimum data requirements for chemical pesticides	Required data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
A	Identity and Properties	59	59	56	59	41	59	56	55	385	**93%**
B	Toxicity Data	13	12	12	13	8	12	13	13	83	**91%**
C	Bio-efficacy Data and Pest information	12	0	12	12	12	4	12	12	64	**76%**
D	Residue Data	15	13	5	13	0	6	7	12	56	**53%**
E	Human Health Exposure/Environmental Data	7	5	7	7	3	7	7	7	43	**88%**
F	Labelling/Packaging/Storage Data	20	12	20	18	17	20	16	17	120	**86%**
	Sum	126	101	112	122	81	108	111	116	751	
	% Harmonized		**80%**	**89%**	**97%**	**64%**	**86%**	**88%**	**92%**		**85%**





These results provide clear feedback to the national authorities with regard to which registration data still need to be required in order to achieve full regional harmonization. By using the agreed-upon list as a reference, progress toward harmonization of registration requirements can now be measured and compared.

2.4 DEVELOPMENT OF A UNIFIED SYSTEM OF MINIMUM DATA REQUIREMENTS

(biological pest control agents)

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

- As any other pesticide product, microbial pest control agents, semiochemicals, insect growth regulators, pheromones and plant extracts (botanicals) should be registered before they are allowed for use. The general procedures for registration of these products are the same as for other pesticides, however, the data requirements and the assessment of the data may be different
- In many countries, microbial pest control agents are still evaluated and registered following the same system as for chemical pesticides. Using the conventional registration for microbial pest control agents can pose an unnecessarily high regulatory burden to satisfy inappropriate testing requirements.

Regional recommendations

Guidelines for Data Requirements for the Registration of Biopesticides

- Types of biopesticides
- Regulatory requirements
- Lists of recommended data requirements for …
  - Botancial pesticides (Technical/provisional; formulation/regular)
  - Microbial pesticides (Provisional and regular registration)
  - Entomotoxic bacteria (Technical substance provisional and regular registration; formulation provisional and regular registration)
  - Baculoviruses NPV & GV (Provisional and regular registration)
  - Entomopathogenic fungi (Provisional and regular registration)
  - Antagonistic fungi (Provisional and regular registration)
  - Antagonistic bacteria (Provisional and regular registration)
- There were 17 different harmonized data requirement lists for microbial pesticides
- There were lists for technical active substance and formulated product
- There were lists for provisional, regular/proprietary and supplementary registration

Recommendations (PMC)

- The registration of biopesticides should follow the project-approved guidelines for biopesticides

Additional suggested recommendations:

- Provide a universal classification system for all biological pest control products to be followed by member countries
- Harmonize the recommended data requirements with international guidelines such as OECD guidelines
- Explain reasons for specific registration procedures and data requirements

Background information

Excerpts for the presentation by Dr Thomas Jäckel (for full presentation, see Annex 3)

Different Categorizations of Biological Control Agents

FAO	IBMA (BCA)	BCPC (BCA)
• (Bio)pesticides – Microbial – Botanical (phyto-chemicals) – Biochemical (semiochemicals, hormones, plant regulators, etc.) • Biocontrol Agents – Macro-organisms	(International Biocontrol Manufacturers' Association) – Microbials – Macrobials – Botanicals – Semiochemicals	(British Crop Protection Council): – Micro-organisms – Macro-organisms – Natural products – Semiochemicals Natural products: Compounds/molecule with a claim for a crop effect, derived from living organisms ('nature')

Importance of Biological Control Agents in ASEAN and regulatory problems (according to ASEAN Biocontrol assessment)	
BCA Category	**Importance and regulatory problems**
	Leading users of BCA in ASEAN: Indonesia, Thailand, Viet Nam
1. Microbials	• Most important group (*Bt*. market leader) • Significant taxonomic and analytical problems • Post-registration quality check needed
2. Botanicals	• Market size second to microbials in ASEAN (Need most abundant product) • Significant analytical problems due to complex mixture of ingredients
3. Semiochemicals	• Use patchy (e.g. plantations), many not registered • No field testing protocols • Large future potential, pheromones could become useful and economic tools if requirements were relaxed
4. Macrobials	• Rarely produced and traded (by local companies); mainly used by government programmes • Most ASEAN countries do not regulate marobials; import and release covered by international guidelines (e.g. FAO)

Source for regulatory guidelines development Special data recommended for improvement of regulatory management of BCA by expert panels (e.g. REBEKA 2007, OECD)	
BCA Category	**Points of Consideration**
Microbials	• More emphasis on existing scientific information than on prescribed tests; non-target safety well documented • Environmental fate and behaviour minor concern in risk assessment of regulatory authorities worldwide • Genetic 'stability' problematic, erase
Macrobials	• Harmonize import and release of non-native species • Harmonize environmental risk assessment (ERA)
Natural Products (here: botanicals)	• Plant extracts complex mixtures, analytical methods should be focusing on active substances or substances of concern • Waiving of data based on history of safe use
Semiochemicals	• Rationales of relaxation of data requirements available; exemption from registration could be considered • Protocols for efficacy testing need to be adapted for semiochemicals (and for other BCA as well)

Issues

- Can the lists in the TCP *Registration Requirement Guidelines* be reduced since they all follow the same pattern?
- Can the 16 lists of the TCP *Biopesticide Guidelines* also be included?
- Registration data requirement in two guidelines were given with different arrangements and information.
- The diversity of data requirement lists may have been confusing and discouraged adoption of the guidelines.
- Registration requirements should encourage safe and effective biological products.
- Registration procedures for non-chemical pest control products should cover all groups.
- Registration requirements may be grouped and simplified.
- Registration requirements that are unique for biological products should be highlighted.

Workshop results

Question 1:

"The regional *Guidelines for Data Requirements for the Registration of Biopesticides* included the following two tables with minimum requirements for botanical and microbial pesticides. Are there reasons why these basic requirements would not be sufficient to verify …

- a satisfactory level of effectiveness against target pests
- adequate safety toward humans
- that the product causes no damage to the environment?"

I. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF BOTANICAL PESTICIDES (page 196 in the Guidance book)

Sl. No.	Particulars	Formulation Regular Registration	
		Group 1	Group 2
A. BIOLOGICIAL CHARACTERISTICS AND CHEMISTRY			
1.	Systemic name (genus and species)	R	R
1.1.	Strain name	NR	NR
2.	Common name	R	R
3.	Source of origin	R	R
4.	Specification of the product	R	R
5.	Composition of the product	R	R
6.	Manufacturing process	R	R
7.	Test procedures and criteria for identification	NR[2]	NR
8.	Method of analysis/biological assay	R[2]	R
9.	Contaminants	NR[3]	R
10.	Shelf life claim	R	R
11.	A sample for verification (or 3rd-party analysis)	R	R
B. BIO-EFFICACY			
12.	Field studies	R	R
13.	Lab. studies	R	NR
C. TOXICITY(non-target/human safety)**			
14.	For mother culture	NR	NR
15.	For formulation	R[4]	R
16.	For formulated products directly manufactured (mammalian toxicity)		NR
17.	Environment safety testing	NR[5]	NR
D. PROCESSING, PACKAGING AND LABELLING			
18.	Manufacturing process/process of formulation	R	R
19.	Labels and leaflets	R	R

Please mention, any other data required/not required besides above in your country:

	Residue data	R

Abbreviations: R = Required; NR = Not required ** Except parts or extract of neem including azadiractin

Comments from Group 1:

Most of the countries agreed with most options listed above as minimum requirement for registration, with different opinions listed bellow:

1. Siri Lanka don't need the manufacture process data.
2. We think the 7th and 8th option should be combined because the method of analysis is mainly based on the test procedures and criteria, and the data requirement depends on the country if they can carry out such analysis.
3. For the need of contaminants, we think it depends on the products.
4. For 15th and 16th option, we also think it should be combined, and required
5. For the environment safety testing, our opinion is that it should mainly focus on the ecotoxicity, toxicity to non-target bios, such as toxicity to bee and fish.
6. We suggest residue data should be taken into account and required.

Comments from Group 2:

4. Common name – need verification is this for active or source plant
8. Contaminant – required e.g. content of heavy metals
11. Sample for analysis or 3rd part analysis
13. Lab studies – NR

II. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PESTICIDES (page 199 in the Guidance book)

Sl. No.	Group 1 Particulars	Regular Registration	
		Group 1	Group 2
A. BIOLOGICIAL CHARACTERISTICS AND CHEMISTRY			
1.	Systemic name (genus and species)	R	R
1.1.	Strain name	R	R
2.	Common name	R	R
3.	Source of origin	R	R
4.	Specification of the product	R	R
5.	Composition of the product	R	R
6.	Manufacturing process	R	R
7.	Test procedures and criteria for identification	R	NR
8.	Method of analysis/Biological assay		R
9.	Contaminants	R	R
10.	Shelf life claim	R	R
11.	A sample for verification	R	R
B. BIO-EFFICACY			
12.	Field studies	R	R
13.	Lab. studies	R	NR
C. TOXICITY**			
14.	For mother culture	R	NR
15.	For formulation	R	R
16.	For formulated products to be directly manufactured (mammalian toxicity)		NR
17.	Environment safety testing	R	R
D. PROCESSING, PACKAGING AND LABELLING			
18.	Manufacturing process/process of formulation	R	R
19.	Labels and leaflets	R	R

Abbreviations: R = Required; NR = Not required

** Except *Bacillus thuringiensis aizawai, Bacillus thuringiensis kurstaki,* Nuclear Polyhedrosis Virus (NPV), Nematode of *Steinernema* spp. (*Neoaplectana* spp.) and *Heterorhabditis* spp.

Comments from Group 1:

As the results with the botanical pesticides, we also agree with most of the options listed above, and we do have some different opinions:

1. We think the 'Source of origin' data should be required.
2. We think the 7th and 8th option should be combined because the method of analysis is mainly based on the test procedures and criteria, and the data requirement depends on the country if they can carry out such analysis.
3. For the bio-efficacy options, we think that a worldwide literature research report should be submitted.
4. For toxicity options, our opinion is that toxicity data for mother culture should required, and toxicity data for formulation should be required in case of toxic additives exist in the formulation.
5. For the environment safety testing, our opinion is that it should mainly focus on the ecotoxicity, toxicity to non-target bios, such as toxicity to bee and fish.

Comments from Group 2:

4. Source of origin – Required
13. Lab studies – NR
16. Formulated product to be manufactured – NR

Question 3:

"Make suggestions, which tests would be appropriate for bio-efficacy and toxicity?"

Group 2

Bio-efficacy	**Toxicity**
Botanical & Botanical	For formulated product
Mode of action Crop and pest controlled Application rate Phytotoxity Effect on beneficial organism and non-target organism	Follow tier approach Min Req: LD50 – oral/dermal/inhalation irritation hypersensitivity cellular immune response

Conclusions

Botanical Pesticides (number of data requirements)

Folder		**Required**	**More discussions**
A	Identity	9	1
B	Toxicity	1	1
C	Bio-efficacy	1	1
D	Residue	0	1
E	Health/Environment	0	0
F	Labelling/Storage	2	0
	Total	13	3
	Percent of total	81%	19%

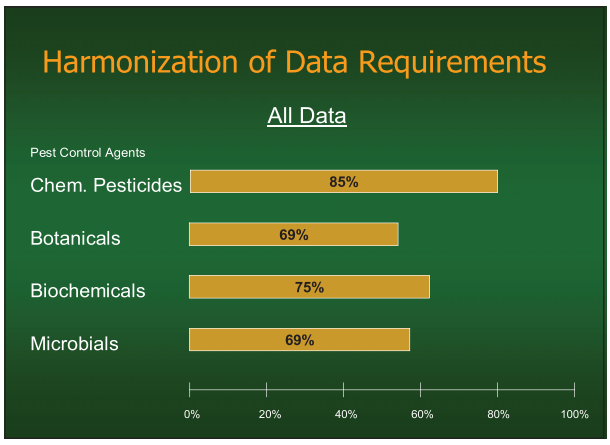
Microbial pest control agents (number of data requirements)

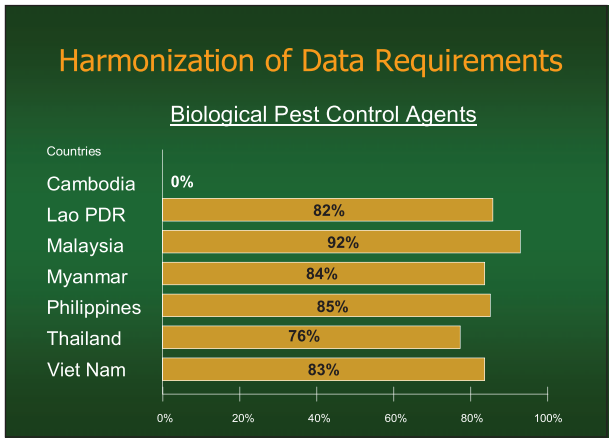
Folder		Required	More discussions
A	Identity	11	1
B	Toxicity	1	1
C	Bio-efficacy	1	1
D	Residue	0	0
E	Health/Environment	1	0
F	Labelling/Storage	2	0
	Total	16	3
	Percent of total	80%	15%

SUMMARY

All countries except Cambodia register biological pest control agents. However, some countries may lack the expertise and experience required to evaluate these products and therefore treat them the same way as chemical pesticides, even though their characteristics and mode of actions are fundamentally different. Most countries require the same registration folders for biological pest control agents as for chemical pesticides. Only three countries required fewer folders, sometimes exempting *bio-efficacy*, *residue* or *human health/environmental fate* data requirements. Thailand does not require toxicity data for biochemical pest control agents since – by definition – these products have a non-toxic mode of action.

The TCP project provided various lists of data requirements in two different guidelines. With regard to the recommendations in the *Guidelines for harmonization of pesticide registration requirements*, the level of harmonization was noticeably lower for biological pest control agents (69%–75%) as compared to chemical pesticides (85%). This indicates a higher level of uncertainty about registration requirements for these products. In those countries that register biological pesticides, the data requirements ranged from 76 percent to 92 percent of the recommended items.





At the Chiang Mai workshop, the workshop participants reviewed two lists of data requirements for botanical and microbial pesticides and agreed on the minimum set of data. Out of 20 registration data requirements, only 3-4 items would need further harmonization discussions, as well as details with regard to test specifications.

With these two lists, countries in Southeast Asia have a starting point to revise their data requirements in a harmonized manner, even though some issues will need further discussions.

2.5 STATUS OF HARMONIZATION OF TECHNICAL EVALUATION
(efficacy, residues, ecotoxicology, risk assessment, label)

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

The responsible authority should take the following evaluation steps:

- Verification of authenticity
- Completeness check
- Waiving request
- Assessment of data quality
- Assessment of registration status in other countries
- Assessment of all technical data
- Risk assessment
- Relevance of data

- The registration dossier should be submitted to qualified experts in relevant fields, including efficacy, human health and environmental effects for technical evaluation of data.
- These experts could either be part of the responsible authority or experts from academia or research institutions.
- Any registration procedure should include evaluation of the potential risks related to the use of the pesticide for which registration is sought.

Mutual acceptance of data

- If relevant data of good quality have been generated in other countries, the responsible authority may waive the requirement for local data generation.
- This is particularly relevant for efficacy trials, residue data and environmental field studies, all of which likely require the involvement of national (public) research institutions.

Efficacy

- Countries should fully evaluate pesticide efficacy, behaviour, fate, hazard and risk with regard to the various anticipated conditions of use in their country.
- Efficacy data generated in another country that has similar ecological or epidemiological conditions should be accepted, whenever relevant.
- Efficacy assessment does not always necessarily involve local trials. In some cases it may suffice to review the results of trials conducted in neighbouring countries that have equal agro-ecological conditions and the same pest species.

Residue Assessment

- The use of maximum residue limits defined by the *Codex Alimentarius* is recommended whenever applicable to the national situation.
- Residue assessments do not always need to be based on local residue trials, however. In some cases it may suffice to review the results of trials conducted in other countries on similar crops, using relevant agricultural practices under comparable climatic conditions.
- Applicants should also make an assessment of human health and environmental risks under the conditions the pesticide is proposed to be used and provide it to the responsible authority for evaluation.
- Ecotoxicological profile of the product based on toxicity to aquatic and terrestrial organisms as appropriate to the intended use, and information of persistence and bioaccumulation is also necessary.
- *Risk assessment:* The responsible authority should ensure that the risks of using the pesticide according to the proposed label are acceptable.

- *Hazard assessments* are generally applicable globally and are available from published sources.
- The registration system may also incorporate innovative approaches that can contribute to risk reduction and greater efficiency in the registration process, such as comparative risk assessment.

Label evaluation

- Draft labels submitted by applicants should be evaluated based on the requirements and criteria set for registration and should include clear information on the permitted use of the product, dosage and other use recommendations, warning and precautionary statements and description of required personal protection, hazard class, warning statement against the reuse of containers, and instructions on safe disposal or decontamination of empty containers.
- The responsible authority should also ensure that the approved labels are written in the major language(s) of the country and also include the registration number, lot or batch number, warning and precautionary statements, date of release of lot (month and year).

Regional recommendations

Guidelines for Preparation of Efficacy Test Protocols

- Adoption of the guidelines and the new test protocols
- Review of existing test protocols in the countries to bring them in line with international/ harmonized guidelines
- Capacity building for staff conducting efficacy tests
- Sharing of bio-efficacy results among countries in the region

Guidelines for Harmonization of Pesticide Labelling

- Labels should include all elements proposed in the guidelines
- All labels in the region should be similar except for the language
- Training should be given on how to design a good label

Risk Assessment Requirements

- There should be more emphasis on evaluating the toxicology data submitted to the agency by trained (internal or external) toxicologists.
- Start mandatory requirement of toxicology data
- Develop guidelines for using hazard data in pesticide risk assessment based on exposure scenarios. External experts may be used to develop this guidance.

Issues

- While requirements, procedures and standards are largely harmonized, there are considerable differences between the countries with regard to the evaluation capacities.
- Since the evaluation of the dossiers is particularly resource intensive, implementation is country specific and harmonization may be difficult to achieve.
- Standards for efficacy testing of chemical pesticides vary widely, even though they could be easily harmonized.
- Evaluation criteria for non-chemical pesticides are largely unavailable.
- There are differences in the required information, symbols, warning statements and color bands on the labels between the countries.

Workshop results

Question 1:

"Which difficulties are faced by a regulatory agency for the evaluation of chemical pesticides? What can be done to overcome these difficulties?"

Group 1

No.	Issues pertaining to evaluation	Proposed solutions
1.	Delayed evaluation due to • Lack of trained evaluators in toxicology/insufficient trained manpower to conduct evaluation • Lack of coordination among agencies • Lack of resources i.e. field plots availability, manpower to conduct field trials within product life cycle in cases whereby the agency conducts field trials for companies	• Send for training • Single agency/inter-agency coordination mechanism • Policy change to allow contract field trials/overseas trials
2.	Difficulty in complying to international guidelines due to lack of resources	Require establishment of internal guidelines/standards

Group 2: TCP-pesticide project countries (ASEAN)

- verification in laboratory
- toxicological evaluation

Question 2:

"Make a list or resources that are available to assist in with the evaluation of dossiers and conduct a survey among the group to what extent these are being used."

Group 1	**Bangladesh**	**China**	**Indonesia**	**Japan**	**Korea, DPR**	**Nepal**	**Pakistan**	**Singapore**	**Sri Lanka**
JMPR (Joint Meeting on Pesticide Residues) evaluation report	Y	Y	–	Y	Y	–	–	Y	Y
FAO/OECD/UN/WHO specifications/guidelines	Y	Y	Y	Y	Y	Y	Y	Y	Y
EPA evaluation reports	Y	Y	Y	Y	Y	–	Y	Y	Y
WHOPES	Y	Y	Y	Y	Y	–	Y	Y	Y
EFSA evaluation reports	Y	Y	Y	Y	Y	–	Y	Y	–
IARC (Int'l Agrochemical Research Council)	Y	Y	Y	Y	Y	–	Y	Y	–
Codex Alimentarius Commission	Y	Y	Y	Y	Y	Y	Y	Y	Y

Group 2: TCP-pesticide project countries (ASEAN)	**Cambodia**	**Lao PDR**	**Malaysia**	**Myanmar**	**Philippines**	**Thailand**	**Viet Nam**
Capacity building for verification of laboratory analysis	Y	Y	N	N	Y	N	Y
Capacity building for toxicology evaluation	Y	Y	Y	Y	Y	Y	Y
Bio-efficacy trial only location data	Y			Y	Y		Y
Two small local trial for certain crops			Y				
Accept bio-efficacy data from other counties trial			Y			Y	
MRLs values from Codex and ASEAN	Y	Y	Y	Y	Y	Y	Y
Personnel							
Registration staff	7	5	35	29	7	9	8

SUMMARY

Data evaluation process

Most countries in the survey evaluate the application dossiers and follow more or less the same procedure. They have written internal evaluation criteria and require data to be generated according to international standards. They also reportedly verify analytical methods and test protocols. However, this applies only to chemical pesticides; evaluation criteria specific for biological pest control agents have not been defined in many countries.

Since all countries basically carry out the same evaluations of the same data, there would be a lot of overlap and duplications which could be overcome with more international work sharing and standardization. For example, countries could accept standard evaluation reports and monographs for agricultural pesticides in the same way they accept the WHOPES evaluations for public health products. However, this is not yet general practice and data submission and evaluation reports in the OECD standard are only accepted by about half the countries.

Creating a regional database of technical data evaluations would be a helpful step toward regional harmonization. Of the TCP harmonization guidelines, four countries reportedly adopted the new efficacy test protocols and risk assessment guidelines, but this is only a small step toward a regional standard for the evaluation of dossiers.

While the evaluation of technical data on pesticide hazard, toxicity or bio-efficacy could be standardized and shared, assessing the risk of a pesticide under local conditions can only been done by the national authorities. For this reason, training in assessing the local risks while using internationally available data would seem a fitting measure. Particularly the evaluation and assessment of biological pest control agents would be a great opportunity for regional cooperation towards establishing regional standards and for strengthening the data evaluation process.

Evaluation capacity

Even though all countries register pesticides, their human and technical resources to evaluate the dossiers differ considerably. About four national agencies appear adequately staffed, but six countries have fewer than 5 registration officers. Considering the number of registrations and their validity periods, each registration officer in three countries would have to process more than 500 registrations or re-registrations each year. Obviously, this does not allow for a proper evaluation of the application dossiers. In addition, about half the countries do not have personnel trained in risk or ecotoxicology assessment, nor do they have adequate laboratory capacity to verify the quality of pesticides. Lack of personnel for toxicity evaluation and even for field trials was mentioned in the survey and at the workshop as one of the major constraints. Thus many countries apparently do not have an adequate capacity to evaluate the data which they require from the applicants. In such cases, international resources could help the national authorities with the evaluation of the dossiers. For those countries with limited resources, it would seem appropriate to accept data generated from other countries in the region instead of insisting on local trial. However, often there are other than scientific reasons why locally generated data are required.

While there are many similarities in the general procedures of data evaluation, there are also marked differences in some of the specific technical evaluations:

Quality assessment

Almost all countries require pesticides to conform to FAO/WHO specification, but their ability to verify the quality of the application product depends on the available laboratory capacity. Six countries appear to have quality control laboratories with sufficient instrumentation. Other countries would have to accept analysis reports from independent laboratories.

Bio-efficacy assessment

There are substantial differences in the number of required field trials (1-10) and growing seasons (1 to >3), indicating significantly different quality standards in the region. The majority of the countries require efficacy trials to be carried out locally. In Southeast Asia, only Malaysia and Thailand also accept bio-efficacy data from other countries.

The TCP project issued guidelines for the preparation of efficacy test protocols. However, only two countries have modified their existing test protocols in line with the new standards. Even if countries adopt FAO and TCP efficacy trial protocols, it would seem equally important to apply the same number of trials to allow for a comparative interpretation of the results and the creation of a regional data base.

Residue assessment

Almost all countries require that the generation of residue data follows the relevant FAO manuals. All countries use the MRLs defined by the *Codex Alimentarius*. While half the countries require residue trials to be conducted in the country, they also accept results from trials conducted in other countries under similar conditions. However, there is not yet a consensus among the countries, which residue studies should be required for chemical pesticides (see section 2.4).

Risk assessment

Even though most countries require health and environmental studies, only half have issued internal guidelines and evaluation criteria for assessing health and environmental risks, and six countries have guidelines for carrying out a risk-benefit analysis. Ten countries assess the risk to consumers, while only eight countries consider occupational and environmental risks. Although most countries have access to a toxicologist or medical doctor within or outside the national authority, three countries indicated that they had no such person involved in the review of the application dossiers.

Label evaluation

The evaluation of label information is probably the most harmonized aspect of dossier evaluation. All but one country have written internal guidelines and evaluation criteria, and require labels to follow the *FAO guidelines on good labeling practices* (1995). Even though only two countries adopted the new TCP guidelines, five countries indicated that they require the recommended contents. In 2011, however, none of the countries had all the label information as listed in the guidelines.

In 2005, a new international labelling standard was introduced, the *Globally Harmonized System for Classification and Labelling* (GHS); until now, only six countries reported that they adopted the system, but it could not be determined, whether it also has been fully implemented. To require labels according to the GHS standard would be an important next step in the regional harmonization efforts.

2.6 STATUS OF HARMONIZATION OF REGISTRATION AND LICENSING

(registration options, validity period, banned and restricted pesticides, re-registration, international treaties)

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

- The pesticide board will take the final decision on the registration of the pesticide, taking into account the review prepared by the responsible authority, and possibly the outcome of the public review procedure.
- The decision of the pesticide board may be provisional or full registration, with or without restrictions and/or conditions, or refusal. The board may also decide to suspend a decision, and request further data or assessments to be provided.
- Use of a pesticide is generally approved only for specific applications. These approved purposes should be incorporated in the registration decision.
- The responsible authority, in addition to publishing and making available to the public, a list of registered pesticides, should also provide a list of banned or severely restricted pesticides.
- The purpose of a list of banned pesticides is to indicate that certain pesticides will not be considered for registration.
- The purpose of severely restricting pesticides is to keep certain pesticides available for very specific purposes, only to be handled by specialists, while acknowledging that hazards are such that they should not be freely available.
- Governments should establish a re-registration procedure to ensure periodic review of active ingredients and formulated pesticide products.
- In addition, there should be a possibility of unscheduled review if new information warrants such a review, thus allowing for prompt and effective measures to be taken in response to
  - (i) concerns based on data and information from post-registration monitoring of the real situation in practical use and from other sources,
  - (ii) new scientific insights about the hazard of products to human health or the environment,
  - (iii) regulatory action taken in other countries regarding the permitted use or permitted residue levels, and
  - (iv) inclusion in relevant annexes of the Rotterdam and Stockholm Conventions.
- For Parties to the Rotterdam Convention, the responsible authority should inform the designated national authority of the Convention (if it is not itself that authority) of any final regulatory action it has taken to prohibit or severely restrict the use of a pesticide.

Issues

- There are different administrative set ups for making the registration decision.
- There are many registration options which differ from country to country.
- There are only few registrations for non-chemical pest control agents.
- There are large differences in the number and types of banned/restricted pesticides.
- Many countries are slow with meeting their obligations under international treaties.

Workshop results

Question 1:

"Who should take registration or licensing decisions (registration agency or an independent pesticide board)? Discussion of advantages and disadvantages, and recommendations."

Group 1

Decision maker	Advantages	Disadvantages
Registration agency* (Regulatory agency)	• Oversight from registration to monitoring & enforcement. • Legislative empowerment (?)	
Independent Pesticide Board*	• Multi-disciplinary oversight (including industry) • External stakeholders engagement	*No follow-up on monitoring/ enforcement*
Recommendations	For the registration agency to make the decision	

* With or without Technical Panel

Group 2

TCP-pesticide project countries (ASEAN)	**Cambodia**	**Lao PDR**	**Malaysia**	**Myanmar**	**Philippines**	**Thailand**	**Viet Nam**
Registration/licensing agency	**RC**	**RC**	**PB**	**PB**	**RC**	**SC (5)**	**RC**

PB = Pesticide Board; RC = Registration Committee; SC = Scientific Committees

Advantage of Registration Committee

- follow government policy
- Technical expert

Disadvantage

- Long time to decide
- No public review/stakeholder consultation/comments
- Registration committee
- Public review/stakeholder consultation

Question 2:

"Should other registration options (e.g. provisional, supplementary, emergency) be harmonized? If so, what should be the criteria (validity period, data requirements, etc.)?"

Group 1:

No! Before the registration options are to be considered for harmonization, the terminology for options i.e. understanding of provisional, supplementary, emergency, temporary, conditional, etc. should first be harmonized. Main priority now should be to harmonize the data requirements for full registration.

Group 2

TCP-pesticide project countries (ASEAN)	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
Supplementary (me-too) registration	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Criteria Agreement between two company Sample and data from originator Originator to notify when agreement terminate Advantage Same product, same a.i., formulation and concentration							
Experimental Use Permit	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Criteria Registration data from originator Efficacy test protocol							

Question 3:

"How can the implementation of international treaties and the banning/restricting of pesticides be further strengthened and harmonized?"

Group 1:

Impossible task. Clearer and simplified rationale for implementation of international treaties and banning/restriction of certain pesticides to reduce reservations by countries.

Group 2: TCP-pesticide project countries (ASEAN):

Each country makes its own decision to register or ban.

SUMMARY

Registration process

While it is recommended that the decision to register a pesticide should be taken by an independent Pesticide Board, this only occurs in a few countries. The more widely practiced procedure is for a registration committee of the responsible authority to decide on the registration of a pesticide. Almost all countries have technical committees supporting the process. Harmonizing the decision making would require fundamental changes in the pesticide law of some countries.

There are great differences among the countries with regard to the types of registrations issued. Only the full registration is granted consistently in all countries. Other registration options such as provisional, experimental use or supplementary registrations are not issued everywhere and therefore cannot yet be harmonized. However, a consensus would be desirable with regard to the actions after a registration expires; presently, some countries require a full re-registration procedure, while others simply renew the license against the payment of a registration fee.

There are also unusually great differences with regard in the length of the validity and data protection periods. Provisional registrations are valid from 1 to 5 years, while full registrations vary from 2 years to unlimited. Data protection period vary from 2 to 20 years. These differences indicate fundamentally different policies and approaches toward registration.

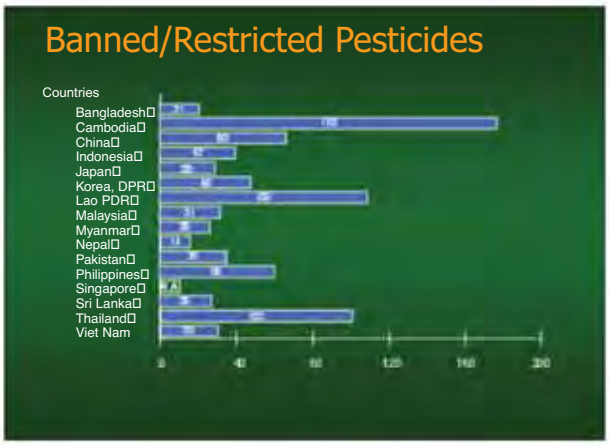
Registered pesticides

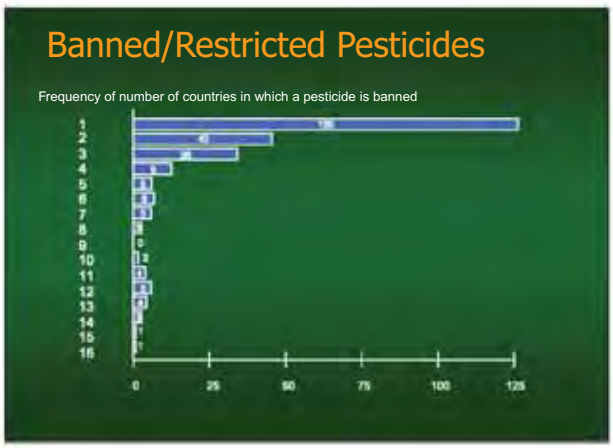
The number of pesticide registrations ranges from 73 to more than 20 000 products. Such a large difference cannot be explained by country-specific needs and obviously different registration strategies and philosophies are applied. The average number of registrations was more than 3 000 products. A large number of registrations would indicate that many identical products are registered under different licenses. This would lead to duplications of the registration data review. Furthermore, multiple registrations for identical products would probably also confuse the user and make it more difficult to make informed decisions.

Almost all registered pesticides in the region are chemical pesticides. Only 1 percent of the registrations are for biological products. While most countries have policies toward less toxic and more environmentally friendly pest control options, their registration systems still seem to be biased toward chemical pesticides and discourage the registration of non-chemical pest control agents. One reasons may be that many agencies simply lack the expertise to evaluate biological products and treat them the same way as chemical pesticides.

Banned or restricted pesticides

There are great differences among the countries with regard to the number of banned or restricted pesticides which ranged from 10 to 170 active ingredients. Such huge differences indicate fundamentally different approaches to regulating highly hazardous products.





While international treaties have identified about 40 undesirable products, there are more than 240 pesticides that are banned or restricted in one country or another. Only 24 chemicals have been restricted in more than half the countries. Only one pesticide, DDT, is banned or restricted in all 16 survey countries. However, the actual number of region-wide regulated products may be higher since some pesticides may have never been registered or formally banned. For example, a number of countries did not list pesticides such as Aldrin, Chlordane or Toxaphene, but it is unlikely that they still use these products.

Surprisingly, more than half the pesticides listed in Annex 2 are only banned or restricted in a single country. Thus it appears that country-specific factors are behind these restrictions and therefore would not be suitable for a regional harmonization. Only pesticides that are included in international treaties should be targeted for regional harmonization and monitored in follow-up surveys.

International treaties

While most countries have joined the international treaties related to pesticides, four countries still have to join the Rotterdam Convention, two the Stockholm Convention and one the Basel Convention. However, not all countries that have joined a treaty are already fully implementing its provisions. About half the countries reported that they need more efforts to fully comply with the treaties they have signed. No country has reported to have restricted all pesticides under the Stockholm and Rotterdam Conventions. Only three countries have notified the secretariat of the Rotterdam Convention of final regulatory actions (FRA) or notifications of PIC procedures. Only two countries have reported on the observance of the Code of Conduct.

Of the 15 pesticides listed under the Stockholm Convention as persistent organic pollutant (POP), the survey showed that most have been banned or restricted pesticides by the majority of the countries. However, only two countries reported 100 percent observance; the average level of compliance was 68 percent. It should be noted that some chemicals may not have been reported because they are obsolete or were never used as pesticides (e.g. Pentachlorobenzene), and therefore the list may not give the full picture.

List of banned or restricted Persistent Organic Pollutants under the Stockholm Convention

	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	
Aldrin		■	■	■	■	■	■	■	■	■		■	■	■	■	■	14
Chlordane	■	■		■	■	■	■	■	■	■		■	■	■	■	■	14
Chlordecone				■	■					■					■		5
DDT	■	■	■	■	■	■	■	■	▒	■	■	▒	■	■	■	■	16
Dieldrin	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	15
Endosulfan		■		■	■	■	■	■		■	■	▒		■	▒	■	12
Endrin		■		■	■	■	■		■	■	■	■	■	■	■	■	13
α-HCH	■	■		■	■	■	■	■	■	■	■	■		■	■	■	14
β-HCH	■	■		■	■	■	■	■	■	■	■	■		■	■	■	14
Heptachlor	■	■		■	■	■	■	■		■	■	■	■	■	■	■	14
Hexachlorobenzene HCB		■	■		■	■		■	■	■		■	■		■	■	10
Lindane (gamma-HCH)		■		■	■	■	■	■	■	■		▒		■	■	■	11
Mirex		■		■	■	■			■	■		■	■		■		8
Pentachlorobenzene (PeCB)				■	■				■	■							3
Toxaphene				■	■	■	■	■	■	■	■	■	■		■	■	12
15	6	13	4	14	15	13	11	11	8	15	7	13	9	10	14	12	190

■ = Banned ▒ = Restricted

With regard to the pesticides regulated under the Rotterdam Convention, only one country has banned or restricted all products and five countries have taken action against more than two-third of the chemicals. Still, more than half the countries have not reported regulatory action against 12 of the 28 chemicals.

While region-wide ratification of the treaty would be the first harmonization goal, full compliance with the treaty appears to be a much longer and more difficult process.

List of banned or restricted pesticides under the Rotterdam Convention

List of PIC pesticides	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	Total countries
2, 4, 5-T and its salts and esters	■	■		■	■	■	■	■	■			■		■	■	■	12
Alachlor		□				■											2
Aldicarb		■		■		■						□		■			5
Aldrin		■	■	■	■	■	■	■	■	■		■	■	■	■	■	14
Binapacryl		■				■	■	■			■				■		6
Captafol		■		■	■	■	■	■	■		■			■	■	■	11
Chlordane	■	■		■	■	■	■	■	■	■		■	■	■	■	■	14
Chlordimeform		■	■	■		■	■	■	■		■	■		■	■	■	12
Chlorobenzilate						■	■	■			■	□			■		6
DDT	■	■	■	■	■	■	■	■	□	■	■	□	■	■	■	■	16
Dieldrin	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	15
Dinoseb and its salts and esters		■		■		■	■	■	■						■		7
Dinitro-ortho-cresol (DNOC) and its salts		■				■		■							■		4
EDB				■		■	■	■	■			■			■		7
Endosulfan		■		■	■	■	■	■		■	■	□		■	□	■	12
Ethylene dichloride		■				■		■			■				■		5
Ethylene oxide		■				■	■	■							■		5
Fluoroacetamide		■	■			■	■	■							■		6
HCH/BHC (mixed isomers)	■	■		■		■	■	■	■	■	■	■		■	■	■	13
Heptachior	■	■		■	■	■	■	■		■	■	■	■	■	■	■	14
Hexachlorobenzene HCB		■	■		■	■	■	■		■		■	■		■	■	10
Lindane (gamma-HCH)		■		■	■	■	■	■		■			□	■	■	■	11
Mercury compound (Hg), fungicides		■	■	■	■	■	■	■	■	■	■	■		■	■	■	14
Monocrotophos	■	■	■			■	■	■	■	■	■	□		□	■	■	13
Parathion		■	■		■	■	■	■	■			■		■	■	■	11
Pentachlorophenol/PCP and its salts and esters		■		■	■	■		■			■	□		■	■	■	9
Toxaphene				■	■	■	■	■	■	■	■	■	■		■	■	12
27	7	24	9	17	14	27	21	25	14	12	12	19	7	16	25	17	0

■ = Banned □ = Restricted

2.7 STATUS OF HARMONIZATION OF POST-REGISTRATION ACTIVITIES
(enforcement, monitoring, information exchange)

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

- Governments should make provision for effective monitoring and enforcement of pesticide regulations, including the establishment of licensing and inspection schemes for importers and retailers.
- Pesticide registration may be placed under one ministry, while the responsible authority for other pesticide regulatory tasks (e.g. licensing, inspection, enforcement) are under one or more other government ministries.
- A pesticide registration scheme should also include an effective post-registration monitoring and evaluation programme, as it plays a very important role in ensuring that the main objective of registration to prevent unacceptable risk to human health and the environment is achieved.
- It involves follow-up monitoring activities to assess whether the registered product is used for the approved purposes and is properly handled, distributed and of good quality. Post-registration monitoring should also provide information on the occurrence of any adverse effects on human health or the environment, inadequate efficacy, resistance development or non-compliance with maximum residue limits.
- It provides a means of measuring the validity of predictions, based on registration data, regarding human and environmental safety and efficacy of a particular pesticide.

The pesticide register should contain

- the trade name/trade mark/commercial name of the product,
- the registration number,
- the name of the active ingredients and their concentrations,
- the authorized uses,
- the name of the registrant and the period of registration.

Other information including the following may also be included:

- the label instructions
- conditions of use,
- possible restrictions to certain types of users,
- classification and all other relevant information.

Regional recommendations

Guidelines for Pesticide Residue Monitoring

- Countries with an established residue monitoring system should provide assistance to those countries that are in the process of building one
- Countries should use same extraction and clean-up methods and sensitive analytical instruments such as LC-MS
- Training programmes should be offered to upgrade the skills of laboratory and field staff

Recommendations for Information Exchange on Pesticide Regulatory Matters

- Establish specific legislation and regulations for information exchange
- Designate responsible authority
- Develop national information management system
- Provide training in information exchange
- Establish a regional internet portal and pesticide database
- Adopt harmonized formats for information exchange

Issues

- Some countries have insufficient capacities for pesticide monitoring, enforcement and information exchange.
- Some TCP-pesticide project countries (ASEAN) have residue monitoring systems, but not according to guidelines; are guidelines too demanding?
- Even though most countries reported to have published lists, they could not share them.
- The harmonized information exchange formats may have been too complicated to be followed.
- If registration could be simplified, more resources could be made available for post-registration activities.

Workshop results

Question 1:

"For a country with limited resources, which post-registration activities should have priority? Why?"

Group 1

No.	Post-registration activities	Priority	Reason(s)
1.	Monitoring of Quality	1	Effective products for crop production, low cost, etc.
2.	Monitoring of Food Residues	5	Ensure food safety
3.	Monitoring of Feed Residues		
4.	Monitoring of poisoning cases	4	Ensure human safety
5.	Monitoring of Environment		
6.	Collecting pesticide data – import, export, manufacture		For trending/statistics
7.	Farm inspection Monitoring of use Monitoring of un-registered pesticides Monitoring of disposal of containers	3	Ensure proper usage on farm
8.	Inspection of retail shops – license for sale, shelf life, labels, packaging, adulteration, etc.	2	Ensure sales of registered pesticides
9.	Training of pesticide operators/retailers/farmers	6	Ensure proper usage and operator safety

Group 2: TCP-pesticide project countries (ASEAN)

Priorities:

1. Poisoning report – the status of poisoning, follow up with the review of pesticide or the check on manufacturer (low quality)
2. Information exchange – registered pesticides, trade volume, lists of banned/restricted pesticide, MRLs
3. Quality monitoring – market sampling
4. Residue monitoring – food safety and review of pesticides

Question 2:

"What aspects of post-registration activities could be regionally harmonized and what would be the benefit?"

Group 1

No.	Post-registration activities	Regional	Country	Benefits
1.	Monitoring of Quality	Y		Consistency
2.	Monitoring of Food Residues		Y	
3.	Monitoring of Feed Residues		Y	
4.	Monitoring of poisoning cases		Y	
5.	Monitoring of Environment		Y	
6.	Collecting pesticide data – import, export, manufacture	Y		For ease of information exchange
7.	Farm inspection Monitoring of use Monitoring of un-registered pesticides Monitoring of disposal of containers		Y	
8.	Inspection of retail shops – license for sale, shelf life, labels, packaging, adulteration, etc.		Y	
9.	Training of pesticide operators		Y	

Group 2: TCP-pesticide project countries (ASEAN)
Harmonized on poisoning – same data base for ASEAN
Information exchange – same data base for ASEAN

Question 3:

"What aspects of post-registration activities are always country-specific and cannot be harmonized?"

Group 1

Refer to table above

Group 2: TCP-pesticide project countries (ASEAN)
Residue monitoring
Quality monitoring
Information exchange – trade volume
Environment monitoring

Question 4:

"Which post-registration activities are low-cost and would require little resources?"

Group 1

No.	Post-registration activities	Low cost
1.	Monitoring of Quality	6
2.	Monitoring of Food Residues	8
3.	Monitoring of Feed Residues	8
4.	Monitoring of poisoning cases	1
5.	Monitoring of Environment	7
6.	Collecting pesticide data – import, export, manufacture	3
7.	Farm inspection Monitoring of use Monitoring of un-registered pesticides Monitoring of disposal of containers	4
8.	Inspection of retail shops – license for sale, shelf life, labels, packaging, adulteration, etc.	2
9.	Training of pesticide operators/retailers/farmers	5

SUMMARY

Even though post-registration monitoring is an important part of a pesticide registration scheme, its implementation is largely country-specific and depends on the available resources. With the exception of regional information exchange and the use of international analytical standards and procedures, most post-registration activities would not offer themselves for regional harmonization.

While the monitoring of pesticides requires sophisticated laboratories and expensive equipment, other activities such as the monitoring of poisoning cases and pesticide use practices could be carried out at relatively low cost and would provide valuable information to the registration authority. However, only five countries reported that they fully monitor poisoning cases, and the same number of countries could provide complete information about pesticide trade and domestic use for the survey.

Only with adequate monitoring and enforcement capacities can a country's pesticide management system properly function and prevent to users, customers and the environment.

Quality monitoring

The sale of adulterated and sub-standard pesticides is a problem in many Asian countries and would be an important aspect of post-registration monitoring. About half the countries reported that they adequately monitor the quality of pesticides in the market, but only 4-5 countries have sufficient laboratory equipment and personnel to carry out such routine surveillance.

A country with limited resources could overcome its constraints by systematically collecting reports about sub-standard and ineffective pesticides. Even though such information could not be used for prosecution, it would provide valuable information about the status of pesticide quality in the country and could pin-point problems for further, more detailed investigations.

Residue monitoring

Most countries have laboratories for residue analysis, but not more than half have sufficient equipment and personnel to carry out systematic monitoring. While eleven countries reported to have set up a system for monitoring residues in food, only six countries rated it as fully functional. Six countries also monitor residues in the environment, and four countries in feed.

In Southeast Asia, four of the seven countries analyze more than 1 000 samples per year. Considering that more than 95 percent of the samples are generally found not to exceed the MRL, very large numbers of samples are needed to obtain a representative assessment of the residue situation. The effectiveness of the monitoring could be enhanced by more targeted sampling and profound knowledge of the pesticide use patterns and practices in the country, as well as poisoning information.

Enforcement

Enforcing a country's laws and regulations is largely an internal matter and only few aspects may be regionally harmonized. While most countries have internal enforcement procedures, only about half the countries indicated an adequate number of staff to carry out the tasks. In some countries, there is only one enforcement officer per more than 10 000 tonnes of pesticide or 10 000 licensed shops. Without sufficient enforcement staff and procedures, a proper pesticide use cannot be guaranteed.

Information management

Information management is largely an internal matter and – except for the regional exchange of information – does not need to be harmonized. The TCP project recommended formats for exchanging of pesticide registers, list of banned or restricted pesticides and other items. However, no country has followed the recommendations in connection with the survey, probably because they were too elaborate and included more information than necessary. While regional information exchange is important in today's world, it must be fully integrated in the internal information management processes so that the information can be easily generated without extra efforts. With today's information technology, this should be easily achievable.

2.8 OPPORTUNITIES FOR ENHANCEMENT OF REGULATORY MANAGEMENT

International recommendations

Code of Conduct Guidelines for Registration of Pesticides (2010)

- Governments should … cooperate with other governments in the establishment of harmonized (regionally or by groups of countries) pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards and, where possible, incorporate these standards into national or regional legislation;
- For countries that have very limited human as well as financial resources, a well implemented regional cooperation scheme is a viable option to assist them in addressing resource constraints.
- It is increasingly recognized that there are advantages to regional cooperation and work sharing in registration as compared to registration on a purely national basis. These advantages include:
  - a stronger expertise base;
  - more efficient use of scarce financial resources (work sharing to improve efficiency and to minimize duplication of work);
  - lower operating cost;
  - less vulnerable to outside pressures;
  - harmonized approach, which will help facilitate implementation and enforcement, and may help combat illegal importation; and
  - broader peer review leading to more robust conclusions and greater uniformity in regulatory decision-making.

Phases registration scheme

- Depending on the resources available, a country should choose the degree of complexity of the registration procedure that suits it best. Countries with limited resources may initially choose a registration scheme requiring less staff or funding.
- As experience is gained with the evaluation of pesticide registration dossiers, expertise and infrastructure will be built up and the scheme can progressively be strengthened and tailored to the specific conditions of use in the country.
- It is generally better to operate a pesticide registration scheme effectively with recognized, but politically accepted, limitations, than to set up a complex system intended to cover all eventualities, which cannot be implemented with the available resources.

Two stages of the pesticide registration process are particularly resource-intensive.

- First, the generation of data for the registration dossier, which is carried out mainly by the applicant but which may also involve public research institutions.
- Second, the evaluation of the dossier, which is primarily done by the pesticide registration body.
- There are various approaches to the phased development of a pesticide registration scheme, which all have their particular advantages and disadvantages. They include, among others:
  - acceptance of registrations in other countries.
  - use of existing risk assessments.
  - mutual acceptance of data.
  - prioritize specific groups of pesticides.
  - prioritize specific protection goals.
  - set up fast-track registration channels.
- *Acceptance of registrations in other countries*. If a pesticide has been authorized in a country with a reputable registration system, the responsible authority may decide to register that same pesticide for the same uses based on only a limited evaluation of the dossier;

- *Use of existing risk assessments*. If risk assessments exist from reputable pesticide registration bodies in other countries or international organizations, the responsible authority may use such assessments as a starting point for the risk evaluation of a pesticide that has been submitted for registration under comparable use conditions. This is sometimes referred to as a "bridging approach" to risk assessment;
- *Mutual acceptance of data*. If relevant data of good quality have been generated in other countries, the responsible authority may waive the requirement for local data generation. This is particularly relevant for efficacy trials, residue data and environmental field studies, all of which likely require the involvement of national (public) research institutions;
- *Prioritize specific groups of pesticides*. In the early stages of development of the registration scheme, the responsible authority may focus on more in-depth evaluation of pesticides which are either likely to be used in high volumes, or by many different groups of users, or on high-value crops that may pose moderate-to-high risk to human health or the environment. This approach would also valuable for the prioritization of pesticides for re-registration;
- *Prioritize specific protection goals*. When evaluating a pesticide for registration, its risk for many groups of non-target organisms (e.g. fish, birds, soil organisms) and several human exposure conditions (e.g. consumer, applicator, worker, bystander) is assessed. In the early stages of development of the registration scheme, the responsible authority may limit data requirements and/or more thorough evaluation to protection goals that are considered high priority for the country;
- *Set up fast-track registration channels*. For certain groups of pesticides, (temporary) fast-track registration channels may be set up, which either limit the data requirements or simplify and shorten the dossier evaluation process. The responsible authority may, for instance, temporarily allow fast-track registration for pesticides that have been used on a large scale in the country, and for a long time, without adverse effects or insufficient efficacy having been reported; for pesticides expected to pose very low risk for minor use products or for active ingredients or products that already have been authorized in the country on another crop or for another use.

OECD VISION:
A GLOBAL APPROACH TO THE REGULATION OF AGRICULTURAL PESTICIDES

OECD's vision is that by the end of 2014, through the co-operation of OECD member countries working with relevant stakeholders–

- the high level of protection afforded to human health, animals and the environment is further enhanced and the levels of risk arising for man, animals and the environment as a consequence of the marketing and use of agricultural pesticides are minimized to the extent possible,
- the regulatory system for agricultural pesticides will have been harmonized to the extent that monographs for pesticides prepared in the OECD format on a national or regional basis (*e.g.* EU or NAFTA) can be used to support independent risk assessments and independent regulatory decisions made in other regions or countries,
- the preparation of data submissions (dossiers) for active substances and for end-use products is co-ordinated globally by industry, to the extent possible, such that opportunities are maximised for work-sharing between the regulatory authorities of OECD member countries,
- work-sharing arrangements between regulatory authorities in OECD countries take place as a matter or routine such that data submissions (dossiers) prepared by industry in the OECD format are accepted in all OECD countries and made available and used globally, notwithstanding the need for supplementary data submissions to address particular local conditions and issues, or country specific legal requirements,

- the generation for each active substance of a single monograph, serving the needs of the regulatory authorities in all OECD countries has become commonplace[1], notwithstanding the need for separate independent risk assessments and separate independent regulatory decisions in each jurisdiction,

OECD's vision in relation to other inter-governmental organizations –

- countries will ensure that the benefits gained through work-sharing and the experiences gained through the work of the OECD Working Group on Pesticides are taken into other relevant international fora (*e.g.* JMPR), thereby facilitating developing countries in the efficient management of their pesticide regulatory systems,
- OECD's vision relates to the regulation of agricultural pesticides. An OECD vision statement on the management of biocidal products may be developed once more experience in international co-operation in their management has been gained and when further progress has been achieved in this area and in the area of work-sharing.

Regional recommendations

Regional guidelines for Harmonization of Pesticide Registration Requirements

Reasons for harmonization

- Address common and regional problems in a harmonized way
- Use similar registration requirements
- Apply similar quality and safety standards
- Share resources
- Lower cost of registration
- Improve trade of agricultural products
- Provide better protection of population and environment against highly hazardous pesticides

Issues:

- There is a middle-way for registration and harmonization; too little or too much could have negative effects.
- Some aspect of pesticide regulatory management are more suitable for regional harmonization than others.
- A harmonized system is only as strong as its weakest members.
- More regional cooperation may free resources that could be assigned to strengthen post-registration monitoring.
- The great diversity of available resources among the countries requires a flexible approach to pesticide management.
- Countries with limited resources may consider a phased development of a pesticide registration scheme.

[1] It is recognized that for existing active substances, even if review schedules become broadly aligned, situations will arise requiring the preparation of monographs for use in just one country or region. Similarly commercial considerations may dictate that particular new active substances are developed on a regional rather than a global basis.

Workshop results

Survey responses

Group 1 **Does your country have provisions for …**	**Bangladesh**	**China**	**Indonesia**	**Japan**	**Korea, DPR**	**Nepal**	**Pakistan**	**Singapore**	**Sri Lanka**
Accepting registrations from other countries	N	N	N	N	N	N	N	N	N
Using existing risk assessments (not follow)	Y	Y	Y	Y	Y	Y	Y	Y	Y
Mutually accepting registration data	P	P	P	P	P	P	P	Y	P
Prioritizing specific groups of pesticides (e.g. non-chemicals over chemicals, assessment for specific groups)	Y	Y	Y	Y	Y	Y	Y	Y	Y
Prioritizing specific protection goals	Y	Y	Y	Y	Y	Y	Y	Y	Y
Setting up fast-track registration channels i.e. waiver, etc.	Y	Y	Y	Y	Y	Y	Y	Y	Y

P = Partial

Group 2: TCP-pesticide project countries (ASEAN) **Does your country have provisions for …**	**Cambodia**	**Lao PDR**	**Malaysia**	**Myanmar**	**Philippines**	**Thailand**	**Viet Nam**
Accepting registrations from other countries	N	Y	P	N	N	N	N
Using existing risk assessments	Y	Y	P	Y	Y	Y	P
Mutually accepting registration data	Y	Y	Y	Y	Y	P	Y
Prioritizing specific groups of pesticides	Y	Y	Y		Y	Y	Y
Prioritizing specific protection goals	Y	Y	Y	Y	Y	Y	Y
Setting up fast-track registration channels	Y	N	N	N	N	N	Y

Question 1:

"Design a phased pesticide regulatory scheme for countries with very limited, limited and adequate resources."

Group 1

Aspect	Very limited resources	Limited resources	Adequate resources
Admin. set up & infrastructure i.e. legislation, independent agency, staffing	• National legislation with simple admin approval (centralised) • One admin./reg. officer	• National legislation with simple admin approval • More than 1 reg. officer	• National legislation with online approval • Internal guidelines • Team
Application for registration	• Hardcopy submission	• Hardcopy submission	• Hardcopy & online submissions
Testing capacity	• No. Then accept overseas reports	• Yes. Defined range of testing	• Yes. Full range
Data review and registration decision	• One person – consider overseas evaluation report & registration decision	• Limited evaluation – consider overseas evaluation report & registration decision	• Comprehensive assessment • Panel/Board review
Registration Options	• 1 option – Full only	• More than 1 options – Full & Provisional	• More than 1 options depending on policy & more review
Post-registration activities	• Concentrate on priority areas i.e. quality & major crops	• Focus on a few priority areas i.e. quality, inspection of retailers, farms, etc.	• Options of full range of activities

Question 2:

"Make lists of registration aspects that are suitable for regional harmonization and those that would always be the responsibility of an individual country."

	Aspects suitable for regional harmonization	Aspects that would always be country responsibility
Administrative set up and infrastructure		✓
Application for registration	✓ Minimum data requirements ✓ Application format	
Registration options		✓
Data review	✓ Guidelines for technical evaluation	
Registration decision		✓
Post-registration activities	✓ Monitoring of quality ✓ Collecting data	

Group 2: (TCP-pesticide project countries (ASEAN))

Survey

- Fill out attached checklist table on "Guideline parameters require harmonization among SEA countries"

Discussion

"Based on the above checklist ….
1. Assess the relevance, practicability, level of detail, etc. of the checklist parameters.
2. Assess the progress made toward harmonization among SEA countries."

Responses

1. Harmonization of pesticide registration not fully implemented yet by all TCP-pesticide project countries (ASEAN).
2. Currently, most TCP-pesticide project countries (ASEAN) are using their own guidelines but there are already partially harmonized with the guidelines developed under the project.
3. Generally, the registration processes are compliant with the Code of Conduct and international conventions, however, the detailed procedures are unique to each country and dependent on the country's capacities, i.e. availability of resources (personnel, expertise, facilities, etc.). All TCP-pesticide project countries (ASEAN) have a registration committee/pesticide board, registration procedures, validity of registration period, etc.
4. Lao PDR and Viet Nam have translated the harmonized guidelines into their local languages.
5. Lao PDR is already using the harmonized guidelines.
6. TCP-pesticide project countries (ASEAN) aim to use the harmonized guidelines but not in unison – each country will have to do at their own pace due to the differing situations in their own countries.
7. Some countries are amending their legislation. Therefore, harmonization will have to wait until the amendments have been finalized and approved by the highest body (e.g. parliament). The harmonized guidelines are taken into consideration during the amendment process.
8. The individual country updates can also be referred to in the country reports presented at this workshop.

CHECK LIST

Guideline parameters required for harmonization of pesticide registration requirements among Southeast Asian countries

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
6.	**GENERAL REQUIREMENTS FOR PESTICIDE REGISTRATION**							
6.1.	***Registration process compliant with Code of Conduct & International Conventions***							
6.1.1.	FAO Code of Conduct on Pesticides	Y	Y	Y	Y	Y	Y	Y
6.1.2.	Rotterdam Convention	Y	Y	Y	Y	Y	Y	Y
6.1.3.	Stockholm Convention	Y	Y	Y	P	Y	Y	Y
6.1.4.	Basel Convention	Y	Y	Y	Y	Y	Y	Y
6.1.5.	Montreal Protocol	Y	Y	Y	Y	Y	Y	Y
6.1.6.	Guidelines "Designing national pesticide legislation FAO, 2007	P	P	N	N	N	P	P
6.1.7.	Guidelines on compliance and enforcement of a pesticide regulatory programme, FAO, Rome, 2006	P	P	N	N	N	P	P
6.2.	***Designation of Responsible Authority & adequate facilities***							
6.2.1.	Designated responsible authority for registration and control of pesticides	Y	Y	Y	Y	Y	Y	Y
6.2.2.	Adequate infrastructure facilities	Y	N	N	Y	Y	Y	Y
6.2.3.	Each and every product of pesticide is registered before import, export, manufacture, storage, distribution, sale and use in the country	Y	Y	Y	Y	Y	Y	Y
6.3.	***Existing of a system of monitoring & observance of Code of Conduct***							
6.3.1.	Regular reporting (as per Annex A) and Adhoc reporting (as per Annex B) of *Guidelines on monitoring and observance of the Code of Conduct, FAO, Rome, 2006*	N	N	N	N	N	Y	N
6.4.	***Documentation of Registration Process***							
6.4.1.	Documentation of the entire registration process of pesticides imported and manufactured for distribution and sale and use in the country and exported outside the country after taking into account the Guidelines for registration and control of pesticides, FAO, Rome. 1985 and the Guidelines for the registration of pesticides, FAO, Rome, 2010 (International Code of Conduct on the Distribution and Use of Pesticides) (draft)	P	P	P	P	P	P	P
6.4.2.	Harmonized registration process	N	N	N	N	N	N	N
6.4.3.	Information exchange relevant to registration process among member countries in the region	P	N	N	P	P	P	P
6.5.	***Establishment of Pesticide Board/Technical Committee***							
6.5.1.	Pesticide Board to render advice on pesticide matters	Y	Y	Y	Y	Y	Y	Y
6.5.2.	An appropriate technical committee to assist in conducting pesticide risk evaluations and making risk management decisions	Y	Y	Y	Y	Y	Y	Y
6.6.	***Establishment of Registration Requirements & Procedures***							
6.6.1.	Harmonized pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards	P	P	P	P	P	P	P

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
6.6.2.	Incorporation of internationally agreed technical guidelines and standards into national legislation	Y	Y	P	P	Y	Y	P
6.6.3.	Establishing a re-registration procedure to ensure periodic review of registered pesticides	Y	Y	Y	Y	Y	Y	Y
6.7.	***Establishment of Monitoring & Reporting Procedures***							
6.7.1.	Monitoring and reporting procedures on health and environmental incidents resulting out of exposure to pesticides	Y	N	P	Y	Y	Y	P
6.7.2.	Appropriate measures to minimize the incidents after taking into account the guidelines established by FAO	Y	Y	Y	Y	Y	Y	Y
SPECIFIC REQUIREMENTS OF PESTICIDE REGISTRATION								
7.	**Different registration procedures for each kind of registration**							
7.1.	***Provisional pesticide registration for 2 years*** (Responses in years)	1	1	5	N	1	N	N
7.1.1.	Minimum data requirements	Y	Y	Y	Y	Y	N	Y
7.1.2.	Quantity restrictions	Y	Y	Y	Y	Y	N	Y
7.2.	***Proprietary pesticide registration for 5 years*** (Responses in years)	Y3	Y2	N	Y5	Y3	Y6	Y5
7.2.1.	Use of standard information and data requirements (as per Annex 2A, 2B, 3A, 3B, 4A and 4B of *Guidelines for pesticide regulatory harmonization, 2011)*	N	P	P	P	N	P	P
7.2.2.	Protection of proprietary data & confidential business information	Y	Y	N	Y	Y	Y	Y
7.3.	***Supplementary (me-too) pesticide registration (after 5 years of original registration)***	Y8	N	Y5	N	Y3	N	Y5
7.3.1.	Use of standard data requirements (Annex 2C, 3C and 4C)	P	N	P	N	P	N	P
7.3.2.	Agreement entered with original registrant	3	N	2	N	3	N	5
7.4.	***Re-registration of pesticides for another 5 years after the expiry of registration***	Y3	Y2	Y3	Y5	Y3	Y6	Y5
7.4.1.	Additional information requirements, if any	Y	Y	Y	Y	Y	Y	Y
8.	**Existence of exemptions from registration requirements**							
8.1.	***Non-pesticide active ingredient substances used in formulating pesticides***	Y	Y	Y	Y	Y	N	Y
8.2.	***Emergency use based on registration in a foreign country and with conditions specified by the Registration Authority***	Y	Y	Y	Y	Y	N	Y
9.	**Registration of Application**							
9.1.	***Application Form***	Y	Y	Y	Y	Y	N	Y
9.1.1.	Harmonized single application format (Annexure 1A) for pesticide registration (in five copies)	P	N	P	P	P	P	P
9.1.2.	Bank draft (registration fees)	Y	P	Y	Y	Y	N	Y
9.1.3.	Applicant's summary statement/conclusions in respect of data fulfillment in support of registration	Y	Y	Y	Y	Y	N	Y
9.1.4.	Information content include: – identity of Applicant, – type of registration requested, – identity of technical grade active ingredient/formulated product, – chemical toxicity category, – use type & use pattern, – registration data requirements,	Y	Y	Y	Y	Y	Y	Y

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
	– additional information if any, – fee details, – list of attached documents, – verification/declaration/signature by applicant.							
9.2.	***Establishment of separate fees structure for***							
9.2.1.	Each type of registration (viz., provisional registration, proprietary registration, supplementary (me-too) registration & re-registration	Y	N	Y	N	Y	N	Y
9.2.2.	Issue of import permit and or/export authorization	Y	Y	Y	Y	Y	Y	Y
9.2.3.	Licensing of: – manufacturing facility – storage – repacking – transport – distribution – sale of pesticides – pest control operators	Y	P	P	P	Y	Y	Y
9.3.	***Receipt of Application/Issue of acknowledgement***							
9.3.1.	Receipt of applications and issue of acknowledgement by the registration counter/desk	Y	Y	Y	Y	Y	Y	Y
9.3.2.	Online submitted applications will automatically generate acknowledgement	N	N	N	P	P	N	N
9.4.	***Document verification/Check list of documents***							
9.4.1.	A check list (Annexure IB) of documents be established for each kind of registration to facilitate verification of receipt of various documents by the registration counter/desk	Y	Y	Y	Y	P	Y	Y
9.4.2.	Information furnished in the application is correct and complete in all respects before accepting the application for registration	Y	Y	Y	Y	Y	Y	Y
9.4.3.	Online monitoring of registration process in order to avoid time delays	N	N	N	Y	N	P	N
10.	**Minimum data requirements**							
10.1.	***Existence of harmonized minimum data requirement lists for***							
10.1.1.	Provisional registration	N	N	N	N	N	N	N
10.1.2.	Proprietary (original) pesticide registration	P	N	N	N	N	P	P
10.1.3.	Supplementary (me-too) registration (commodity product registration) and/or	N	N	N	N	N	N	P
10.1.4.	Re-registration	P	P	P	P	N	P	P
10.2.	***Submission of minimum data in the following separate sealed folders***							
10.2.1.	Chemistry/Biochemical/Microbiological data (Folder A)	Y	N	N	N	Y	N	Y
10.2.2.	Toxicity data (Folder B)	Y	N	N	N	Y	N	Y
10.2.3.	Bio-efficacy data (Folder C)	Y	N	N	N	Y	N	Y
10.2.4.	Labelling/Packaging/Storage (Folder D)	Y	N	N	N	P	N	Y
10.2.5.	Health Exposure/Environmental fate & effects' data (Folder E)	Y	N	N	N	Y	N	Y
10.2.6.	Residues data (Folder F)	Y	N	N	N	Y	N	Y
10.2.7.	Additional information, if any (Folder G)	Y	N	P	N	P	Y	Y

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
10.3.	***Proprietary data handling and confidential business information***							
10.3.1.	Specific authorization of staff	Y	Y	Y	Y	Y	Y	Y
10.3.2.	Documentation of specific procedures	Y	Y	Y	Y	Y	Y	Y
11.	**Technical evaluation of Registration Dossiers**							
11.1.	***Verification that the data submitted fulfills all the requirements of registration***	Y	Y	Y	Y	Y	Y	Y
11.2.	***Verification of data waiver of requirements in certain instances***	Y	Y	Y	Y	Y	Y	Y
11.3.	***Verification of analytical methods/test protocols***	Y	N	Y	Y	Y	Y	Y
11.4.	***Verification of manufacturing process, where necessary***	Y	N	Y	Y	Y	Y	Y
11.5.	***Verification to meet FAO/WHO specifications***	Y	N	Y	Y	Y	Y	Y
11.6.	***Consideration of validation studies of existing/new data***	Y	Y	Y	Y	Y	Y	Y
11.7.	***Comprehensive summaries and conclusions by the reviewer for Pesticide Board decision***	Y	Y	Y	Y	N	Y	Y
11.8.	***Decision by the Pesticide Board/Committee to grant a provisional or regular registration, with or without restrictions and/or conditions, or refusal***	Y	Y	Y	Y	Y	Y	Y
11.9.	***Acceptance of data obtained under controlled laboratory conditions or under similar agro-climatic conditions based on internationally accepted test protocols and adequate scientific standard***	Y	Y	Y	Y	Y	Y	Y
11.10.	***Verification of compliance with Good Laboratory Practices (GLP):*** Verification of authenticity of the data with the concerned GLP certified laboratory	Y	Y	Y	Y	Y	Y	Y
12.	**Data Protection/Data Access/Information sharing**							
12.1.	***Internal guidelines to protect and safeguard the proprietary rights to the data and confidential business information***	P	N	P	P	Y	Y	P
12.2.	***Public access to health and safety data***	Y	Y	N	N	Y	Y	Y
12.3.	***Information sharing on pesticide regulatory system with other member country in this region in order to achieve pesticide regulatory harmonization***	N	N	N	N	P	P	P
13.	**Time period for review of data/Communication of data gaps**							
13.1.	***Prescribing specified time period for completion of registration process*** (Responses in months)	Y18	Y2	Y6	Y6	Y6	Y18	Y1
14.	**New data submission to fill the data gaps**							
14.1.	***Provision of notice to applicant to provide new data to fill the data gaps identified during the technical review of data giving appropriate time period for the submission of new data*** (Responses in months)	N	Y2	Y1	Y3	Y3	Y3	N
14.2.	***Provision of notice to applicant to provide additional information requirements, in the event of Re-registration*** (Responses in months)	Y3	Y1	Y3	Y3	Y7	Y3	Y1
15.	**Pesticide Risk Assessment (as per FAO guidelines)**							
15.1.	***Detailed toxicological data***	Y	Y	Y	Y	Y	Y	Y
15.2.	***Data on long time dietary exposure***	Y	Y	Y	Y	Y	Y	Y
15.3.	***Data on health exposure to very low level of pesticides***	Y	Y	P	N	N	Y	Y
15.4.	***Environmental fate/effects' data***	Y	Y	Y	Y	Y	Y	Y
15.5.	***Development of pest resistance***	Y	Y	Y	Y	Y	Y	Y
15.6.	***Assessment of phytotoxicity***	Y	Y	Y	Y	Y	Y	Y

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
16.	**Bio-efficacy Assessment as per FAO Guidelines**							
16.1.	***Adoption of new modality guidelines for preparation of efficacy test protocols in the harmonized process***	P	P	P	P	P	P	P
16.2.	***Adoption of 29 new efficacy test protocols developed and modifications of existing 40 efficacy test protocols developed by FAO on new modality guidelines***	P	P	P	P	P	Y	P
17.	**Classification of pesticides based on hazard & toxicity**							
17.1.	***According to the WHO hazard classification/modified toxicity classification***	Y	Y	Y	Y	Y	Y	Y
18.	**Review of labelling/packaging/storage requirements**							
18.1.	***Reviewing of pesticide labelling according to harmonized guidelines***	P	Y	P	P	N	N	P
18.2.	***Bilingual labelling format (English/National)***	P	Y	Y	Y	Y	P	N
18.3.	***Testing tamper-proof packaging***	N	N	N	N	P	N	N
18.4.	***Testing storage stability (shelf life) of product***	Y	N	P	Y	P	Y	P
19.	**Approval & issue of registration certificate**							
19.1.	***Guidelines for approval of registration***	Y	N	Y	Y	Y	Y	Y
19.2.	***Issue of Registration Certificate with a unique registration number, date of issue and validity, date & signature by registration authority***	Y	Y	Y	Y	Y	Y	Y
20.	**Validity period of certificate for different kind of registration**							
20.1.	***Provisional registration: 2 years*** (Responses in years)	Y1	Y1	Y5	N	Y1	N	N
20.2.	***Proprietary (original) registration: 5 years*** (Responses in years)	Y3	Y2	N	Y	Y3	Y6	Y5
20.3.	***Supplementary (me-too) registration: 5 years after original registration*** (Responses in years)	Y3	Y2	Y	N	Y3	N	Y
20.4.	***Re-registration***	Y	Y	Y	Y	Y	Y	Y
21.	**Denial of issue of Registration Certificate**							
21.1.	***Issue a notice of denial of registration to the applicant of registration within reasonable period of time giving reasons for denial by the Registration Authority***	Y	Y	Y	Y	Y	Y	Y
22.	**Appeal by the Applicant/Appeal Procedures**							
22.1.	***Providing for appeal by the applicant against the decision giving grounds for appeal within 30 days of issue of denial notice by the Registration Authority***	N	N	Y	Y	Y	N	N
22.2.	***Establishing a formal approval procedure under pesticide regulations***	Y	Y	Y	Y	Y	Y	Y
23.	**Notification of prior informed consent (PIC) procedures**							
23.1.	***Notification of final regulatory action for certain hazardous chemicals and pesticides included under Rotterdam Convention***	Y	Y	Y	Y	Y	Y	Y
23.2.	***Notification of prior informed consent procedures for certain hazardous chemicals & pesticides included under Rotterdam Convention***	Y	Y	Y	Y	Y	Y	Y
24.	**Un-conditional/Conditional registration**							
24.1.	***Providing of appropriate criteria for unconditional registration, which include:***	N	N	N	N	N	N	N
	(a) that the application was complete and was accompanied by all materials required by the requirements of registration, including but not limited to, evidence that the applicant had complied with the data compensation requirements;							

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
	(b) all relevant data in its possession were reviewed and accepted;							
	(c) no further additional data were necessary to make the determinations required under pesticide regulation with respect to the subject product;							
	(d) the composition of the product is such as to warrant the proposed bio-efficacy claims for it, if bio-efficacy data were required;							
	(e) the product will perform its intended function without adverse effects on the environment, and that when used in accordance with widespread and commonly recognized practice including instructions and information on the label, the product will not cause adverse effects on the environment;							
	(f) provided that the proposed labelling bears directions for use on food, animal feed, or food or feed crops, or the intended use of the pesticide results and/or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances or exemptions from the requirement of a tolerance, and food additive regulations, have been accounted for; and							
	(g) Unconditional registrations can be granted for a variety of applications such as identical/substantially similar (me-too) (described below), new uses, or new active ingredients as long as all criteria above are met with.							
24.2.	(h) Providing appropriate criteria for conditional registration, which include:	Y	N	N	N	Y	N	N
	(i) Registration Authority may conditionally approve an application for registration or amend a registration of a pesticide product. This may occur if Registration Authority determines that, while a registration decision can be made, further data, studies, or action by the registrant is required by the Registration Authority for further review. This conditional registration may be granted depending on whether it is a new active ingredient, a new use, or an identical/substantially similar (formerly "me-too") product or it is for a new use.	Y	N	N	N	Y	N	N
	(j) Registration Authority may not approve the conditional registration of a pesticide product for a new use if the pesticide is the subject of a special review, based on its use that results in human dietary exposure and that the proposed new use is for a major food or feed crop, or involves use on a minor food or feed crop for which there is an effective alternative registered pesticide that does not meet the risk criteria associated with human dietary exposure is available.	Y	N	N	N	Y	N	N
25.	**Amendments to previous registration**							
25.1.	***Any amendments issued to previous registration certificates should be limited to extension of label claims, formulation change, repacking and local formulation and subject to provision of additional data requirements***	Y	Y	Y	Y	Y	Y	Y
25.2.	***Any amendment issued to previous registration certificate should be properly endorsed by the Registration Authority and have linkage to the previous registration certificate***	Y	Y	Y	Y	Y	Y	Y

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
26.	**Re-registration**							
26.1.	***The Registration Authority may issue a re-registration certificate for previously registered products prior to expiry of previous registration granted to the original applicant. Before any such re-registration granted, the Registration Authority will review previous data submitted by the applicant as well as any new data generated consequent to previous registration***	Y	Y	Y	Y	Y	Y	Y
26.2.	***The re-registration certificate issued will bear linkage to the previous registration and is valid for further period of five years. (However, no banned and/or severely restricted pesticide should be allowed for re-registration)***	Y	Y	Y	Y	Y	Y	Y
27.	**Supplementary (me-too) registration**							
27.1.	***The Registration Authority may consider supplementary (me-too) registration only after the expiry of period of registration granted to the original applicant (i.e. after five years)*** (Responses in years)	Y3	Y2	Y5	N	Y3	N	Y5
27.2.	***Supplementary registration will be subject to production of a written agreement that was entered upon with the original registrant and the supplementary (me-too) applicant***	Y	Y	Y	N	Y	N	Y
27.3.	***Supplementary (me-too) registration will be granted after following the guidelines established under the FAO/WHO chemical equivalence process for supplementary registration***	Y	Y	Y	N	Y	N	Y
28.	**Import/Export Authorization**							
28.1.	***The Registration Authority will ensure that all pesticides imported into their territory from foreign manufacturers are covered under import permit system and registered before further manufacturing (where applicable), distribution, sale and use and meet all the requirements applicable to domestic producers***	Y	Y	Y	Y	Y	Y	Y
28.2.	***However, a sample quantity of new pesticide may be permitted for import as a registration sample only for experimental purpose under provisional registration***	Y	Y	Y	Yep	Yep	Yep	Y
28.3.	***The Registration Authority will ensure that all pesticides exported outside the country conform to the registration requirements of importing country. The pesticides must be registered in the country in which they are manufactured even it is meant exclusively for export and are covered under export license***	Y	Y	N	N	Y	Y	N
29.	**Licensing of manufacturing facility/repacking facility**							
29.1.	***The licensing authority will undertake a site visit to the manufacturing facility/repacking facility to ensure that the facility is in compliance with the pesticide regulations and other relevant regulations and that appropriate safeguards are in place to protect workers safety including effluent treatment and monitoring of air pollutants, where applicable***	Y	Y	Y	N	Y	Y	Y
30.	**Licensing of stockiest/distributors/retailers & storage premises**							
30.1.	***The licensing authority will undertake inspection of premises for the purpose of licensing of stockiest/distributor for stock/distribution/sale and storage for sale of pesticide in compliance with the provisions of pesticide regulations***	Y	Y	Y	Y	Y	Y	Y
31.	**Licensing of pest control operators**							
31.1.	***The licensing authority will undertake licensing of pest control operators to ensure that all commercial pest control operations are carried out according to the provision of pesticide regulation***	Y	Y	Y	Y	Y	Y	Y

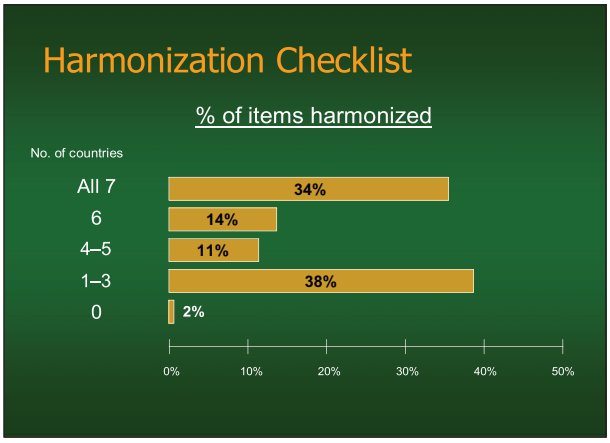
Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Viet Nam
32.	**Quality control of pesticides**							
32.1.	***Employing of qualified personnel as pesticide inspectors for drawing pesticide samples from import entry points, manufacture premises, storage houses, distribution/sale points for quality control of pesticides***	Y	Y	P	P	Y	Y	Y
32.2.	***Employing qualified personnel as pesticide analyst for testing pesticide samples***	Y	P	P	Y	Y	Y	Y
32.3.	***Establishing of pesticide testing laboratory(s) for routine testing the quality of pesticides and,***	Y	P	Y	Y	Y	Y	Y
32.4.	***Designation of an apex laboratory for reference analysis of pesticides in the event of legal disputes***	Y	P	Y	Y	Y	N	Y
33.	**Cancellation/suspension of registration/licensing**							
33.1.	***Existence of procedures to cancel/suspend the registration/licensing in the event of violation of pesticide regulations***	Y	Y	Y	Y	Y	Y	Y
34.	**Pesticide review/Re-evaluation of Pesticides**							
34.1.	***Establishing procedures for re-evaluation of registered pesticides on a regular cycle or based on harmonized guidelines***	P	P	P	P	P	P	P

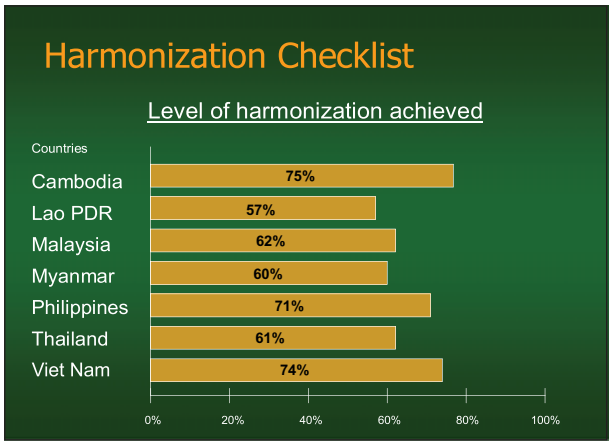
SUMMARY

TCP Harmonization checklist

Out of the 123 items on the checklist, 42 (34%) were found to be fully accomplished in all seven countries. Another 17 items (14%) have been fulfilled in all but one country. Thus a high degree of harmonization has been achieved with about half the items on the checklist. The majority of the remaining items, however, have only been realized in 1-3 countries and are such still far from being harmonized. None of the countries attempted to introduce data requirements for provisional and criteria for unconditional registration. It is questionable whether such items are important for regional harmonization and should have been included in the checklist.

According to the checklist, all countries have fully or partially fulfilled between 60 percent and 75 percent of the harmonization items. However, the actual figure may be somewhat lower if details are considered; for example, all countries claimed to be compliant with five international conventions or have established re-registration procedures, but the survey gave a more differentiated picture. For each country, there are still between 40 and 60 checklist items that need to be realized in order to achieve full harmonization. These items may be the ones that are more difficult to achieve, so that much work is still needed until pesticide management is harmonized in Southeast Asia.





Opportunities for regional harmonization

Not all items on the harmonization checklist may be necessary or essential for regional harmonization. Administrative procedures such as bank drafts for payment of registration fees or separate fee structures have no positive or negative consequences whether they are harmonized or not. Many items of the check list simply pertain to good registration practices that are applicable to every country regardless of harmonization. The workshop participants therefore identified the administrative set up, registration option and decision as aspects that are always country responsibility, whereas application procedures, data requirements and application of uniform evaluation and quality standards were suitable for regional harmonization.

Regional harmonization must be more than regional capacity building in pesticide regulatory management. Harmonization aims at creating synergistic effects from increased collaboration and cooperation. For regional harmonization to be successful, it must therefore provide tangible benefits to some of the stakeholders. Harmonization of the application process and data requirements would be beneficial to the industry since it would make it easier to register products in multiple countries. To free resources, lower costs, increase efficiency and other benefits for the countries themselves would probably require more substantial work-sharing activities toward a regional registration scheme.

The Chiang Mai workshop tried to raise awareness about the ultimate goals of harmonization and the advantages from regional cooperation and work sharing. However, it was also recognized that such a level of harmonization is still in the distant future and not yet subject for discussions.

2.9 SUMMARY AND CONCLUSIONS

The discussions on the various issues of pesticide regulatory management and harmonization arrived at the following results:

- While in many countries, pesticide management is under one legislation and agency, others have multiple legislations and different agencies registering pesticides; the advantages and disadvantages of different systems were discussed, and the experience in other countries can be considered when a country in the process of reviewing its pesticide management.
- The harmonization of registration data requirements was a common concern; it was decided that harmonization efforts should focus on the requirements for a full registration of the formulated product. other registration options and issues in relation to the registration of only the active ingredient should be addressed later.
- For the registration of chemical pesticides, a priority list of registration data requirements was developed by the participants which can be used by the individual countries as a checklist for their own requirements and to measure their progress toward harmonization.
- Registration of biological pest control products is an area that is still under development internationally; national registration authorities need find practical ways to encourage non-chemical pest control while adhering to the high registration standards. In the TCP guidelines for harmonization of biopesticide registration, the tables with the priority data requirements for biochemicals and microbials were identified, which can be used to initiate specific registration requirements suitable for non-chemical pesticides. Further work in this area by the ASEAN/GIZ project would be of interest for all countries in the APPPC region.
- Internationally available resources were identified which can help registration authorities to facilitate the data review process.
- Post-registration activities need strengthening in most countries; however, this is largely determined by the available resources. A priority list was developed to help countries with fewer resources to set up activities that are within their means.
- It was realized that some aspects of pesticide management offer themselves for regional harmonization, while other aspects will always be the responsibility of individual countries and can be excluded from the harmonization process; these items were identified in separate lists.
- Since there is a high diversity among countries, the participants identified the areas of high priority in the registration process that can be strengthened even with limited resources by making full use of internationally available information and active collaboration with neighbouring countries.
- There is a need for governments to make resources available and for international organizations to facilitate the harmonization process.
- The participants from the TCP pesticide project countries (ASEAN) went through the checklist of parameters for pesticide registration requirements among Southeast Asian countries that was adopted at the end of the project to monitor progress made towards regional harmonization; significant progress was already identified in many areas while others still need to be addressed and need continued effort in the coming years.

3. Country reports

3.1 BANGLADESH

STATUS OF PESTICIDE MANAGEMENT IN BANGLADESH

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

Presented by:
NAZMUL AHSAN
Pesticide Regulation Officer

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 2-2$^{1}/_{2}$ 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, trolly as according the condition of railway or trolly aulthority in Red Tariff, No pesticide shall be transported if have the possibility to direct contact with foods stuff. to safe from pesticide riskes and helth harzard PPW arranged the training programme on safe use pesticide

Procedure and data requirement for the registration of chemical procedure have 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 trial for Bio-efficacy

Review the dossier by nominated chemist of PPW – and highly harzadous product it will be rejected on according WHO classification of pesticide.
Bio-efficacy, toxicolosical data, ecotoxical data all review by chemist of PPW
Formulation analysis and quality control have been done sby chemist of PPW
Bangladesh have 6 type of licence:

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

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

3.2 CAMBODIA

STATUS AND RECENT DEVELOPMENT IN PESTICIDE MANAGEMENT IN CAMBODIA

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

Presented by:
Dr Dy Sam An
Mr Uch Sothy

OUTLINE

I. Status of Pesticide Registration in Cambodia before 2012
II. Status of Pesticide Registration from 2012

I. Status of Pesticide Registration in Cambodia before 2012

Pesticide Registration and Licensing

Pesticide Registration and Licensing Issuing in Cambodia has been implemented under:

- 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

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

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

1. Permit of Agriculture Materials Trade (con't)

- Can be granted to individual or company who is Cambodian or Foreigner who already registered for trade registration with the Ministry of Commerce
- Individual or company must have warehouse location certified by Ministry of Environment

2. Pesticide Registration Process

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:

- Registration Certificate
- Import/Export License
- Distribution License for wholesale company
- Distribution License for retailer issued by PDA

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

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 heath.

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

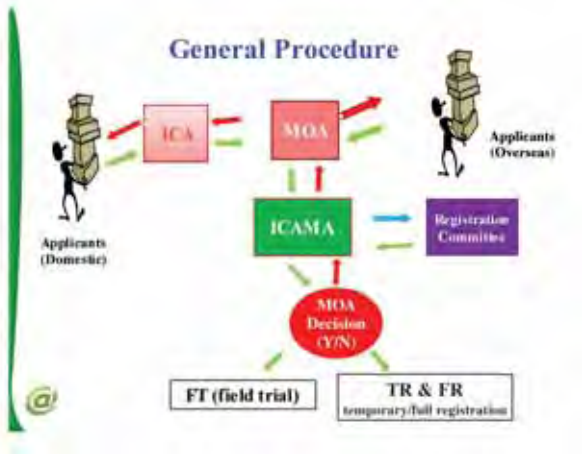
[a] Residue data can be exempt for some kind of biochemistry and biological pesticides according depending on the decision of the Registration Committee.

[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

3.4 INDONESIA

MINISTRY OF AGRICULTURE

PESTICIDE REGULATORY IN INDONESIA

By

YULIA PURWANTI
DEPUTY DIRECTOR FOR PESTICIDE

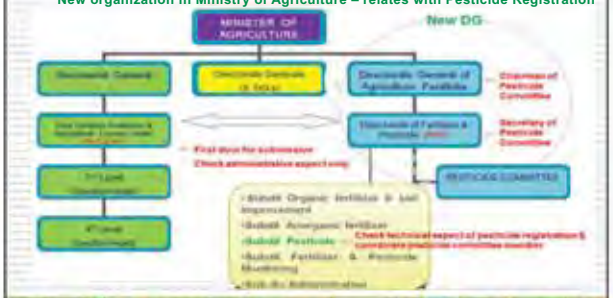
DIRECTORATE OF FERTILIZER AND PESTICIDE,
DIRECTORATE GENERAL OF AGRICULTURAL FACILITIES & INFRASTRUCTURE,
MINISTRY OF AGRICULTURE

PESTICIDE ACT/RULES/REGULATIONS

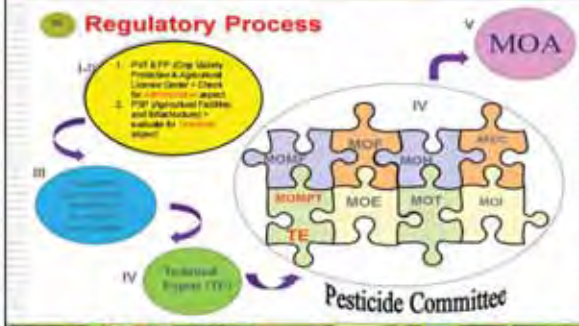
1. GOVERNMENT LAW NO. 12/1992 ON CROP CULTIVATION SYSTEM
2. GOVERNMENT REGULATION NO. 7/1973, STATED THAT ALL PESTICIDES WHICH DISTRIBUTED, STORED AND COMMERCIALIZED IN INDONESIA SHALL BE REGISTERED AND HAVE PERMIT FROM MINISTER OF AGRICULTURE.
3. MINISTER OF AGRICULTURE DECREE NO. 24/2011, GUIDELINES 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.

REGULATORY AUTHORITY CHANGE (since Dec. 10/Jan. 11)

New organization in Ministry of Agriculture – relates with Pesticide Registration



Regulatory process



Regulatory Bodies

PESTICIDE COMMITTEE
Under Ministry of Agriculture

Inter Ministries (±30 persons):

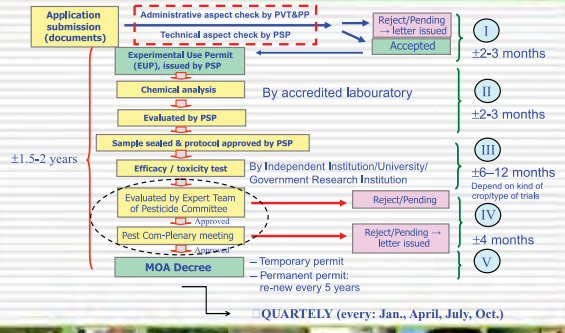
1. Ministry of Agriculture (MOA)
2. Ministry of Marine and Fishery (MOMF)
3. Ministry of Forestry (MOF)
4. Ministry of Health (MOH)
5. Agency for Food and Drugs Controlling (AFDC)
6. Ministry of Environment (MOE)
7. Ministry of Trade (MOT)
8. Ministry of Industry (MOI)
9. Ministry of Man Power & Transmigration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

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

TECHNICAL EXPERT TEAM

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)

Registration Process & Flow



CORE Data Requirement for Products 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.

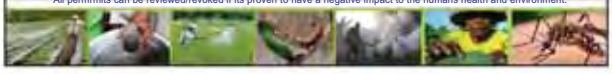
B. TEMPORARY PERMIT

- 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 * : asumption 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 permrmits 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.

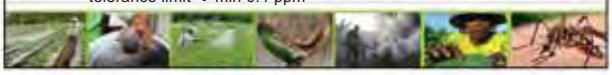
Technical Requirement

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 - 25	0 - < 25	± 15 %

- Impurities content of paraquat technical should meet the tolerance limit ➔ terpiridine: max 1 ppm; bipiridil: max 1 000 ppm.
- Emectic 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

1. 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 OR
   - 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 ben established.
2. Chronic toxicity of active ingredient:
   No effect on carcinogenic, teratogenic & mutagenic (IARC, FAO, WHO, US-EPA & other international bodies)

Technical Requirement

4. Environment Toxicity

1. DT50 of active ingredient in soil <120 days for pesticide registered in agriculture ecosystem (food crops, horticulture & plantation).
2. 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:
   2.1. Fish toxicity in laboratory – for liquid & powder formulation:
      a. Toxic unit >3 (harmful): not allowed to be registered.
      b. Toxic unit 0.3-3.0 (slightly harmful): should be completed with field test.
      c. Toxic unit <0.3 (harmless): wil be given permanent permit.
   2.2. Fish toxicity in the field – for granule formulation:
      a. T50 (half life) >7 days ➔ harmful – not allowed to be registered.
      b. 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

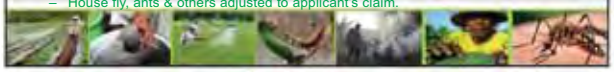
6. Resurgence againts Brown Plant Hopper (BPH)
Insecticide will be registered in RICE must not induce & produce resurgence effect against BPH (*Nilaparvata lugens*). Local test (laboratory & field) is mandatory & required for registration in all rice pests.

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 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 (*Blatella 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

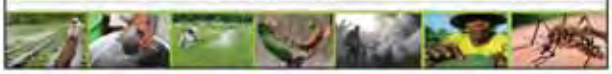
Via INSW portal:

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 decimenate to stakeholder.**
- ❑ **Publish via www.deptan.go.id**

Labelling & Packaging of Pesticide

Mandatory information must be included in the label:
1. **Trade name of pesticide**
2. **Type of pesticide**
3. **Name & active ingredient content**
4. **Content or net weight in packaging**
5. **Safety warning**
6. **Classification & hazard symbol**
7. **Safety instruction**
8. **Poisoning symptoms**
9. **First aid**
10. **Medical treatment**
11. **Storage instruction**
12. **Instruction of use**
13. **Pictogram**
14. **Registration number**
15. **Name & adres of registration holder**
16. **Batch number and expired date.**
17. **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	Alumunium 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 floride	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 Kusukawa
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

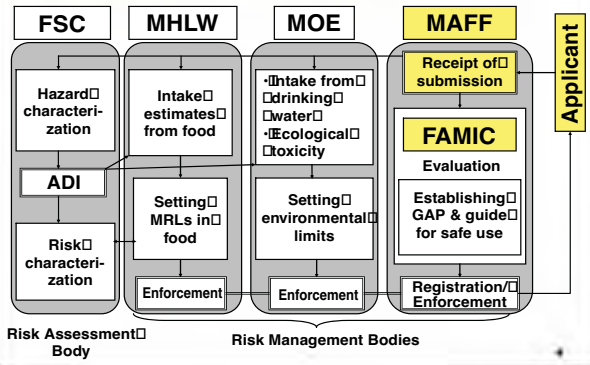
Pesticides are used on "crops"

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

AC Registration and MRLs Setting



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

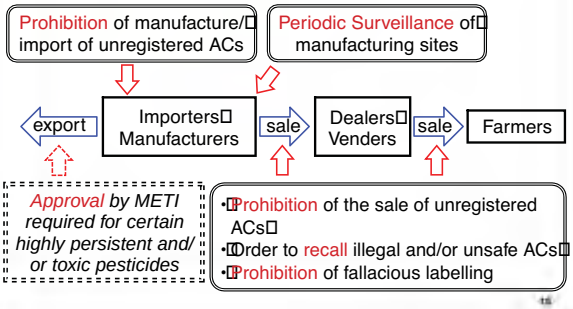
Emulsion

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

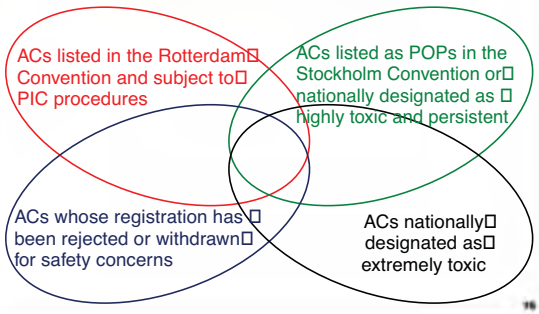
Examples of Guide for Safety Use

- **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.**

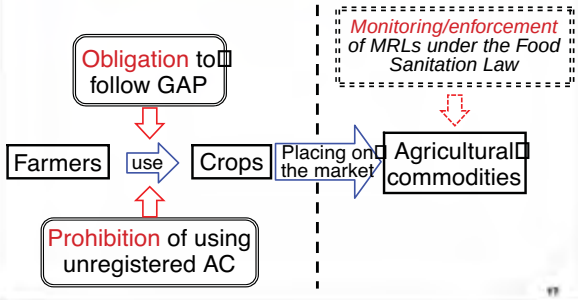
Regulations of Agricultural Chemicals (ACs) under the AC Regulation Law (1)



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 evaluatiing risks of pesticide residues ~

1. Number and quality of supervised residue trials
2. Rotational crop studies
3. Processing studies
4. 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

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

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

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.

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

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~)

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

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

Animal Metabolism/Transfer Studies

~ Agreed New Approacch ~

- 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

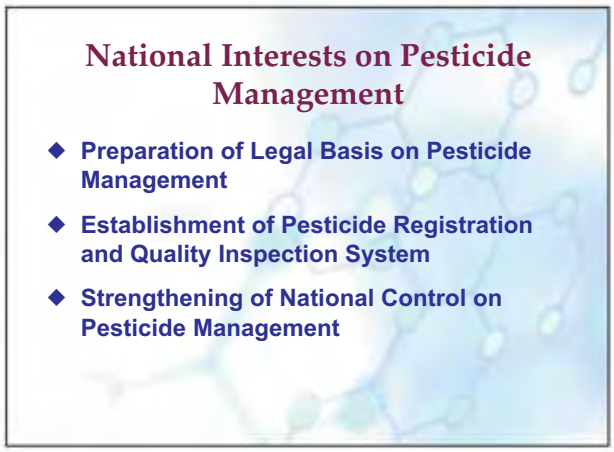
3.6 KOREA, DPR

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.

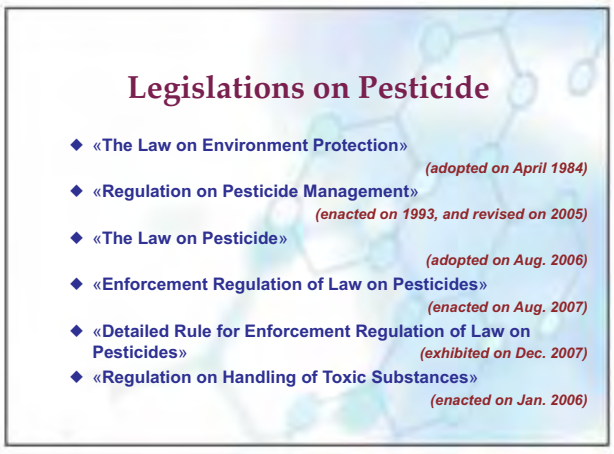
So the regulation on the botanical pesticides and micro-organism pesticides is less strong than that on chemical pesticides, and some biopesticides like plant-incorporated-protectants (e.g. Bt. in genetically modified plants) are not regulated by the pesticide legislations at present.

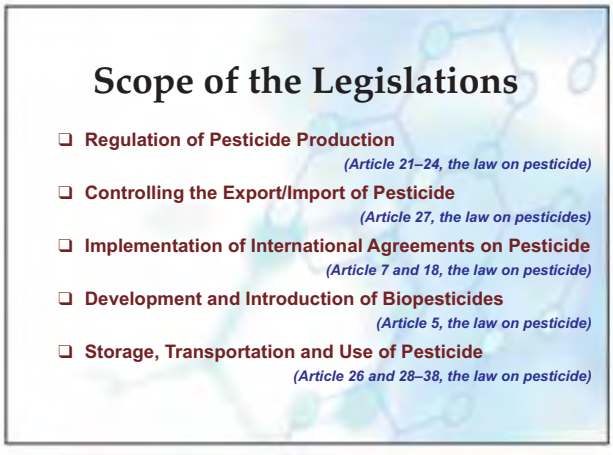
For example, the Detailed Rule is prescribing the botanical pesticides to be produced and used on the basis of regional technical condition in consonance with the realities of the region. This regulative alleviating measure is actively promoting the development and, production and use of botanical pesticides,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





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.

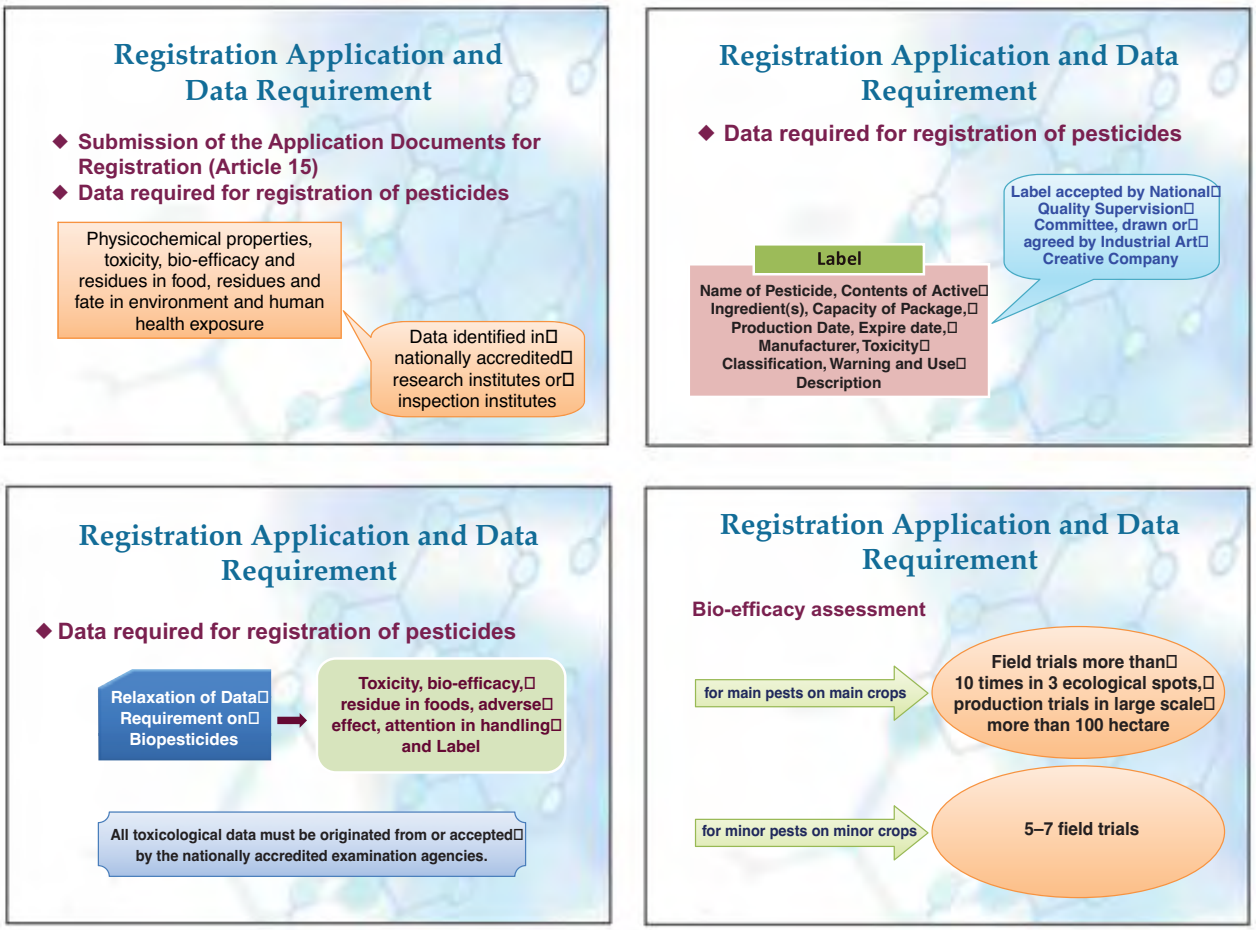
The field trials for bio-efficacy assessment of pesticides for major pests on major crops should be done in at least 3 ecological spots for totally more than 10 times including production trials in 100 hectare scale, and the bio-efficacy data of pesticides for minor pests on minor crops should be acquired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

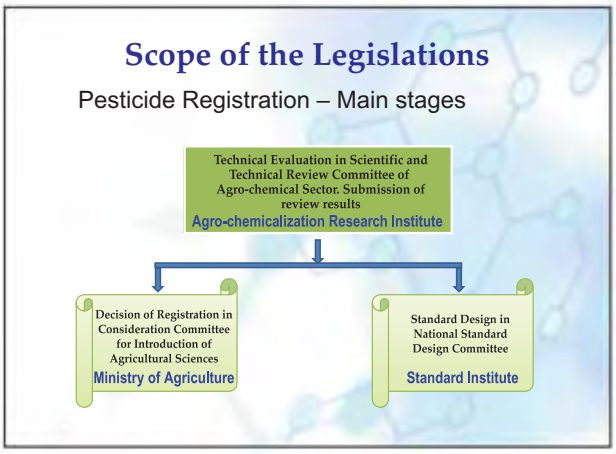
The application documents for registration are submitted to the Scientific and Technical Review Committee of Agrochemicals Sector which carries out the mission of technical committee, for technical evaluation of them.

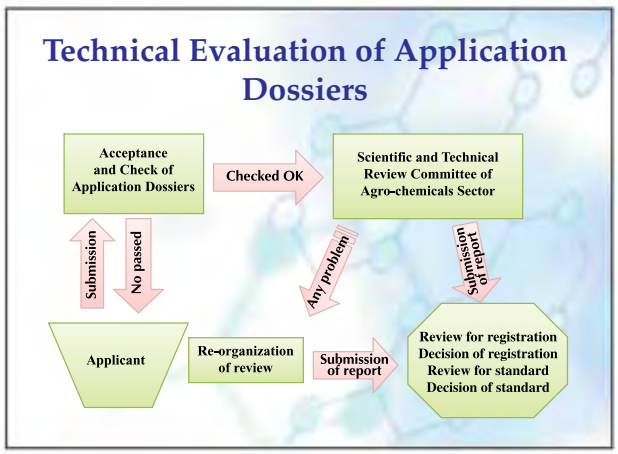
Before review, officers in the committee check the completeness of the documents according to the regulated format and enclosure of necessities including experiment documents, and send back the application documents to applicants to be corrected and added.

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 accidence 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 accidence 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 decresing 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 carring 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 dada 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

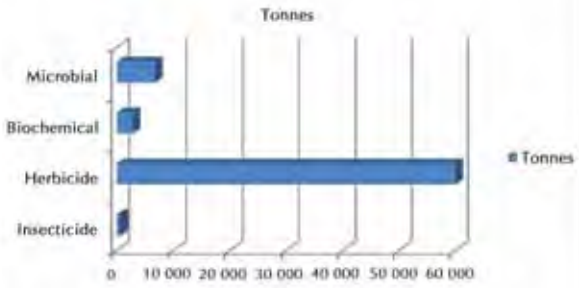
Presented by Khamphoui Louanglath
Department of Agriculture
Regulatory Division

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:

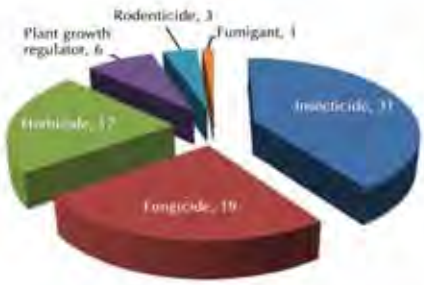
1. Review applications for the registration of pesticides and take registration decisions;
2. Regularly review the list of registered pesticide to determine whether these still meet the requirements, taking into consideration the latest scientific information;
3. Edit and approve labels of pesticides;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

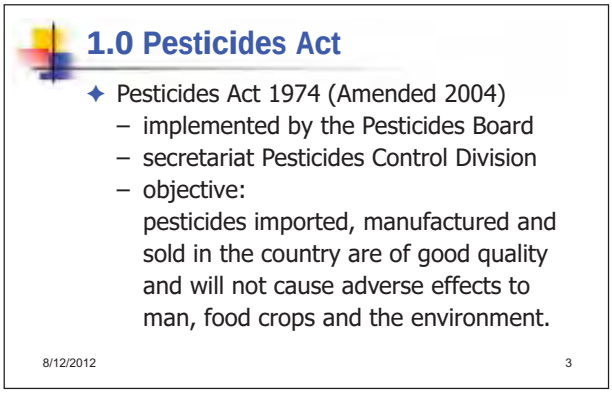
Recent developments on pesticides management

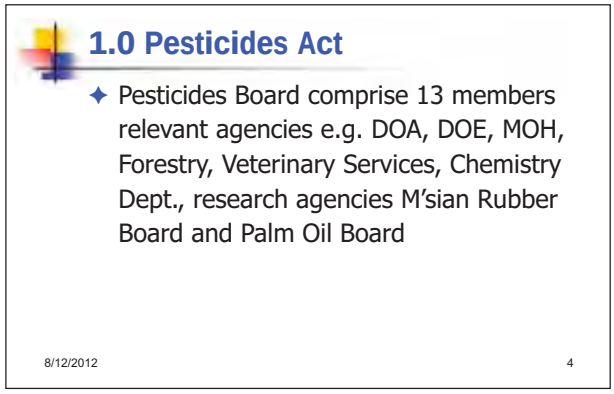
1. Pesticides regulations in Malaysia

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.





1.2 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

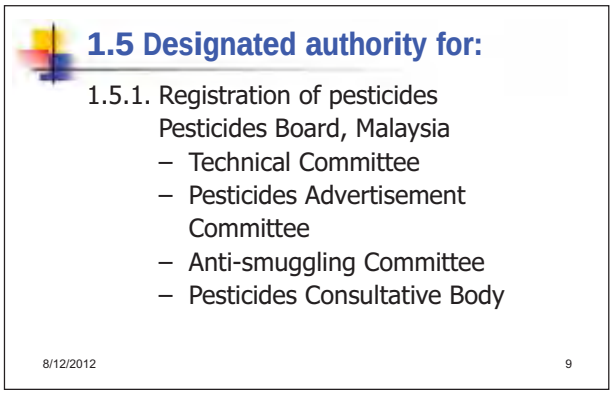
1.5 Designated authority for:

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).



1.5.3 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 Regulatatory 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 registrated. 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

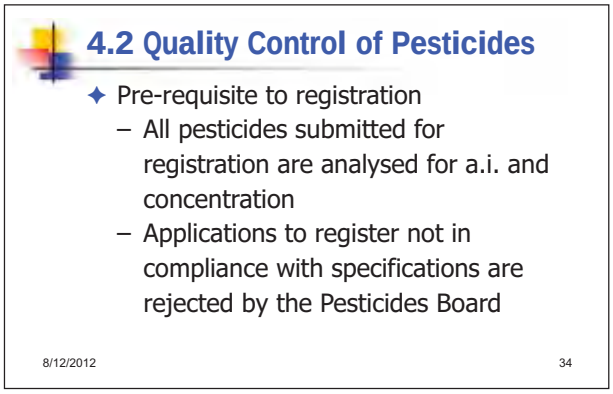
Pesticides	Usage	Status	Action Taken (Year)
23. Parathion	Insecticide	Banned	Never registered
24. Sodium PCP	Fungicide	Banned	2000
25. Toxaphene	Insecticide	Banned	Never registered
26. Phosphamidon	Insecticide	Banned	Never registered
27. Methyl-parathion	Insecticide	Banned	Never registered
28. Methamidophos	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

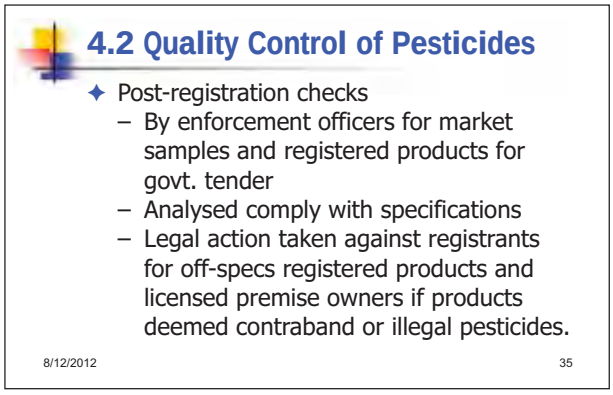
4.1.6 Information exchanged among the participating countries since the inception of this FAO-TCP Project.

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.





4.3 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/Tran 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 quechers technique for pesticides residue analysis

Technical Evaluation-Seminar on Risk Assessment on Chemicals

Enforcement-Lab Focus Group Business Process Reengineering
Agris-Geoportal 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

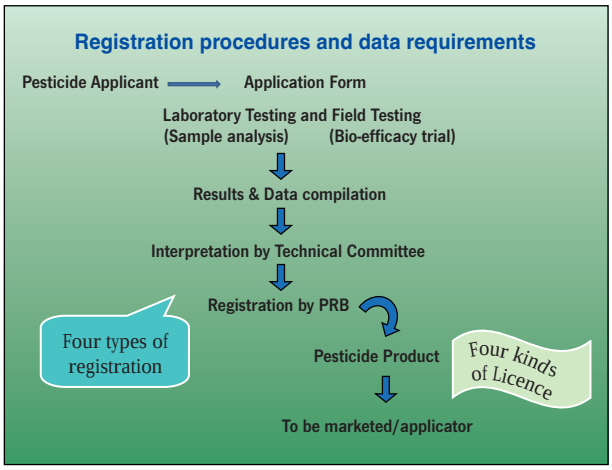
The Pesticides Law was enacted on 11th May 1990 as the State Law and Restoration Council Law No. 10/90. Procedures' relating to the pesticide law was issued by Ministry of Agriculture and Forests on 8th July 1991 by Notification No. 4/94. Formation of Pesticide Registration Board (PRB) was issued by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

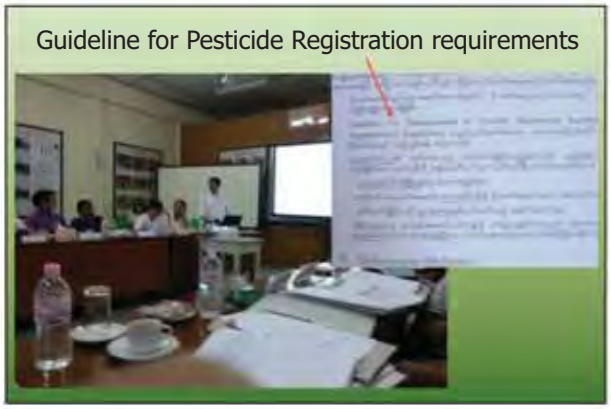
  Even though two guidelines were translated and proposed to PRB have not officially published yet, other remaining guidelines will be continued to generate.

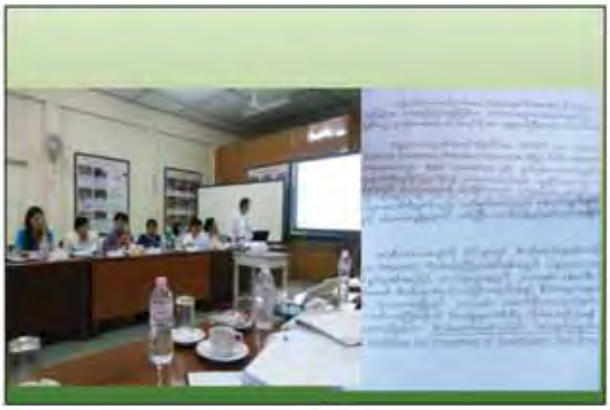
Legislation of pesticides in the country has improved the pesticides safety use in the country. Most toxic (WHO toxicity classification Ia = GHS Category 1) products have been rejected for registration and less toxic formulation are allowed.

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.





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 26º22' to 30º27' North latitude and 80º4' to 88º12' 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. Insure 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
Terai	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).

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

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,

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*, *Trichodrma 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 judicial 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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Acknowledgement:

Sincere gratitude is expressed to Ministry of Agriculture Development, Government of Nepal for nominating and providing opportunity to participate in this workshop. Sincere thank goes to FAO for providing financial assistance to cover the travel and other expenses incurred in connection to attend this workshop. The Organizing team of APPPC is highly acknowledged. Last but not least, cordial thanks go to host authority for providing assistance to organize this Workshop.

Websites for important information:

Websites	**Information**
www.moacwto.gov.np	List of pest, regulations, policies
www.spsenquiry.gov.np	SPS-Enquiry point
www.ppdnepal.gov.np	Plant Protection Directorate

Annex 1

Current pesticide consumption scenario of Nepal

S.N.	Pesticide	Total a.i. (kg or L)	Formulation			Total monitary 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 Pyrethoids	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					
	1.6.1 Avermectin	*5.8*		*116.00*	*116.00*	929.20
	1.6.2 Diamide	*19.675*	*50.00*		*50.00*	42.50
	1.6.3 Pyrazole	*83.2*	*180.00*	*23 883.20*	*24 063.20*	2 644.21
	1.6.4 Nicotinoid	*1 696.509*	*3 193.00*	*3 156.70*	*6 349.70*	17 914.37
	1.6.5 Nerestoxin (Cartap)	*7 840*		*191 400.00*	*191 400.00*	13 395.67
	1.6.6 IGR	*0.501*	*5.00*	*100.00*	*105.00*	59.22
	1.6.7 Misc (Al. phosphide)	*4 384.5648*		*7 829.58*	*7 829.58*	8 120.18
	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

Annex 2

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	”

Annex 3

Banned/prohibited Pesticides in Nepal

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

Annex 4

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

Annex 5

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)], 22nd 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.
- Cottonand 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.
  i) Punjab
  ii) Sindh
  iii) Balouchistan
  iv) Kyber Pakhtunkhawa

LAST FIVE YEARS AVERAGE AREA UNDER RICE IN PAKISTAN

YEAR	BASMATI	IRRI	OTHERS	TOTAL
	000 hectares	000 hectares	000 hectares	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	IRRI	OTHERS	TOTAL
	000 tonnes	000 tonnes	000 tonnes	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	AVERAGE PRODUCTION
	000 hectares	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	AVERAGE PRODUCTION
	000 HECTARES	000 TONNES
2006–2011	8 950.8	23 226.8

LAST FIVE YEARS AVERAGE AREA AND PRODUCTION OF SUGARCANE IN PAKISTAN

YEAR	AREA	TOTAL PRODUCTION
	000 HECTARES	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

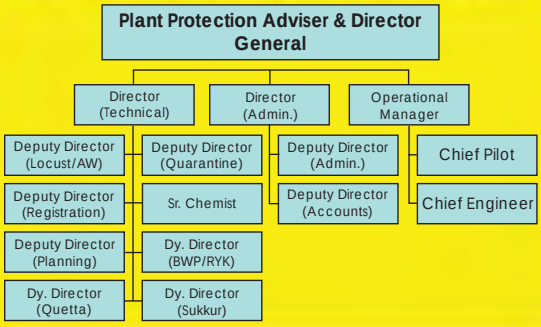
MAJORDISEASE OF COTTON IN PAKISTAN

✪ 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 Refiling 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 KG/LTS	AVERAGE VALUE OF IMPORT 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
2. BINAPACRYL
3. BROMOPHOS ETHYL
4. CAPTAFOL
5. CHLORDIMEFORM
6. CHLOROBENZILATE
7. CHLORTHIOPHOS
8. CYHEXATIN
9. DALAPON
10. DDT
11. DICROTOPHOS
12. DISULFOTON
13. DISULFOTON
14. ENDRIN
15. LEPTOPHOS
16. MEVINPHOS
17. TOXAPHENE
18. ZINEB
19. HEPTACHLOR
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)

Ms Jerolet E. Calawag Sahagun
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Fertilizer & Pesticide Authority (FPA)
Department of Agriculture
Philippines

(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-D0H)
  - 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 Accredition
- Downloadable forms

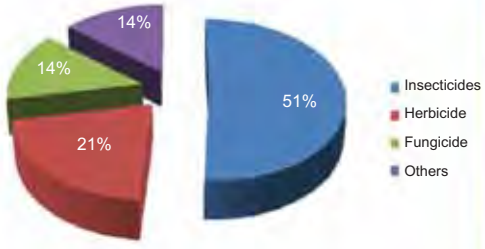
E-mail Address:
fpa_77@yahoo.com

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
Rodcnticide	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 (11ST 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 PD 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, nematicide, 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 (1st Sem)
Registered	477	534	221
Renewed	580	642	360
Total	1 057	1 176	581

LIST OF REGISTERED AGRICULTURAL PESTICIDES as of 01 JANUARY 2010

A. CLASSIFICATION BASED ON PEST CONTROLLED:

Pesticide	Pest controlled
1) Acaricide	1. mites, ticks and spiders
2) Algicide	2. algae
3) Arboricide	3. tress, 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) Nematicide	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:

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

C. Classification based on Mode of Action or Entry

1) Stomach poison:
Generally enters the pest through the mouth by ingestion and absorption in the digestive tract.

2) Contact poison:
penetrates the insect body as result of contact of the legs and other parts of the body on treated surfaces.

3) 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 weigth)			
		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 a 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

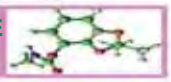
- Pesticide products, chemicals and biorationals intended for registration shall be tested for efficacy under local conditions. For field-testing necessary to generate data for registration purposes or other uses, Experimental Use Permit (EUP) shall be applied for and under no circumstance shall the 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 Process[3]

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 each[5]
- Appearance, color, state, odor
- Melting point
- Boiling point
- Vapor pressure
- Density or Specific Gravity
- Octanol Partition Coefficient

TOXICOLOGY

- Estimation of Acute Oral LD507
- Estimation of Acute Dermal LD507
- Inhalation LC50
- 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

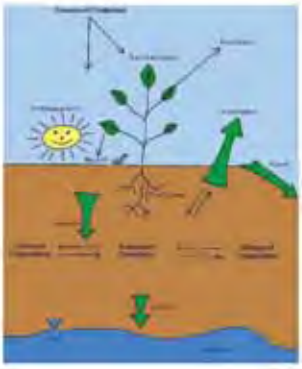
HUMAN EXPOSURE AND SAFETY

- 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 REGSTN

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 ½ 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. Thalium sulfate
13. 1-Naphthylthiourea (ANTU)
14. Gophacide
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 categorizated 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 Production 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.

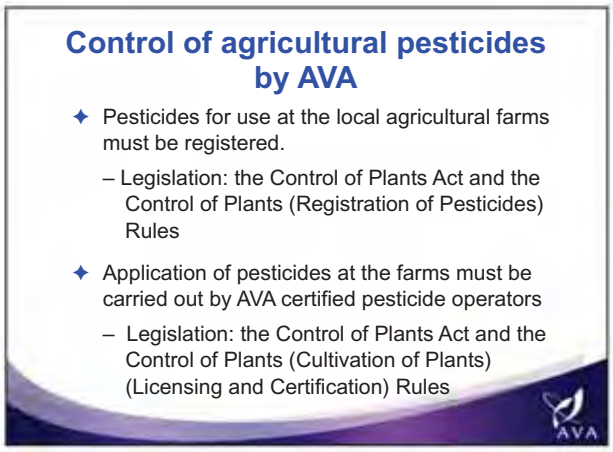
Import of Biological Control Agents

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.

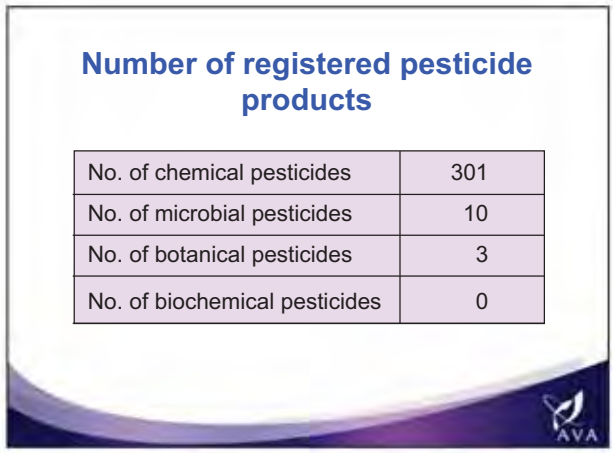


3. Pesticide Evaluation and Registration

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.



4. Post-Registration Activities

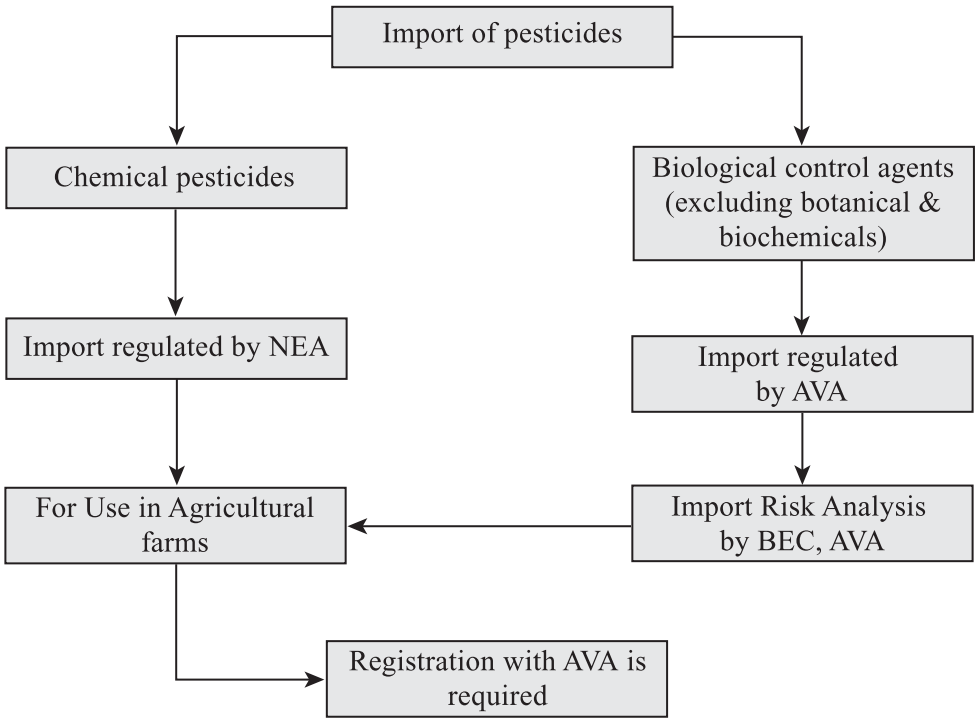
4.1 Once the pesticide products are registered with AVA, they are allowed for use in the agricultural farms. Only AVA certified pesticide operators are allowed to apply or supervise the application of pesticides at the farms. This is in accordance to Section 11 of the Control of Plants Act.

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.

Annex A

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)
   - Taxanomic 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 transmissibililty
  - Transmissibililty to other non-target organsims
  - 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 parasities/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 (35ºC 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) he 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
- TRI
- RRI
- Government Analyst
- SLSI
- Health Ministry
- Labour Ministry
- ROP
- CRI
- CEA

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

6

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

7

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, distributer, packing size, date of production or expiration and registration number.

10

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

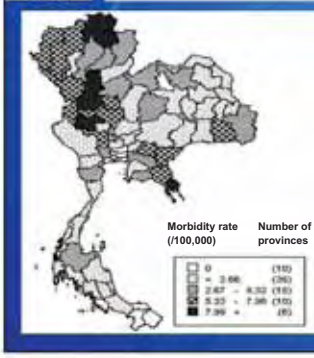
DOA monitors pesticide residues in food commodities in the market, GAP farm, packing house and port of export. Reported in DOA annual conference.

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.

14

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

15

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).

16

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.

17

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

19

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

20

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

21

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

23

THE END

THANK YOU FOR YOUR ATTENTION

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3.16 VIET NAM

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

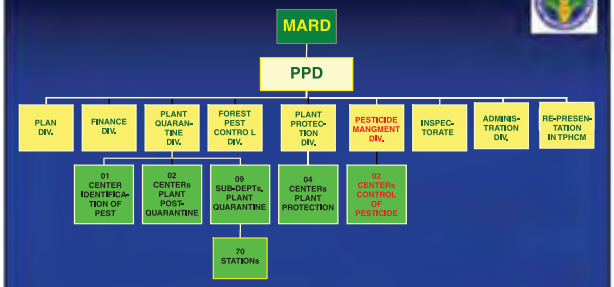
Pesticide Legislation and Regulation

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



- ☞ Headquarters in Hanoi
- ☞ Rep. off. in HCMC
- ☞ 09 specialized divisions.
- ☞ 02 Pesticide Control Centre
- ☞ 04 plant protection centres
- ☞ 09 plant quarantine sub-depts
- ☞ 70 plant quarantine stations
- ☞ 63 subPPD in the Locals

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)

Bio-efficacy trial

- For small-scale for one crop: 1 trial/location x 2 locations x 2 production area (North and Shouth) x 2 season (8 trials)
  The time testing: 2–2.5 years
- For large-scale for one crop: 1 trial/location x 1 season x 2 production area (2 trials)
- The time testing: 1 year
- PHI
- 1 trial/season x 2 season x 2 production area (4 trial)
  The time testing: 1 year
- Full registration and mixture product: Small-scale and large-scale
- Subplementary registration: large-scale

Documents for Pesticide Registration

- Aplication form for pesticide registration
- Copy of permit for pesticide field trial
- Label
- The result reports of bio-efficacy testing
- The result reports of PHI testing (chemical pesticide registry to use on vegetable, fruit or tea)

TECHNICAL DATA (1)

A. Chemistry data

I. ACTIVE INGREDIENT

I.1. Product chemistry

1. Common name
2. Chemical name (IUPAC)
3. Structural formula
4. Molecular formula/Molecular mass
5. Appearance, color, odor, physical state
6. Boiling point, melting point, Vapor pressure
7. Solubility in water and organic solvent
8. Hydrolysis
9. Photolysis
10. DT_{50}

1.2. Technical grade

1. A.i. content and amount of isomers, impuries and other by-product
2. Appearance, color, odor, physical state
3. Solubility in water and organic solvent
4. Density (liquid)
5. Process of manufacture
6. Specification with analytical methods

REQUIREMENTS FOR TECHNICAL DATA (2)

I.3. Toxicity

1. Toxicity class (WHO)
2. Acute toxicity (oral, dermal, inhalation, eye irritation, skin irritation, sensitization)
3. Chronic toxicity (short term, long term, sub-chronic)
4. Carcinogenicity
5. Teratogenicity
6. Mutagenicity
7. Effect on reproduction
8. Effect on human and environment
9. Metabolise on animal
10. ADI
11 MRL
12. Others (if available)

I.4. Ecological effects

1. Effect on fish, aquatics
2. Effect on bird, bee and wild animals
3. Effect on natural enemies
4. Others (if available).

I.5. Environment fate

1. Metabolise and degradation on plant
2. Metabolise and degradation on soil
3. Metabolise and degradation on water
4. Others (if available).

I.6. Method

1. Quality analyse
2. Residue analyse

REQUIREMENTS FOR TECHNICAL DATA (3)

II. FINISH PRODUCT

II.1. Introduce:

1. Trade name
2. Formulation type
3. Composition
4. Appearance

II.2. Physical properties:

1. Persistent foaming (depend on formulation type)
2. Suspensibility (depend on formulation type)
3. Wet sieve test (depend on formulation type)
4. Dry sieve test (depend on formulation type)
5. Flowability (depend on formulation type)
6. Emulsion stability (depend on formulation type)
7. Re-emulsification (depend on formulation type)
8. Vapour pressure
9. Solubility
10. Flash point
11. Melting point (solid), boiling point (liquid)
12. Flammability
13. Explosibility
14. Corrosiveness

REQUIREMENTS FOR TECHNICAL DATA (4)

II.3. Toxicity

1. LD50 acute oral
2. LD50 acute dermal
3. LC50 acute inhalation
4. Eye irritation
5. Skin irritation
6. Sensitization
7. Others (if available)

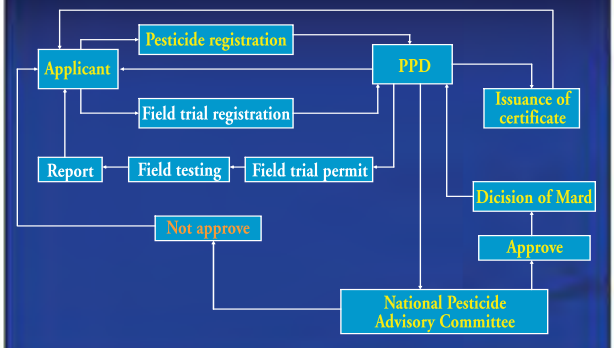
II.4. Ecological effects

1. Effect on fish, aquatics
2. Effect on bird, bee and wild animals
3. Effect on natural enemies
4. Others (if available)

II.5. Guidelines on

1. Mode of action
2. Application: Crop, target, dosage, method of use
3. Pre-harvest interval (PHI)
4. Safety directions
5. Storage and shelf life
6. First aid

Pesticide Registration Process in Viet Nam



ACTUAL STATUS – Registration

Pesticides permitted, restricted and banned to use in Viet Nam until February, 2012

Pesticides	Permitted		Restricted		Banned
	A.I.	F.P.	A.I.	F.P.	A.I.
1. Insecticide	662	1 549	6	11	21
2. Fungicide	468	1 098	-	-	6
3. Herbicide	195	584	-	-	1
4. Rodenticide	10	21	1	3	1
5. P.G.R	49	113	-	-	-
6. Insect attractant	8	9	-	-	-
7. Molluscicide	21	120	-	-	-
8. Spray adjuvant	5	6	-	-	-
9. Termiticide	12	16	2	2	-
10. Timber protection	5	7	4	4	-
11. Fumigant	5	5	3	9	-
Total	1 440	3 528	16	29	29

Note: Active ingredient may contain a single substance or a mixture.

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 restric a chemical (Annex 5)**
  - **Import response to Annex II: 33 (2011-2012)**
  - **Acknowledging Export Notification**
  - **Participate in Rotterdam Convention meeting**

MONTREAL PROTOCOL

- **PPD contol 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 Sience (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 Sience (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

- Personel for pesticide registration: 8 persons
- Personel for pesticide monitoring and enforcement: 558 persons
- Personel 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 god 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 let 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 publicizes 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.

4. Action plans and way forward

Introduction

Harmonization is generally a two-step process:

- First, international agreements need to be negotiated to define common standards or desirable ranges of acceptable practices. This may also include agreements about common strategic approaches, methods for validation or channels of communication.
- Second, individual countries then need to adjust their laws, procedures or standards so that they are in line with the international agreements and also in harmony with local needs and interests.

On the one hand, international harmonization aims to encourage the free flow of goods and services in today's globalized world. On the other hand, governments have the responsibility to protect their populations and environments against adverse effects from toxic pesticides. Pesticide regulatory management has the find the right balance between these two principles. Unilateral actions by governments can be challenged as unfair restrictions to free trade and therefore need to be justified by scientific arguments. To avoid such trade disputes, regulatory agencies are better off following international standards than setting their own norms.

Local registration authorities therefore must be aware of the consequences of their harmonization efforts and seek the right balance between the benefits from globalization and standardization, while protecting health and the environment. Under the framework of international treaties, global and regional guidelines and best practices, countries need to design their own road map into the future and the best regulatory management scheme for their needs.

At the Chiang Mai workshop, delegates compared the pesticide regulatory practices in the various countries to identify similarities and differences. Furthermore, international and regional standards as described in the 2010 *Code of Conduct Guidelines for Registration of Pesticides* and the *2011 TCP Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia* were reviewed in order to agree on priority common norms and standard procedures.

Based on the topics discussed, participants at the workshop were asked to identify which issues in the areas of

(1) legislation and administration,
(2) registration application and data requirements,
(3) data review,
(4) registration decision,
(5) post-registration activities, and
(6) regional harmonization.

were of relevance to the situation in their country and how they could be implemented within the short (2-year) and medium (5-year) term. This would help in the efforts to self-assess the progress made and identify areas where further harmonization and regional cooperation would strengthen regulatory management. Each country identified priority activities for developing regulatory capacities in a step-wise manner toward international standards as expressed in the Code of Conduct and international treaties. Such progress would also contribute toward increased food safety and sustainable development.

The following vision statements and action plans may serve the countries as a roadmap for the coming years.

4.1 BANGLADESH

Vision Statement

To establish a effective national pesticide capacities which effectively regulated and managed pesticide registration activities. Activities is a prerequisite for ensuring that pesticide use in Bangladesh are useful for controlling pest and would not causes adverse effects to human and the environment.

Action Plan

Activities	Time	Responsibility
1. To inclusion of livestock and fisheries (Amend rules)	Short time	GoB
2. To set up fast track registration (Amend rules)	Long time	GoB
3. To capacity building for further training biopesticide evaluation analysis and risk assess of the pesticide	Long time	GoB, FAO
4. To evaluation hazardous pesticides	Short time	GoB, FAO
5. Introduce written instructions for the botanical and microbial registration application	Short time	GoB
6. Establish online monitoring of registration process	Long time	GoB
7. To set full set of folders for chemical and biological control products	Long time	GoB, FAO
8. To establish labs	Short time	GoB, donors
9. Establishing of information service center	Long time	GoB
10. To assess hazardous of pesticides	Long time	GoB
11. To establish MRL labs and training of analysts	Short time	GoB, FAO
12. To adopt harmonization of labelling, data requirement, etc.	Long time	GoB, FAO
13. To capacity building efficacy protocols on pesticides	Long time	GoB

GoB: Government of Bangladesh; Short time: 2 years; Long time: 5 years

4.2 CAMBODIA

Action Plan

Activity	Description	2012	2013	2014	2015
Development regulation under the Law	1. Sub-decree 2. Proclamation 3. Joint Proclamation 4. Circular				
Translation of the five guidelines on harmonized pesticide registration and put in the regulation	1. Guidelines for harmonization of pesticide registration requirements 2. Guidelines for data requirements for the registration of biopesticide 3. Guidelines for the preparation of efficacy test protocols 4. Guidelines for harmonization of pesticide labelling 5. Guidelines for pesticide residue monitoring system				
Adaptation	– Adopt guidelines for minimum requirement for chemical pesticide and biopesticide – Adopt the guideline for labelling in line the harmonized Guideline – Adopt the guideline for information exchange in line the harmonized Guideline – Adoption of the 29 new efficacy test protocol and 40 modified FAO bio-efficacy test protocol – Adoption of guideline for pesticide residue monitoring system				
Training	1. Capacity building for pesticide registration Provide Training on pesticides formulation analysis, toxicology, risk assessment … 2. Training of relevant personnel who are direct involved in the evaluation of pesticide label 3. Capacity building and up-gradation of skill of the men who are conducting efficacy evaluation of pesticides 4. Training on advance analytical techniques, multi residue analysis and method 5. Capacity building for residue laboratory: equipment, working place…				
Strengthening and monitoring	1. Law enforcement activities 2. Law extension activities to wholesales and retailer as well as farmers 3. Strengthen awareness raising activities on proper pesticides usage application to wholesalers retailers and farmer 4. Monitor strictly for pesticide smuggling 5. Collaboration with other related in the region on pesticide management				

4.3 CHINA

Vision Statement

Build up an effective and efficient pesticide management system from legislative and practice aspects. Make sure the pesticides in sale meet the needs of consumers, and take control of the harmfulness to food safety, human health and environment.

Action Plan

Goals	Time
1. Legislation and regulations	
• Amend the Regulation of pesticide management	2013
• Renew the Guidelines on data requirements for pesticide registration	2013-2014
• Set up the Guidelines for pesticide retail licensing management	2013
• Combine and renew the Guidelines for accreditation of testing institutions for pesticide registration	2013
2. Registration Application	
• Extend the online submission and monitoring for pesticide registration	2013-2014
3. Technical evaluation	
• Designate the administrative department of agriculture on provincial level to take charge of advertisement assessment	2013
4. Registration	
• Cancel the temporary registration option	2013-2014
• Set up re-registration option	Unscheduled
5. Post-registration activities	
• Built up the licensing system for pesticide retailers	2013
• Enable the English version of notifications related to pesticide management issued by Ministry of Agriculture	2015
• Set up a system for pesticide package and waste recovery and incinerate treatment	2018

4.4 INDONESIA

Vision Statement

- To achieved sustainable and efficient pesticide regulation, which decision will be base on scientific data, by participating in regional harmonization system based on the latest FAO harmonized guidelines on pesticide regulation.
- Ensure the products that distribute and use, will be at minimum risk to human health and environment.

Action Plan

1. Legislation and Regulation

Yardstick		2013	2014	2015	2016	2017
a. REVIEW MOA DECREE ON GUIDELINES AND REQUIREMENTS FOR PESTICIDE REGISTRATION						
• Definition (to establish the similar perception)	Smooth implementation regulation					
• Clarification of biopesticide classification	Better regulation					
• Data Protection (only for new a.i. after off patent) Establish data protection frame work	compliance with WTO-TRIPS agreement					
• Technical criteria Identify what need to harmonize in the technical criteria evaluations for registrations	Better regulation					
• Harmonization guidelines (minimum data requirement, trial protocols, technical criteria)	Identify what need to harmonize in the minimum requirements evaluations for registration					
b. REVIEW MINISTER OF AGRICULTURE DECREE ON PESTICIDE MONITORING						
• Sampling method	Establish SOP and scope of work, for National Pesticide supervisor team					
• Licensing for pesticide supervisor						
• Scope of work						

2. Registration Application

Yardstick		2013	2014	2015	2016	2017
a. Procedures						
• Establish guidelines	Finale review of new MOA decree					
• Establish online monitoring system	Propose project proposal for Budget					
• Establish online application	To establish online monitoring system and mechanism for online application					
b. Minimum data requirements						
• Chemicals	Identify what need to harmonize in the minimum requirements evaluations for registered chemicals, biopesticide and microbial pest control agent					
• Biopesticide						
• Microbial Pest control agent						

3. Technical Evaluation

Yardstick		2013	2014	2015	2016	2017
• Risks assessment (Toxicity data)	Enhance the risk assessment criteria based on current international guidelines					
• Bio-efficacy (minimum efficacy, number of trials)	Identity gaps in the harmonization of bio-efficacy evaluation criteria					
• Ecotoxicity (e.g. bees)	Identify what need to harmonize in the ecotoxicology evaluation criteria					

4. Registration

Yardstick		2013	2014	2015	2016	2017
• Registration	Regional harmonization on minimum requirement of dossier					
• Label and Validity period	Labelling requirements according to GHS					
• Banned and restricted pesticides	According to new implementation on harmonized pesticide regulations					
• Active ingredients banned for all uses of pesticide/ household only and fishery						
• Raw materials banned in formulation for all uses of pesticides/for household only.						
• Active ingredients as restricted use						
• Raw materials restricted for crop protection use						

5. Post-Registration Activities

Yardstick		2013	2014	2015	2016	2017
• Licensing According to new MOA decree implementation on harmonized pesticide regulations	Better and harmonized regulation					
• Bio-efficacy According to new MOA decree implementation on harmonized pesticide regulations	Better and harmonized regulation					
• Quality and residue monitoring Develop guideline for monitoring pesticide quality	SOP for pesticide monitoring					
• Enforcement regulation with requirement of international treaties	Better and harmonized regulation					
• Information exchange Harmonize the criteria	Better and harmonized regulation					
• Publish “green book” (annually) Distribute the products information which already approved by the MOA	Transparency and publish the list of products which valid and approved by MOA					

6. Harmonization

Yardstick		2013	2014	2015	2016	2017
• Harmonize the pesticide regulation based on the latest FAO code of conduct (FAO guidelines)	Identify what are the gaps of the current guidelines compared to the latest FAO guidelines					
• Regional Harmonization Identify what are the requirements need to regional harmonization Establish Asian information exchange portal	Better regulation and harmonized					
• International treaties	Strengthen compliance to commitment to international treaties					
• Information exchange	Harmonize the criteria for information exchange					

7. Others Issues

Yardstick		2013	2014	2015	2016	2017
• ESTABLISH RULE ON PESTICIDE ADVERTISING	Set up for the enhancement of the rule on pesticide advertising activities					
• ESTABLISH RULE ON PESTICIDE TRANSPORTATION	Set up for the enhancement of the rule on pesticide advertising activities					
• TRANSPARENCY	Support transparency and accountability in the regulation of pesticide					
• Review and enhance qualifications and capability of the Pesticide Registration committee	Need to have a solid team and enhance qualifications especially for registration teams					
• Capability Building for registration Officer handling biocontrol agents	Need to have capacity building training by expert in the evaluation and assessment of crop protection products. Especially for Biological pesticides					

4.5 JAPAN

Vision Statement

(1) Ensure that decisions are made on the basis of scientific data and information taking into account magnitude of risk, rather than hazard

(2) Participate in international rule-making in Codex Alimentarius Commission, OECD, etc. and harmonize with these rules

(3) Ensure transparent decision-making through risk communication with all stakeholders

Action Plan*

*Note: Actions listed are all relevant, but the indicated time frames only reflect the view of the presenter and should not be taken as national commitments.

Registration applications

~ Procedures ~

	Time frame
Acceptance of electronic files	By 2014
Acceptance of study reports in English	By 2014
Acceptance of dossiers in OECD format	By 2014

~ Minimum data requirement ~

	Time frame
Crop grouping for residue evaluation	By 2015
Residues in follow-up crops (to be required on more regular basis)	By 2014
Processing study on crop residues (as optional requirement)	By 2013
Livestock metabolism and transfer study	By 2013
Test guidelines for natural enemies (macrobials)	By 2015
Reorganization of test guidelines into a single documents, possibly taking a tiered approach for data requirement	By 2016

Technical evaluation

	Time frame
Protocol to establish ARfDs (Acute Reference Doses)	By 2014
Protocol to evaluate short-term dietary intake	By 2014
Protocol to establish AOELs (Acceptable Operator Exposure Levels)	By 2014
Establishment of an exposure mode to estimate operator exposure levels	By 2015

Registration

	Time frame
New policy on the risk management options on pesticide residues in follow-up crops (e.g. establishment of MRLs for follow-up crops)	By 2014
Establishment of fast-track registration procedure based on national specification for least hazardous pesticides	By 2017
Establishment of rules on third-party use of the data submitted by original registrants for the purpose of registering generics	By 2017
Establishment of national specifications on technical material as criteria for substantial equivalence of generics	By 2017
Establishment of an exposure mode to estimate operator exposure levels	By 2017

Other aspects

~ Transparency ~

	Time frame
Publication of the SOP (Standard Operating Procedures): work flow	By 2013
Publication of the SOP: detailed rules for technical evaluation	By 2014

4.6 KOREA, DPR

Action Plan

Category	Activity	Period
Legislation and regulations		
• changes in sector responsibilities	Set up committee for the Integrated Pesticide Management	2013-2014
• legislation amendments	Detailed Rule for Enforcement Regulation based on Int. Code of Conduct, etc. • registration, decision making set up, • license Import/Export • Labelling/Package/Advertise	
• in-country harmonization	Training on revised Detailed Rule for Enforcement Regulation with requirement of Int. Treaties	
Registration Application		
a. Procedure • written guidelines	Harmonization of data requirement for application based on intern. test protocols Renewal of local test protocol for main crops and pests	2013– 2015
• online application	National Network for Registration Application	
b. Minimum data requirements • chemical • biochemical • microbial pest control agents • other	Particularly toxic and adverse effects to Environment	
Technical evaluation		
• risk assessment, • bio-efficacy, • ecotoxicology • quality • residue • hazard • labelling	Renewal guidelines for each assessment based on Int. Treaties	2013– 2015
Registration		
• registration options • label • validity period	Review registration procedures on provisional, full, conditional, renewal and re-registration; labelling and validity period	2013–2015
• banned and restricted pesticides	Update the list of Banned/Restricted pesticides in practice	
Post-registration activities		
• quality/residue monitoring	Monitoring quality control and adverse effects to human food and environment	2013–2018
• information exchange	Establishment of Centre for Pesticide Information Integration and Sharing • Capacity Building for monitoring Quality, Residue and Environment – Personnel – Laboratory	

Category	Activity	Period
Harmonization		
• regional harmonization	Regional harmonization on quality, label, residue, risk and hazard	
• international, treaties	Int. Harmonization on Guidelines of FAO, OECD, WHO	

Timetable

No.	Activities	2013	2014	2015	2016	2017	2018
1.	Set up committee for the Integrated Pesticide Management						
2.	Detailed Rule for Enforcement Regulation based on Int. Code of Conduct						
3.	Training on revised Detailed Rule for Enforcement Regulation with requirement of Int. Treaties						
4.	Harmonization of data requirement for application based on Int. Test Protocols						
5.	National Network for Registration Application						
6.	Particularly toxic and adverse effects to Environment						
7.	Renewal guidelines for each assessment based on Int. Treaties						
8.	Review registration procedures on provisional, full, conditional, renewal and re-registration; labelling and validity period						
9.	Update the list of Banned/Restricted pesticides in practice						
10.	Monitoring quality control and adverse effects to human food and environment						
11.	Establishment of Centre for Pesticide Information Integration and Sharing						

4.7 LAO PDR

Vision Statement

Pesticide management is very important for protecting human health, animal and environment, therefore need to make attention to harmonize with others countries by using international acceptance guideline for regulating the importation, distribution and use in the country.

Action Plan

Legislation and regulations, agencies, committees

- Disseminate pesticide regulation and overall of guideline for harmonization on data requirement of pesticide registration.
  - Organize meeting with National Codex committees of Lao PDR on identification and certification of evidence of pesticide effect and setting up system of residue monitoring.

Registration Application

- The Pesticide Registration Unit should revise the application form for plant protection product and submit to Director General for approval.
- Develop check list related data requirement on chemical, biochemical, microbial and botanical pest control agents.

Technical evaluation

- The registrar should revise all documents of registered pesticide that provided by applicants based on harmonization guidelines.
- The DOA will organize training workshop on evaluation of pesticide inspection for 44 provincial staffs.

Registration

The registration unit should revise the process of pesticide registration and obligate applicants to translate label into Lao language by using simple format that DOA determine.

Registration pesticide should be also made attention on registration certificate from exported country and all related data.

Post-registration activities

DOA set up criteria for province in issuing license for importation pesticide.

The registration unit will develop guideline for monitoring pesticide quality and provide to provinces.

- Build up infrastructure on pesticide formulation analysis

	Action plan	Year
1.	Revise the application form and data requirement	2013
2.	Organize training workshop on evaluation of pesticide inspection	2013
3.	DOA set up criteria for province in issuing license for importation pesticide	2013
4.	Revise the process of pesticide registration	2013
5.	Organize meeting with National Codex committees of Lao PDR on identification and certification of evidence of pesticide effect and setting up system of residue monitoring	2014
6.	Revise all documents of registered pesticide	2013-2014
7.	Disseminate pesticide regulation and overall of guideline for harmonization on data requirement of pesticide registration	2013-2014
8.	Develop guideline for monitoring pesticide quality and pro	

4.8 MALAYSIA

Action Plan

Proposed Action Plan	Timeline	2013	2014	2015	2016	2017
Legislation & regulation	2013-2014	/	/			
Amendments of Law to strengthen enforcement, to comply with government directives & to remove inconsistencies	2013	/				
Amendment of the Rules and Regulations for pesticides advertisement & Pest Control Operators	2013	/				
Amendment of the Rules and Regulations for Labelling and Registration Rules	2013-2014	/	/			
Registration Application						
a. Procedure						
Amendment of written guidelines to incorporate harmonization of data requirement in Labelling, Registration & Residue Guidelines	2013-2014	/	/			
Amendment of written Guidelines to incorporate harmonization of data requirement in Toxicology & Efficacy Guidelines	2015			/		
Amendment of written guidelines to incorporate harmonization (minimum data requirement) for Biochemical & Microbial PCA	2016				/	
Technical Evaluation – Training in assessment						
• Risk assessment BPCA	2016-2017				/	/
• Bio-efficacy BPCA	2016-2017				/	/
• Analysis of BPCA	2016-2017				/	/
• Technical evaluation following Principle of Equivalence	2015-2016			/	/	
Registration – Amend pesticide labelling requirements according to GHS if required	2014		/			
Post-registration Activities						
Improve Information exchange	2013	/				
Harmonization						
Adoption of harmonized guidelines						
Pesticides registration	2014		/			
Pesticide labelling	2014		/			
Residue monitoring system	2014		/			
Efficacy test protocols	2015			/		
Toxicology protocols	2015			/		
Biopesticide and microbial PCA	2017					/
Other issues						
(Capacity Building) Training for:						
• Information exchange on pesticides regulatory requirements (2 participants, e.g. request APPPC)	2013	/				
• Application of Principles of Equivalence (4 participant) for pesticide assessment	2014		/			
• Risk assessment of BPCA (2 participant, e.g. request GIZ)	2015			/		
• Bio-efficacy for BPCA (2 participant, e.g. request GIZ)	2015			/		
• Analysis of BPCA (2 participant, e.g. request GIZ)	2015			/		

4.9. MYANMAR

Vision Statement

To avoid negative impact on agro-ecosystem, human health and their environment and favourable for adoption the pesticides safety use in Myanmar, the country will harmonize its pesticides implementing rules and regulations among the TCP countries based on harmonized new guidelines section and related to other international guidelines, particularly the latest FAO harmonized guidelines on pesticide regulatory management.

Action Plan

Proposed work plan	Activity	2-year plan	5-year plan
Legislation and Regulation			
• Legislation amendments	Legislation amendments in line with pesticide harmonization requirements and parliament discussions	2013-	2015
• Changes in Pesticide Procedure relating to the current Law	The related procedure in Law in line with new guidelines of harmonized on pesticide regulatory management	2013-	2015
• Changes in pesticide definitions in details	According to the International Code of Conduct on the Distribution and Use of Pesticide latest version FAO (2010)	2013-2014	
• Changes decision making set up	Reform the Pesticide Registration Board members	2013-2014	
Registration Application			
(a) Procedure • Written guidelines – Labelling – Bio-efficacy protocols – Residue monitoring – Registration requirements – Biopesticide registration	Installation of new guidelines that based on harmonization of data requirements for application Labelling requirements according to GHS. Renewal of local test protocols	2013-	2015
• Application form with instructions for applicants	Considering with Initial administrative actions/Issue of acknowledgement	2013-2014	
(b) Minimum data requirements • chemical pesticides • botanical pesticides • biochemical pesticides • microbial pesticides • others	Fully regulate for chemical, botanical and biochemical pesticides with the harmonized data requirements in TCP Need to identify and fully regulate for microbial pesticide and biocontrol agents	2013- 2013-	2015 2017
Technical evaluation			
• Labelling • Bio-efficacy • Ecotoxicology • Residue • Risk assessment • Check list	Make renewal & adopt the harmonized technical evaluation and analysis criteria Adopt the check list for completeness of documents from this workshop	2013- 2013-2014	2015
Registration			
• Registration types	According to new implementation on harmonized pesticide registration as supplementary registration	2013-	2015
• Validity period	Procedures to cancel or restrict a valid registration	2013-2014	
• Label	Bilingual labels (English & national language)	2013	

Proposed work plan	Activity	2-year plan	5-year plan
Post-registration activities			
• Licensing	Support to post-registration activities by using national & international programmes	2013-	2017
• Monitoring on pesticide quality and application	Monitoring of adverse effects on the environment and correct pesticide usage in field	2013-	2017
• Enforcement	Procedure against: – low-quality, unregistered, illegal trade and misleading advertisement	2013-	2017
• Information exchange	Publishing of list/database on registered pesticides Publishing the list of Banned/Restricted pesticide in practice Unscheduled reviews when new information becomes available	2013-	2017
Harmonization			
• Regional harmonization • International implementation, treaties	Further development through coordination with regional and international harmonization on guidelines of FAO, WHO, UN, OECD	2013-	2017

4.10 NEPAL

Vision statement

1. Short term: Having judicious and rational use of pesticide so that there will be minimum risk to human health & environment.
2. Long term vision: Having established and at least optimum harmonized legislative framework with equipped organizational set up (HR, FR, Technical capability) for pesticide management.

Action Plan

Aspects	2 years action plan	5 years action plan	Assumptions	Indicators
Legislation & regulation, Agencies, Committee		• The formation of New act will be completed which is in the process • Pesticide policy will also be completed which is in the process	• Stable government • Actors positive towards new act	• Regionally and internationally harmonized act & policy instrument available • Efficient & rational use of pesticide • Minimum risk to human health and environment

Aspects	2 years action plan	5 years action plan	Remarks
Registration Application	Separate registration procedure for different types of pesticides		
Technical Evaluation	Technical committee will be upgraded to registration committee with qualified experts from concerning field		
Registration		Regional harmonization at least on minimum requirement of dossiers	
Post-registration activities	• Pesticide quality analysis • Residue monitoring on agri. product • Monitoring & supervision (retailer, formulator, whole seller)	• Continuous • Pesticide Lab will be operationalized	With an assumption that there will be a stable government which gives priority on pesticide management programme
Harmonization	Information exchange PRMD will have pesticide database software and website	Regional & International harmonization at least on minimum requirement of pesticide registration, DATA review, residue analysis, etc.	

Time frame

Aspects	2013	2014	2015	2016	2017
The formation of new act will be completed which is in the process					
Pesticide policy will also be completed which is in the process					
Separate the registration procedure for different types of pesticides					
Technical committee will be upgraded to registration committee with qualified experts from concerning field					
Regional harmonization at least on minimum requirement of dossiers					
Pesticide quality analysis					
Residue monitoring on agri. product					
Monitoring & supervision (retailer, formulator, whole sellor)					
Pesticide Lab will be operationalized					
Information exchange PRMD will have pesticide database software and website					
Regional & International harmonization at least on minimum requirement of pesticide registration, DATA review, residue analysis, etc.					
Training curriculum & training schedule will be revised to ensure that capable person involved in pesticide affair (selling, spraying, using)					

4.11 PAKISTAN

Vision

- To maintain hazardous free environment and human health in collaboration with and under guidelines of International Organizations like WHO/FAO framing and introducing harmonized legislative framework and pesticides management system.
- To introduce fast track Registration and Import Permission of safe pesticides with minimum requirement according to needs of farmers for ensuring food security and food safety.

Action Plan

Goals	Time frame	
	2-year plan	5-year plan
I. LEGISLATION AND REGULATIONS, AGENCIES, COMMITTEES		
• Make amendment for including registration of House Hold pesticides under National Authority along with Agricultural Pesticides.		2013–2015
• Make amendment for registration of pesticides for export purpose, biological pest control agents, Biochemical Pesticides, Non-Pesticides Active Ingredients, experimental and emergency use pesticides, setting up of guidelines in connection with prompt decision implementation of international treaties regarding hazardous pesticides and Persistent Organic pollutants, evaluation of residue, risk assessment of pesticides locally and trans-boundary movement of waste, development of more simple national pesticides registration scheme, good labelling practice, globally harmonized system of classification, industry data submission on plant protection products and their active substances, enforcement of pesticides regulatory programme, pest and pesticides management policy development to establish a common quality standards, experimental use pesticides.		2013–2016
• Make amendment for granting powers of legislation in Agricultural Pesticides law by the Federal Govt. to provincial Govt. to the extent of licensing of Distributors, retailers, dealers, storage, sale, application, disposal, inspection at retailer end, setting up of quality control labs, supply of quality pesticides to the consumers, Judicious use of pesticides, Integrated pest Management, risk assessment, residues, eco-toxic, bio-efficacy and hazards study, inspection, setting up of quality analysis labs, and offences and punishments.	2012-2013	
• Make amendment for constitution of Provincial Agricultural Pesticides Technical Committee to advise the Provincial Govt. on technical matter related to pesticides use, storage, sale and any other matter assigned to them.	2012-2013	
• Make amendment in definition of Pesticides scope as per latest FAO guidelines.	2012-2013	
• Make amendment and guidelines for introducing in-country harmonized law.	2013-2014	
II. PESTICIDES REGISTRATION APPLICATION		
• Amendment for revised and comprehensive written guidelines for registration of all kinds of Agricultural and House Hold pesticides in application Form as per FAO guidelines and OECD format.	2013-2014	
• Amendment for acceptance of study reports from any internationally accredited labs of the manufacturer, independent accredited labs, internationally recognized Universities, Research Institutes and any published data in an internationally recognized paper for registration of any pesticides.	2013-2014	

Goals	Time frame	
	2-year plan	5-year plan
• Amendment for acceptance of electronic files for registration and import permission of pesticides along with supporting documents and their online verification from concerned authorities.		2013–2016
• Amendment for online monitoring of registration, length of data protection period, online sharing of non-protected data regarding public, health and safety, grant waivers from certain data requirement in case of emergency and request.		2013–2016
• Amendment for minimum data requirement for safe and highly used pesticides to incorporate them in Integrated Pest Management Plans.	2013-2014	
III. TECHNICAL EVALUATIONS		
• Make amendment for acceptance of dossiers regarding quality assessment of impurities of Active Substance, inert materials, hazards to environment, Maximum Residue Limit, risk assessment, bio-efficacy, labelling, ecotoxicology from the manufacturer of OECD countries, China and India where the product is manufactured, extensively used on target pest and registered or any internationally recognized University and Research Institute in case of import permission of pesticides under generic name and newly developed pesticides.	2013-2014	
• Make amendment for local evaluation of quality assessment of impurities of Active Substance, inert materials, hazards to environment, Maximum Residue Limit, risk assessment, bio-efficacy, labelling, Ecotoxicology in case of introduction of newly developed chemical, molecules and hazardous pesticides.	2013-2014	
IV. PESTICIDES REGISTRATION		
• Amendment for grant of registration and import permission for least hazardous pesticides verifying its online registration, extensive use and manufacturing in its country and relying on electronically dispatched documents from the registered manufacturer in support of applications.	2012-2013	
• Amendment for grant of registration and import permission, in case composition and specification against a registered product in the country of manufacturer from its principal manufacturer is accepted by the department, to all applicants from the said source based on same composition and specification on production of even direct electronic consent from the manufacturer in favour of other applicant.	2012-2013	
• Make amendment for grant of registration and import permission in case of newly developed pesticides with trade name based on the information of its principal manufacturer but after complete verification of valid and authentic dossiers from their concerned quarters.	2012-2013	
• Make Amendment for good labelling practice as per recent FAO and OECD countries guidelines.	2013-2014	
• Make amendment for revoking/cancel registration and prohibit import, sale, and storage and ensure safe disposal of banned and restricted pesticides declared by international treaties.	2013-2014	
V. POST-REGISTRATION ACTIVITIES		
• Made Amendment in Federal pesticides law for transfer of powers of making legislation in pesticides law to the extent of monitoring and inspection of quality of pesticides at distributor and retailers, sale of quality pesticides at consumer end, storage of pesticides, disposal of pesticides, quality analysis of pesticides, licensing of distributors, dealers, offences, punishments, introducing Integrated Pest Management approach, study of MRL, hazardous effect on environment, training of farmers in judicious use of pesticides, pesticides poisons cases of humans, etc. and Federal inspectors to the extent		2012–2015

Goals	Time frame	
	2-year plan	5-year plan
of import, registration, formulation, refilling and for introduction of uniform and harmonized enforcement system in the country.		
• Make amendment for a) Specific guidelines for information sharing. b) Publication of data based list of registered pesticides regularly. c) Notifications of regular reports on observance of Code (Annex A). d) Final regulatory actions (Rotterdam), PIC procedure. e) MRL established in the country. f) Restricting Transport and marketing of pesticides along with consumer goods. g) Illegal trade of pesticides. h) Misleading advertisement. i) Monitoring and analysis of inert material, impurities of active ingredients, imported intermediates and precursors for pesticides manufacturing.		2013–2015
VI. HARMONIZATION		
• Make amendment to ensure regional harmonization on registration, quality, 100 percent break up of finished product and its technical, label, bio-efficacy, Ecotoxicology hazards, residues, and risk test protocols under guidelines of FAO, OECD, and WHO.		2013–2016
• Make amendment to ensure compliance of International Treaties like, Rotterdam Convention, Stockholm Convention, Basal Convention under guidelines of FAO, WHO, and OECD	2013-2014	
• Make amendment for information exchange among regional countries, importing countries, OECD countries, etc.	2013-2014	
VII. OTHER ISSUES		
• For transparency, guidelines/SOP for registration of pesticides, formulation plants, re-filling plants, all kinds of studies shall be made public online.	2013-2014	
• Public participation shall be enhanced by arranging seminars, workshops, walks, and trainings.	2013-2014	

4.12 PHILIPPINES

Vision Statement

In order to ensure the safe use of pesticides and protect human and animal health and the environment from any detrimental effects of pesticides in harmony to the global vision to achieve sustainable development, in 2018, the country will harmonize its pesticides implementing rules and regulations among the TCP countries based on international guidelines, particularly the latest FAO harmonized guidelines on pesticide regulation provided that the approach/ chosen criteria is politically & financially feasible for the country; will not compromise the human health; nor create negative impact to the biodiversity and environment.

Action Plan

Legislation and regulations, agencies, committees

2-year plan	5-year plan
• Draft guidelines on biopesticides for the review of technical advisory committee	• Issue a legislation and publish FAO harmonized guidelines on the registration of biopesticides & biocontrol agents
• Adopt the latest definition of pesticides by FAO (2010) which include biocontrol agents	• Complete institutionalization and of harmonized pesticide guidelines that covers biopesticides
• Issue legislation on the harmonization of data requirements for different types of pesticides	• Harmonize the pesticide regulation in the Philippines based on the latest 2010 FAO Code & Conduct in the use and distribution of pesticides & other related FAO guidelines
• Review and enhance qualifications and capability of the Pesticide Registration Committee	• Capability building for the members of Registration Committee and Pesticide Registration officers
• Capability Building for registration officer handling biocontrol agents/biopesticides	Continue technical capability building

Registration Application

a. Procedure

2-year plan	5-year plan
Identify the gaps and weakness of the current Philippine registration application versus the harmonized FAO guidelines	Harmonize registration application procedures, enhancing the current written application guideline procedure
Propose project proposal for financial budget and allocation from sponsoring agencies to establish online monitoring system and mechanism for online application	Establishment of functional online system for registration of application and online monitoring

b. Minimum data requirements

2-year plan	5-year plan
Identify what need to harmonize in the FAO latest data requirements for chemical, microbial and biochemical and biological pesticide registrations	Harmonized data requirements with other TCP countries

Technical evaluation

2-year plan (2013-2014)	5-year plan (2013–2018)
Enhance the risk assessment criteria based on current international guideline and current situation of the country	Adopt the harmonized risk evaluation criteria
Identify gaps in the harmonization of bio-efficacy evaluation criteria	Adopt the agreed harmonized bio-efficcay evaluation criteria
Identify what need to harmonize in the ecotoxicology evaluation criteria	Adopt the harmonized ecotoxicology evaluation technical evaluation criteria

Registration

2-year plan (2013-2014)	5-year plan (2013–2018)
Deliberate the need of the country to have all types of pesticide registration options are available & issue related guidelines	Adopt harmonized registration options
Identification of gaps and testing of comprehensibility of the farmers on the FAO harmonized guidelines	Adopt harmonized FAO labelling guidelines
Defend and rationalize the need to harmonize validity period of registration, current practice: 1 yr for condition registration and 3 yrs for full registration	If politically feasible, amendment of guidelines based on the harmonized validity period of pesticide registration

Post-registration activities

2-year plan (2013-2014)	5-year plan (2013–2018)
Set up programmes for the enhancement of the pesticide postregistration activities such as licensing, enforcement, residue monitoring, information exchange, publishing updated database on pesticide registration	Utilize national and international programmes that support pesticide post-registration activities
Establish and strengthen information exchange within the country's regional territories particularly about the banned and restricted pesticides	Establishment of the functional Information Exchange National Portal with linkages among asian nations
Strengthen the pesticide residue monitoring system through provision for financial support and more coordination with other concerned agencies.	Establishment of a sustainable residue monitoring system nationwide

Harmonization

2-year plan (2013-2014)	5-year plan (2013–2018)
Identify what are the gaps of the current Philippine guidelines on pesticide regulation compared to the current FAO guidelines and the current pesticide regulatory system of other TCP asian countries Identify what are the requirements need to harmonize aside from the biopesticides that the current Philippine pesticide regulation guideline failed to cover	Adoption of the agreed regional harmonized criteria of the different FAO guidelines
Harmonize the criteria for information exchange	Establish asian information exchange portal
Strengthen compliance to commitment to international treaties	Continue capability building related to international treaties

Other issues

1. **Transparency**
   Support transparency and accountability in the regulation of pesticides
2. **Capacity Building**
   The Philippines is in need to have capacity building by experts in the evaluation and assessment of crop protection products; experts from different fields most particularly in biological pesticides and experts in the application of harmonized labelling of pesticides. While the country is open for harmonization, other aspects such as budget allocation and manpower resources are worth considering. All registration officers must be trained adequately (e.g. annually) by the recognized experts of FAO in the field of crop protection products.
3. **Adoption of FAO harmonized pesticide regulation** guidelines shall be based on the need of the country. The Philippines has in place pesticide registration system that protects human, animal health and environment from the adverse effects of chemical pesticides. However in the current guideline, some of the biopesticides are not covered.
4. There is a need to identify what are the gaps of the country's current registration system compared to other asian countries for a horizontal harmonization approach in order to protect the right of other country to practice "self-determination" with respect to the concept of precautionary principles.

4.13 SINGAPORE

Action Plan

Registration Aspects	Action Plan – Initiatives for Enhancement of Pesticide Regulatory Management	
	2-year	5-year
Administrative set up and infrastructure	Status quo Improved communication between agencies involved i.e. from import to registration Import is regulated by another government agency	Status quo
Application for registration	• Fast track approval for specific products • Minimum data requirements for specific products	• Consider adoption of ASEAN data requirements for biological control agents
Data review and registration decision	• Strengthening technical evaluation by adopting guidelines applicable to SG's context. • Adoption of GHS for pesticide hazards evaluation & labelling when available.	• Strengthening technical evaluation by adopting guidelines applicable to SG's context. • Adoption of GHS for pesticide hazards evaluation & labelling when available.
Post-registration activities	Phased in strengthening of post-registration activities: • Monitoring of farm usage • Collection of data – farm usage	Phased in strengthening of post-registration activities

4.14 SRI LANKA

Vision Statement

Management of Pesticides in the country in order to cater the all stakeholders in the best manner ensuring minimum risk & maximum efficacy.

Action Plan

Objective	2013	2014	2015	2016	2017
Registration of microbial pesticides & biocontrol agents in the country	Preparation of national guidelines for registering of microbial pesticides & biocontrol agents (with tiered approach) accordance with the FAO guidelines				
Ensure the proper pesticide dossier evaluation procedure			Increase the number of professional personal involve in the data evaluation process by 4		
Ensure no pesticide residues in consumables	Establishment of MRLs & do residue analysis of consumables				
Ensure Non polluted environment	Start residue analysis of environmental samples (i.e. Soil, water, etc.) & if there are residues Do awareness campaigns to farmers on proper use				
Obtain reliable data		Get the quality control lab & residue analysis lab accredited internationally			
Upgrade the expertise of the Human resources in the agency			Sending existing personal for overseas trainings on residue analysis, maintenance & proper usage of analytical equipments		
Exchange Information easily among APPPC countries	Harmonization of the agreed matters according to the APPPC workshop				

4.15 THAILAND

Action Plan

	Activity	Period
Legislation and regulations, agencies, committees		
• legislation amendments	Amend data requirement for biocontrol agent to be minimum to facilitate more registration.	2013
• in-country harmonization	Harmonized standard deviation of technical material and finished product labelling (adopt GHS).	Currently
Registration Application		
a. Procedure		
• written guidelines	Details of registration procedure have been put in Notification of DOA entitled Determination of details, criteria, and procedure for registration of pesticide under responsibility of DOA B.E. 2552 (2009).	Currently
• online monitoring	Results of quality control monitoring will be uploaded on DOA website	2014
• online application	Import and having in possession license shall be applied online	2015
b. Minimum data requirements		
• chemical,	The minimum data requirement shall be finalized	2015
• biochemical and	The minimum data requirement shall be finalized	2015
• microbial pest control agents	The minimum data requirement shall be finalized	2015
Technical evaluation		
• bio-efficacy	Develop bio-efficacy protocols for microbial and botanical control agent as well as pheromone	2015
Registration		
• registration options	Full registration experimental use permit	Currently 2013
• label	Draft notification relating to label Adopt GHS	2015
• banned and restricted pesticides	Currently 96 pesticides banned Reviews registration of carbofuran, dicrotofos, EPN, methomyl. If the result of the review leads to ban, DOA will take action.	2012-2013
Post-registration activities		
• residue monitoring,	TCP guideline adopted	Currently
• information exchange	Information relating to pesticide will be uploaded	2014
Harmonization		
• regional harmonization	Harmonized TCP guideline shall be adopted	2015
• International, treaties	Already complied with Rotterdam, Stockholm and Basel Conventions; Montreal protocol and FAO Code of Conduct.	
• Information exchange	Recommendation for information exchange shall be adopted	2015
Other issues		
• Public participation	Public hearing has to be done before issuing every rules and regulations	Currently

4.16 VIET NAM

Vision Statement

Set up the pesticide management systems are effective, safety and transparency

Action Plan

Legislation and regulations, agencies, committees

- Submit the pesticide law in 2013

Building up the regulation under law

Registration Application

Minimum data requirements

Building up Guideline for: chemical, biochemical and microbial pest control agents (in line with TCP guideline)

Bio-efficacy protocol

Adoption of the 29 new efficacy test protocol and 40 modified FAO bio-efficacy test protocol.

Technical evaluation

Building up Guideline on technical evaluation in line with TCP guideline for: risk assessment, bio-efficacy, ecotoxicology.

Registration

Building up labelling guideline following GHS

Post-registration activities

Building up Guideline on residue monitoring in line with TCP guideline

Building up: Guideline in line with TCP guideline for information exchange

Time frame for action plan

No.	Action	2013	2014	2015	2016	2017	2018
1.	Building up the regulation under pesticide law	V	V	V			
2.	Guideline minimum data requirement for chemical pesticide and biopesticide	V	V	V			
3.	Guideline for labelling following GHS (in line with the TCP guideline)	V	V	V			
4.	Building up Guideline on technical evaluation for: risk assessment, bio-efficacy, ecotoxicology	V	V	V			
5.	Guideline in line with TCP guideline for information exchange	V	V				
6.	Capacity building for registration division Training on risk assessment, bio-efficacy, ecotoxicology, toxicology, evaluation of pesticide label	V	V	V			
7.	Capacity building for conducting efficacy			V	V		
8.	Capacity building for residue monitoring	V	V	V			
9.	Bio-efficacy protocol Adoption of the 29 new efficacy test protocol and 40 modified FAO bio-efficacy test protocol (2014)	V	V				

4.17 OPPORTUNITIES FOR FUTURE HARMONIZATION

International harmonization refers to the process of standardizing laws, regulations and practices to facilitate global trade and to encourage the free movement of capital, goods, people and services. It aims at adjusting differences and inconsistencies to make them more uniform or mutually compatible. Harmonization is usually an open-ended process that gradually moves toward greater uniformity by setting limits to the degree of variation.

Advantages from standardization and harmonization are often reduced cost, improved quality and easier management. Harmonization makes processes more reliable, it improves efficiencies and ensures fair competition. For example, common standards have been essential prerequisites for the effective functioning of various global sectors, particularly international trade and communication. It also facilitates the development of innovative new practices as it makes it easier to compare the performance of different units.

The exchange of agricultural commodities constitutes an important part of world trade. Pesticides are also developed and marketed globally, but because of their toxic nature, their trade and movement is generally restricted and they require local registration. Even though local conditions and practices are considered when assessing their risk, the data required for registration are the result of global research efforts and advances in risk assessment. Since all countries reserve the right to register a pesticide based on their own evaluation, there is abundant duplication of efforts in these parallel review processes of basically the same sets of data.

The ultimate goal of pesticide regulatory harmonization is reducing duplication of efforts and streamlining review processes. This would increased the efficiency of regulatory agencies and reduce the cost of data submission. Industry would benefit from faster and broader access to international markets, while growers gain prompt and equitable access to a wider range of more effective pest control products. Finally, the public would benefit from reduced health risks as newer and safer pest control agents are introduced, and it would have increased confidence in a regulatory process that follows international norms.

While there would be many benefits from a greater harmonization and work sharing, countries are generally reluctant to give up this source of authority, power, income and employment. While the national authorities are quite willing to accept international norms and follow standard procedures, they are not so willing to give up duplication of efforts and accept assessments and registrations from other countries. Besides protecting people's health and the environment, registration can also be a tool to protect commercial interests of local businesses and research institutions. Similarly, while multinational chemical companies would benefit from greater harmonization through an easier access to a wider market, unreasonably high registration data requirements could help them suppress competition from smaller companies, producers of cheaper generic products or safer biological pest control agents. Balancing these competing interests of the various stakeholders is a complex and difficult task for the national regulatory agencies.

The harmonization of norms, application data and technical evaluations mostly benefits the industry since this facilitates the registration process in multiple countries. However, these harmonization efforts produce fewer benefits for the countries since no resources are freed which could be put to better use. Such tangible benefits for individual countries would require more far-reaching efforts in harmonization.

For example, it would be conceivable that there could be a standard application dossier for industry data in the OECD format that would be acceptable in all countries. To avoid duplication of evaluations, nations could cooperate by dividing the review work over different, specialized agencies and share the results in a common evaluation report. Individual countries still could make own independent regulatory decision with the goal of harmonizing supplementary studies and MRL establishment. Such work sharing could be organized regionally or globally with the objective of reducing duplication of efforts and streamlining the review process. This would free resources in the individual countries that could be used for country-specific tasks such as post-registration monitoring, enforcement or assistance to growers.

Such a level of harmonization could produce substantial benefits for multiple stakeholders:

Regulatory authorities would benefit from a complete data submission and sounder scientific conclusions that could serve as a basis for more timely regulatory decisions. It would require fewer resources, harmonize MRLs and strengthen international cooperation.

Registrants would benefit from submitting one uniform application to one or multiple authorities, thus saving time, costs and uncertainties. At the same time, it would give new products access to a larger market and it could make the introduction of lower risk products faster and easier.

Growers would benefit from being able to use new, lower risk products on export commodities and would face fewer trade barriers because of different MRL levels.

The *Public* would benefit from more confidence in an independent, scientific regulatory system in which lower risk products would be registered sooner. Furthermore, it would benefit from a more efficient use of public resources.

ANNEXES

ANNEX 1

APPPC Regional Workshop on Enhancement of Regional Collaboration in Pesticides Regulatory Management

COMPILATION OF QUESTIONNAIRE RESPONSES ON PESTICIDE REGULATORY MANAGEMENT

Chiang Mai, Thailand
26–30 November 2012

Table of contents

A. Compilation of Questionnaire on Pesticide Regulatory Management

I. PESTICIDE LEGISLATION AND REGULATIONS

1. Regulatory bodies

Background

The Code of Conduct calls on countries to have legislation concerning the manufacture, distribution or use of pesticides and to make a government agency or agencies responsible for regulating the pesticides and more generally for implementing pesticide legislation. The final decision on registration should be taken by a legally appointed body of highly qualified independent experts (Pesticide Board) from the sectors of agriculture, health and environment.

Survey responses

1. Does your country have a …		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Responsible national authority for pesticide registration	**Yes = 16 No/NR = 0**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Pesticide Board	**Yes = 8 No/NR = 8**	**Y**	**N**		**Y**	**N**	**Y**		**Y**	**Y**	**Y**		**Y**		**N**	**N**	**Y**
Registration Committee	**Yes = 13 No/NR = 3**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**		**Y**	**Y**	**Y**
Technical committee	**Yes = 15 No = 1**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Other committees: (please specify): Y	**Yes = 8**				**Y**	**N**	**Y**		**Y**	**-**	**Y**	**Y**	**Y**		**Y**	**Y**	
Total	**Yes =**	**4**	**3**	**3**	**5**	**1**	**5**	**3**	**5**	**4**	**4**	**4**	**5**	**2**	**4**	**4**	**4**

Indonesia: Pesticide Committee
Malaysia: Pesticide Advertisement Committee, Committee on Determination of National Pesticide MRLs, Pesticide Licensing Committee, Anti-Smuggling Committee (Illegal Pesticides), Pesticides Consultative Body
Nepal: Legal sub-committee and Obsolete Pesticide Disposal and Implementation Committee
Pakistan: Pesticides Advertisement Material Committee
Philippines: FPA Biotech Core Team (for Biotech based pesticides)
Sri Lanka: Agricultural Pesticides Sub-Committee; Public Health Pesticide Sub-Committee; Industrial Pesticides Sub-Committee
Thailand: – Sub-committee for Control of Pesticide Advertisement and Direct Sale; – Working group for pesticide surveillance

Y = Yes; N = No; NR = No response

Observations

- All countries have a responsible national authority or authorities for pesticide registration
- Some countries have a Pesticide Board, others a registration committees, many both.
- In almost all countries is registration supported by a technical committee

Conclusions

- All responding countries in the APPPC region have established legal structures for pesticide registration

2. Please indicate which type of pesticides fall under the responsibility of the national authority for pesticide registration

Background

The FAO/WHO registration guidelines promote the establishment of a single national authority for the registration of all pesticides to optimize the use of limited resources available in most countries.

Survey responses

2. Please indicate which type of pesticides fall under the responsibility of the national authority for pesticide registration		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Agricultural pesticides	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Livestock pesticides	**Yes = 8** **No/NR = 8**		Y	N	Y	N*	Y		Y		Y		Y		Y	Y	
Forestry pesticides	**Yes = 12** **No/NR = 4**		Y	Y	Y	Y	Y		Y	Y	Y		Y		Y	Y	Y
Fisheries pesticides	**Yes = 6** **No/NR = 10**		Y	N	Y	N*	N		Y		Y		Y		N	Y	
Public health pesticides	**Yes = 11** **No/NR = 5**	Y	Y	Y	Y	N*	Y		Y	Y	Y		Y	*	Y	Y	
		2	5		6	2	4	1	6	3	6	1	5	1	5	5	2
Other: (please specify)					Y	N			Y		Y				Y		

Indonesia: Yield Storage, Quarantine and Pre-shipping, Transportation Mode, Human Vector Disease Control
Japan: Livestock and fish drugs by Veterinary Ministry; Public Health by Ministry of Health, Labour and Welfare
Malaysia: Household, Pest Control Operator
Nepal: Household pesticides
Philippines: Public Health Pesticides like household pesticides are under the regulation of the Department of Health-Food and Drug Administration, the rest of the pesticides are under the regulation of the Department of Agriculture-Fertilizer and Pesticide Authority
Singapore: Regulated by the National Environment Agency (NEA)
Sri Lanka: Industrial Pesticides
Thailand: Pesticide used for crop production is under responsibility of DOA; livestock pesticide is under responsibility of Dept. of Livestock Development; fisheries pesticide is under responsibility of Dept. of Fisheries; public health pesticide is under responsibility of Food and Drug Administration, MOPH

Y = Yes; N = No; NR = No response

Observations

- All national authorities in the responding countries regulate agricultural pesticides.
- In more than 1/3 of the responding countries, the national authority regulates the full range of pesticides.
- In about 2/3 of the countries, agricultural pesticides are regulated together with forestry and public health pesticides.
- In about half the countries, pesticides used on livestock and fisheries are not regulated by the same national authority.

Conclusions

- It should be clarified whether pesticides that do not fall under the responsibility of the national authority are regulated according to the same standards.
- The advantages of having a single authority or several authorities should be reflected in the respective countries.

3. Please indicate the status of international treaties regarding pesticide management

Background

A number of international treaties related pesticide matters provide common international standards for pesticide management

Survey responses

3. Please indicate the status of international treaties regarding pesticide management		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Signed/Ratified																	
Rotterdam Convention	**R = 12**	(R)		**R**	**S**	**R**	**R**	**R**	**R**		**R**	**R**	**R**	**R**	**R**	**R**	**R**
Stockholm Convention	**R = 15**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**S**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**
Basel Convention	**R = 15**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**		**R**	**R**	**R**	**R**	**R**	**R**	**R**
Montreal Protocol	**R = 16**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**	**R**
S = signed; R = ratified; ( ) = not verified	**R =**	**3**	**3**	**4**	**3**	**4**	**4**	**4**	**3**	**2**	**4**	**4**	**4**	**4**	**4**	**4**	**4**
Fully/Partially Implemented																	
Rotterdam Convention	**F = 9**	**F**				**F**	**P**	**P**	**F**	**P**	**P**	**F**	**F**	**F**	**F**	**F**	**F**
Stockholm Convention	**F = 8**	**F**				**F**	**P**	**P**	**P**		**P**	**F**	**F**	**F**	**F**	**F**	**F**
Basel Convention	**F = 9**	**F**				**F**	**P**	**P**	**F**	**P**	**P**	**F**	**F**	**F**	**F**	**F**	**F**
Montreal Protocol	**F = 10**	**F**				**F**	**F**	**P**	**F**		**F**		**F**	**F**	**F**	**F**	**F**
F = Fully; P = Partially	**F =**	**4**				**4**	**1**		**3**		**1**	**3**	**4**	**4**	**4**	**4**	**4**

Observations

- More than 2/3 (11) of all countries have ratified all four treaties
- The only treaty ratified by all responding countries is the Montreal Protocol
- The Rotterdam Convention still needs to be ratified by 4 countries
- Only about half the countries (7) indicated that they have fully implemented all 4 treaties

Conclusions

- Implementation of the treaties is lagging behind their official ratification.
- About half the countries in the region may need further efforts/assistance with implementing all treaties.

4. Please indicate whether you have legislation or regulations concerning the following products

Background

To protect its citizens and the environments, countries should have legislation or regulations concerning groups of high-risk chemicals.

Survey responses

4. Please indicate whether you have legislation or regulations concerning the following products		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
• Highly toxic products (WHO Class 1a and 1b)	**Yes = 14 No = 2**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**N**	**Y***	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
• Persistent organic pollutants (Stockholm Convention)	**Yes = 13 No/NR = 3**	**Y**		**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**N**	**Y***	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
• Methyl-bromide (Montreal Protocol)	**Yes = 16**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y***	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
All 3 = 13	**Y =**	**3**	**2**	**3**	**1**	**3**	**3**	**3**	**3**	**1**	**3**	**3**	**3**	**3**	**3**	**3**	**3**
* Nepal: Regulated, but not separately																	
Y = Yes; N = No; NR = No response																	

Observations

- Most countries have legislation or regulations concerning all of the listed chemicals;
- Not all countries that have legislation and regulations have fully implemented the respective treaties.

Conclusions

- A few countries still need to establish legislation or regulations concerning certain highly hazardous and persistent pesticides.
- Some countries still need to pass legislation in support of international treaties they have joined.

5. Please indicate which pesticide management functions are covered by your country's legislation or regulations

Background

The Code of Conduct calls on countries to regulate all parts of a pesticide life-cycle from manufacture/ import to use/disposal and remaining residues in the environment.

Survey responses

5. Please indicate which pesticide management functions are covered by your country's legislation or regulations		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
• import	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y*	Y	Y	Y
• export	**Yes = 15**	Y	Y	Y	Y	Y	Y	Y	Y*	N	Y	Y	Y	Y*	Y	Y	Y
• manufacture	**Yes = 15**	Y	Y	Y	Y	Y[1]	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y
• transport	**Yes = 13**	Y	Y	Y	N	Y	Y	Y	N	N	Y	Y	Y	Y*	Y	Y	Y
• storage	**Yes = 16**	Y	Y	Y	Y	Y[2]	Y	Y	Y	Y	Y	Y	Y	Y*	Y	Y	Y
• distribution	**Yes = 14**	Y	Y	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y*	Y	Y	Y
• labelling	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
• packaging	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
• advertising	**Yes = 14**	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y
• sale and retail shops	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y*	Y	Y	Y
• quality control	**Yes = 15**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
• use (registered only for specific crop/pest)	**Yes = 14**	Y	Y	Y	Y	Y	Y		Y	N	Y	Y	Y	Y	Y	Y	Y
• method of field application	**Yes = 14**	Y	Y	Y	N	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y
• personal protective equipment	**Yes = 15**	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
• specialized application (e.g. fumigation)	**Yes = 14**	Y	Y	Y	Y	Y	N		Y	Y	Y	Y	Y	Y	Y	Y	Y
• residues	**Yes = 14**	Y	Y	Y	Y	Y	Y		Y	Y	Y		Y	Y	Y	Y	Y
• disposal	**Yes = 15**	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
• transboundary movement of waste	**Yes = 13**	Y	Y	Y	N	Y	Y		Y	N	Y	Y	Y	Y	Y	Y	Y
• public participation in regulatory process	**Yes = 13**	Y	Y	Y	Y	Y[3]	Y		Y	Y	Y	Y	Y	N	N	Y	Y
• information sharing on risks and health hazards	**Yes = 13**	Y	Y	Y	Y	Y	N		Y	Y	Y	Y	Y	N	Y	Y	Y
• information sharing on pesticide regulatory matters	**Yes = 13**	Y	Y	Y	Y	Y	N		Y	Y	Y	Y	Y	N	Y	Y	Y
	All = 8	21	21	21	16	21	18	13	19	14	21	20	21	15	20	21	21

Japan:
*1 Export of POPs, including certain pesticides whose domestic sale and use are forbidden, is subject to permission by the Minister for Economy, Trade and Industry.
*2 For pesticides designated as poisonous or deleterious substances.
*3 Though not provided in relevant laws, important decisions concerning the pesticide registration system are made after consultation with various stakeholders. In addition, the process of public comment is legally required for the introduction or change of any regulation.
Malaysia: only those pesticides considered as strategically hazardous
Singapore: by NEA

Y = Yes; N = No

Observations

- Most of the countries regulate all or almost all pesticide management functions.
- Least regulated (in more than 3 countries) are public participation and information sharing.
- Fully regulated in all 16 countries are: import, storage, labelling, packaging and retail.

Conclusions

- The range of pesticide management functions is largely harmonized among APPPC countries.
- A few countries still need to broaden their pesticide management functions.

6. Please indicate which type of pest control products are regulated by the above legislation and regulations?

Background

Pesticides are not only distinguished by their use, but also by chemical and biological characteristics

Survey responses

6. Please indicate which type of pest control products are regulated by the above legislation and regulations?		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
• Chemical pesticides	**F = 16**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**
• Botanical pesticides (Neem, Rotenone, Pyrethrin, Nicotine, etc.)	**F = 12** **P = 3** **N = 1**	**P**	**N**	**F**	**P**	**F**	**P**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**
• Biochemical pesticides (Semichemicals, hormones, plant regulators, insect growth regulators, enzymes)	**F = 11** **P = 4** **N = 1**	**P**	**F**	**F**	**P**	**F**	**F**	**F**	**P**	**F**	**N**	**F**	**F**	**F**	**P**	**F**	**F**
• Microbial pesticides (entomotoxic bacteria, NPV/GV, entomopathogenic fungi, antagonistic fungi, antagonistic bacteria, genetically modified micro-organisms)	**F = 10** **P = 5** **N = 1**	**P**	**F**	**F**	**P**	**F**	**P**	**N**	**F**	**P**	**F**	**F**	**F**	**F**	**P**	**F**	**F**
• Plant-Incorporated-Protectants (PIPs; e.g. Bt. in genetically modified plants)	**F = 5** **P = 2** **N/NR = 9**	**P**	**N**	**F**	**N**	**N**	**N**	**N**	**F**	**P**	**N**	**N**	**F**	**F**	**N**	**N**	**F**
• Biocontrol agents	**F = 5** **P = 7** **N = 4**	**P**	**P**	**F**	**N**	**P[1]**	**P**	**N**	**P**	**P**	**F**	**N**	**F**	**F**	**P**	**N**	**F**
• Non-pesticide active ingredients in formulations	**F = 4** **P = 5** **N/NR = 7**	**F**	**N**		**N**	**P[2]**	**P**	**N**	**P**	**N**	**N**	**P**	**F**	**N**	**P**	**F**	**F**
• Other substances such as defoliants, desiccants, agents for setting or thinning of fruits, or substances to protect commodities from deterioration during storage and transport	**F = 4** **P = 5** **N/NR = 7**	**P**	**N**	**P**	**N**	**F**	**P**	**N**	**P**	**N**	**N**	**N**	**F**	**P***	**N**	**F**	**F**
	Fully =	**2**	**3**	**6**	**1**	**5**	**2**	**3**	**4**	**3**	**4**	**4**	**8**	**6**	**2**	**6**	**8**

Japan:
*1 Indigenous natural enemies can be sold and used for pest management without registration.
*2 Acute effects of adjuvants and other non-active ingredients are assessed through acute toxicity tests of pesticide formulations.
Singapore: * only for defoliants & desiccants defined as pesticide under the Act.

F = Fully, P = Partially; N = Does not apply; NR = No response

Observations

- Among the biological pest control products, botanical and biochemical pesticides are more often fully regulated than other products.
- Fewer than 1/3 of the countries regulate PIP, non-pesticide active ingredients and other substances.
- Biocontrol agents (macrobials) are regulated in more than 2/3 of the countries (fully or partially).

Conclusions

- Even though all countries regulate agricultural pesticides, the do not fully regulate all types of agricultural pest control products.

7. Which international guidelines are reflected in the national legislation and regulations?

Background

A number of international guidelines are available to countries to enhance and harmonize their pesticide management

Survey responses

7. Which international guidelines are reflected in the national legislation and regulations?		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
FAO 1988. *Guidelines on the registration of biological pest control agents*	**Fully = 4 Part. = 5 ?/NR = 7**	F	F	P	F		P	P		-	P		F	-	?	-	P
FAO 1989. *Guidelines for legislation on the control of pesticides*	**Fully = 8 Part. = 6 ?/NR = 2**	F	F	P	F		P	F	P	P	P	F	F	-	F	F	P
FAO 1991. *Initial introduction and subsequent development of a simple national pesticide registration and control scheme*	**Fully = 5 Part. = 4 ?/NR = 7**	F	F	P	F		?	?		P	F	P		-	F	-	P
FAO 1995. *Guidelines on good labelling practice for pesticides*	**Fully = 10 Part. = 5 NR = 1**	F	F	P	F		P	F	P	F	P	P	F	F	F	F	F
FAO 2002. *International Code of Conduct on the Distribution and Use of Pesticides (revised edition)*	**Fully = 9 Part. = 2 ?/NR = 5**	F	F	P	F		F	F		F	P	F	?		F	F	
UN 2005. *The Globally harmonized system of classification and labelling of chemicals (GHS)*	**Fully = 5 Part. = 5 ?/NR = 6**	F	F	P	F	P	P	P		F	?	?	?		F	-	P
OECD 2005. *Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances*	**Fully = 3 Part. = 3 ?/NR = 10**	F	F	P	P	P	?	?		-	?	?	?		F	-	?
FAO 2006. *Guidelines on efficacy evaluation of plant protection products*	**Fully = 6 Part. = 7 ?/NR = 3**	F	F	P	P		F	P	P	P	P	F	?		F	F	P
FAO 2006. *Guidelines on monitoring and observance of the Code of Conduct*	**Fully = 6 Part. = 5 ?/NR = 5**	F	F	P	P		F	F	P	P	?	F	?		F	-	P
OECD 2008. *Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances*	**Fully = 2 Part. = 5 ?/NR = 9**	F	F	P	P	P	P	?		-	?	?	?		P	-	?
WHO 2009. *The WHO recommended classification of pesticides by hazard and guidelines to classification*	**Fully = 10 Part. = 4 ?/NR = 2**	F	F	P	F		P	P	P	F	F	F	?	F	F	F	F
FAO 2006. *Guidelines on compliance and enforcement of a pesticide regulatory programme*	**Fully = 5 Part. = 6 ?/NR = 5**	F	F	P	P		P	F	P	P	F		?		F	-	P
FAO/WHO 2010. *Guidelines for the Registration of Pesticides*	**Fully = 5 Part. = 5 ?/NR = 6**	F	F	P	P		P	?	P	P	F	F	?		F	-	?
FAO 2010. *Guidance on Pest and Pesticide Management Policy Development*	**Fully = 3 Part. = 5 ?/NR = 8**	F	F	P	?		?	P	P	P	P	?	?		F	-	?

		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
	Fully =	**14**	**14**		**7**		**3**	**5**		**4**	**4**	**6**	**3**	**2**	**12**	**5**	**2**
	Partially =			**14**	**6**	**3**	**8**	**5**	**8**	**7**	**6**	**2**			**1**		**7**
	Don't know =				**1**	**11**	**3**	**4**	**6**	**3**	**4**	**6**	**11**	**12**	**1**	**9**	**5**
Japan: The establishment of our national legislation predated the publication of the documents unchecked above. Philippines: The latest Philippine Guidelines on Pesticide Regulation was updated in year 2001 and all guidelines issued by FAO, WHO and EPA were used as reference in crafting the aforesaid guidelines. The said guideline served as the basis in managing pesticides in the Philippines.																	
F = Fully; P = Partially; ? = Don't know; NR = No response																	

Observations

- The most widely followed guidelines were the FAO guidelines on good labelling practice for pesticides and the WHO recommended classification of pesticides by hazard.
- The least known guidelines were the OECD guidelines and the 2010 FAO Guidance on Pest and Pesticide Management Policy Development.
- The international guidelines were particularly appreciated by developing nations.

Conclusions

- While not all guidelines are fully applicable to all countries, they establish a common quality standard for pesticide management.
- Some OECD guidelines may also offer important guidance to non-OECD countries.

II. PESTICIDE REGISTRATION APPLICATION AND DATA REQUIREMENTS

1. Please indicate the level of implementation of the following registration steps

Background

The FAO/WHO guidelines recommend the registration process to follow a set sequence of steps.

Survey responses

1. Please indicate the level of implementation of the following registration steps (according to the guidelines)		**Bangladesh**	**Cambodia**	**China**	**Indonesia**	**Japan**	**Korea, DPR**	**Lao PDR**	**Malaysia**	**Myanmar**	**Nepal**	**Pakistan**	**Philippines**	**Singapore**	**Sri Lanka**	**Thailand**	**Viet Nam**
• Application form with instructions for applicants	**F = 13 P = 1 M = 2**	**F**	**F**	**F**	**F**	**F**	**F**	**M**	**F**	**P**	**M**	**F**	**F**	**F**	**F**	**F**	**F**
• Initial administrative actions/issue of acknowledgement	**F = 13 M = 3**	**F**	**F**	**F**	**F**	**F**	**F**	**M**	**F**	**M**	**M**	**F**	**F**	**F**	**F**	**F**	**F**
• Check list for completeness of documents	**F = 13 P = 1 M = 2**	**F**	**F**	**F**	**F**	**F**	**P**	**M**	**F**	**F**	**M**	**F**	**F**	**F**	**F**	**F**	**F**
• Technical and scientific evaluation	**F = 14 M = 2**	**F**	**F**	**F**	**F**	**F**	**F**	**M**	**F**	**F**	**M**	**F**	**F**	**F**	**F**	**F**	**F**
• Risk assessment and risk management evaluation	**F = 8 P = 5 M = 3**	**F**	**F**	**F**	**P**	**F**	**P**	**M**	**FM = P**	**M**	**M**	**P**	**F**	**F**	**F**	**F**	**P**
• Preparation of summaries and conclusions	**F = 12 P = 1 M = 3**	**F**	**F**	**F**	**F**	**F**	**F**	**M**	**F**	**F**	**M**	**M**	**F**	**F**	**F**	**F**	**P**
• Registration decision	**F = 16**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**	**F**
• Publication and dissemination of registration decision	**F = 12 P = 3 M = 1**	**F**	**F**	**F**	**F**	**F**	**P**	**F**	**F**	**P**	**F**	**P**	**F**	**M**	**F**	**F**	**F**
	F =	**8**	**8**	**8**	**7**	**8**	**5**	**2**	**7**	**4**	**2**	**5**	**8**	**7**	**8**	**8**	**6**
	P =				**1**		**3**		**1**	**2**		**2**					**2**
	M =							**6**		**2**	**6**			**1**			
F = Fully; P = Partially; M = More effort needed; NR = No response																	

Observations

- Most countries follow all the recommended steps.
- Risk assessment and risk management are the weakest steps in about half the countries.

Conclusions

- There is generally a high degree of harmonization of the registration steps.
- Some registration steps need more attention; two countries need a more extensive strengthening of the registration process.

2. Please indicate which registration application options are available?

Background

In addition to the regular, full, proprietary registration of finished products, countries generally also offer other registration options.

Survey Responses

2. Please indicate which registration application options are available?		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Active Substance																	
Pre-registration (with limited dossier)	**Y = 1**				-			Y							-		
Provisional registration	**Y = 3**			Y	-		Y			Y					-		
Full registration (regular, proprietary)	**Y = 9**			Y	Y		Y	Y	Y	Y		Y			Y	Y	
Supplementary registration (me-too for identical, substantially similar products)	**Y = 2**				-			Y				Y			--		
Amended registration (minor changes)	**Y = 6**			Y	Y		Y					Y			Y	Y	
Amended registration (major changes)	**Y = 5**			Y	Y		Y					Y			--	Y	
Conditional registration	**Y = 2**						Y					Y			-		
Renewal of registration (without review)	**Y = 4**			Y	-		Y					Y			--	Y	
Re-registration (with review of dossiers)	**Y = 7**				Y		Y	Y	Y	Y		Y			Y		
Re-registration (unscheduled review)	**Y = 3**				-		Y	Y				Y			-		
Fast-track registration (e.g. low risk products)	**Y = 3**				-			Y		Y		Y			-		
Experimental use registration	**Y = 0**				-										-		
Emergency use registration/permit	**Y = 0**				-										-		
Exception from registration/permit	**Y = 2**				-			Y							-	Y	
	Sum = 47			5	4		8	7	2	4		9			3	5	
Finished Product																	
Pre-registration (with limited dossier)	**Y = 5**				-		Y	Y					Y		Y		Y
Provisional registration	**Y = 9**		Y	Y	Y		Y	Y		Y		Y	Y		Y		
Full registration (regular, proprietary)	**Y = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Supplementary registration (me-too for identical, substantially similar products)	**Y = 6**	Y			-		Y	Y		Y			Y		--		Y
Amended registration (minor changes)	**Y = 12**	Y		Y	Y	Y	Y		Y		Y	Y	Y		Y	Y	Y
Amended registration (major changes)	**Y = 10**	Y		Y	Y	Y	Y			Y		Y	Y		--	Y	Y
Conditional registration	**Y = 7**	Y			Y		Y				Y		Y		Y		Y
Renewal of registration (without review)	**Y = 9**	Y	Y	Y	-	Y	Y					Y	Y		--	Y	Y
Re-registration (with review of dossiers)	**Y = 10**	Y	Y		Y		Y	Y	Y	Y		Y	Y		Y		
Re-registration (unscheduled review)	**Y = 4**	Y			-	Y	Y						Y		--		
Fast-track registration (e.g. low risk products)	**Y = 9**	Y			-		Y	Y		Y		Y	Y	Y	Y		Y
Experimental use registration	**Y = 7**	-			Y		Y			Y	Y	Y	Y		--		Y
Emergency use registration/permit	**Y = 7**	-			Y	Y	Y		Y				Y		Y		Y
Exception from registration/permit	**Y = 7**	-			-	Y	Y	Y	Y				Y		Y	Y	
	Sum = 104	9	4	5	9	7	14	7	5	7	4	8	14	2	10	5	10
Other types: (please specify)		-			Y										Y		

Indonesia: Export registration
Sri Lanka: Export only
Thailand: – Exception from registration is applied to pesticide used as analytical standard in laboratory. No exception for permit.
– Re-registration has not been done yet since registration under the new Act has not been expired.

Y = Yes

Observations

- All responding countries register finished, formulated products;
- About half the countries give registrations to active substances;
- About half the countries give provisional registrations, and 1/3 allow supplementary registrations;
- Half the countries allow for a renewal of the registration without a review of the dossier; however, in 5 countries, only re-register with a full review of the dossier;
- Most countries allow to amend a registration;
- Some countries offer as many as 10-14 different registration options;
- Four countries offer exemptions from registration under certain prerequisites.

Conclusions

- Too many registration options may be confusing and unnecessary, and difficult to manage;
- Special registration requirements and guidelines for active substances may be unnecessary since pesticide products are always marketed as finished, formulated products; the majority of the responding APPPC countries do not register active substances separately;
- Harmonization efforts of data requirements should focus on full proprietary registration of formulated, finished products since other registration options are not available in all countries.

3. Please indicate for which type of pest control product you have separate written instructions for the applicant concerning registration procedures and data requirements

Background

It is essential that all steps in the registration process are transparent, based on sound and published criteria and guidance documents. Therefore, registration authorities should provide comprehensive, clear and harmonized instructions to the applicants with regard to the proper procedures and data requirements to provide transparency of the registration process. Different requirements for different products should be clearly communicated.

Survey Responses

3. Please indicate for which type of pest control product you have separate written instructions for the applicant concerning registration procedures and data requirements		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Chemical pesticides	**Yes = 12**	Y	N	Y	N	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y
Botanical pesticides (e.g. neem)	**Yes = 11**	Y	N	Y	N	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	N
Biochemicals	**Yes = 5**		N	Y	N	Y		Y	N	-		N	Y	Y			N
semi-chemicals (e.g. pheromones)	**Yes = 4**	Y	N		N		Y		N	Y	N				N	Y	N
hormones	**Yes = 3**	Y	N		N		Y		N	-	N				N	Y	N
plant growth regulators	**Yes = 4**	N	N		N		Y		N	Y	N				Y	Y	N
insect growth regulators	**Yes = 4**	N	N		N		Y		N	Y	N				Y	Y	N
enzymes	**Yes = 1**	N	N		N		Y		N		N				N	-	N
Microbial pesticides	**Yes = 8**	Y	N	Y	N	Y	Y	Y	N			N	Y	Y		Y	N
entomotoxic bacteria	**Yes = 5**	Y	N		N		Y		N	Y	Y				Y	-	N
NPV/GV	**Yes = 2**	Y	N		N				N	N	Y				N	-	N
entomopathogenic fungi	**Yes = 3**	Y	N		N				N	Y	Y				N	-	N
antagonistic fungi	**Yes = 2**	Y	N		N				N		Y				N	-	N
antagonistic bacteria	**Yes = 2**	Y	N		N				N	N	Y				N	-	N
Biocontrol agents	**Yes = 7**	Y	N	Y	N	N	Y	Y	N	Y	Y	N	Y		N	N	N
	Yes =		0	5	0	4	10	5	0	8	8	0	6	4	5	7	1
Other (please indicate)													Y		N	-	
Philippines: • Botanical, Biochemical, microbial and biocontrol agents are classified under Biorational pesticides with the same registration procedures and data requirements. • Biotech based pesticide e.g. Plant-Incorporated-Protectant (PIP) is separately regulated under DA Administrative Order No. 8, series of 2002.																	
Y = Yes; N = No																	

Observations

- Most countries have written instructions for the registration application;
- Most of the written instructions cover chemical and botanical pesticides;
- Four countries have no written instructions for applicants;
- In about half the countries, instructions do not cover biochemical and microbial pest control agents
- There are registration instructions for (microbial) biocontrol agents in 5 countries; in some of these countries, however, these organisms are not legally regulated (see I.6).

Conclusions

- Too many separate registration instructions may be confusing and unnecessary since countries often require the same dossiers for different types of pest control products;
- Requesting the same dossiers does not imply that the same data are requested;
- Due to the inherent differences among the various types of pest control agents, some products may require different registration requirements and instructions.

4. Registration Procedure

Background

The responsible authority may consider requesting an electronic dossier to facilitate storage and retrieval of the data. Increasingly, authorities apply tiered or step-wise approaches to evaluation and data requirements. While following international standards for confidential data protection, governments should develop legislation and regulations to permit information exchange to the public about pesticide risks and benefits as well as to facilitate the participation of the public in the management of pesticides in the country.

Survey Responses

4. Registration Procedure		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you allow online submission of application?	**Yes = 1**	N	N		N	N	N	N	N	N	N	N	N	Y	N	N	N
Do you provide online monitoring of registration process?	**Yes = 0**	N	N		N	N	N	N	N	N	N	N	N	N	N	N	N
Have you adopted a tiered approach to data requirements?	**Yes = 8**	Y	Y	Y	N	Y		N	Y	N	N	N	Y	Y	?	Y	
Do you have internal guidelines to protect and safeguard proprietary data and confidential business information?	**Yes = 12**	Y	Y	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	Y
Do you follow the arrangements under the TRIPS agreement for data protection?	**Yes = 10**	Y	N	Y	N	Y	N	Y	Y	N	N	N	Y	Y	Y	Y	Y
Length of data protection period: _ years	Low = 2 High = ∞		8	6	5	15	5	2	∞	*			8	5	20	10	5
Do you make all non-protected data available to the public?	**Yes = 6**	Y	Y		N	N	Y	N	N	N	N	N	Y*	N	Y	N	Y
Do you make health and safety data available to the public?	**Yes = 10**	Y	Y		N	Y*	Y	N	N	Y	Y	Y	Y*	N	Y	N	Y
Do you grant waivers from certain data requirements upon request?	**Yes = 11** **No = 5**	N	Y	Y	Y	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	N
	Y =	5	5	4	1	5	4	2	4	1	1	2	6	5	5	4	4
Myanmar: Under consideration Philippines: As per request																	
Y = Yes; N = No; NR = No response																	

Observations

- No country provides online monitoring of the registration process, and only one country (Singapore) accepts online submission of dossiers;
- About half the countries reported to have adopted a step-wise, tiered approach to data submission under which a more limited data set is required in a first submission, and more data may be requested if the need arises;
- Ten countries follow the TRIPS agreement for data protection; the period of data protection ranges from 2 years to 20 years and indefinite;
- About 2/3 of the countries make health and safety information available to the public and grant waivers from certain data requirements;
- Only about 1/3 of the countries make non-protected data available to the public.

Conclusions

- There are great differences in registration procedures among the APPPC countries with regard to data protection and information to the public;
- Modern information technologies are hardly used to facilitate registration application and to monitor the registration process.

5. Please indicate which folders are required to be submitted or resubmitted by the applicant for the following substances and registration options

A. Provisional Registration

Background

When a pesticide is introduced for the first time, it may be registered provisionally for a shorter period based on a limited set of data.

Survey Responses

Provisional registration / Folder		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Chemical Pest Control Products																	
A. Identity and properties	**Yes = 8**			Y	Y	/	Y	Y		Y	Y		Y		Y		
B. Toxicology data	**Yes = 8**			Y	Y	/	Y	Y		Y	Y		Y		Y		
C. Bio-efficacy data	**Yes = 8**			Y	Y	/	Y	Y		Y	Y		Y		Y		
D. Residue data	**Yes = 7**			Y	Y	/		Y		Y	Y		Y		Y		
E. Human health/Environmental fate and effect data	**Yes = 7**			Y	Y	/		Y		Y	Y		Y		Y		
F. Labelling, packaging/storage data	**Yes = 7**			Y	Y	/		Y		Y	Y		Y		Y		
G. Additional data requirements	**Yes = 3**				Y	/	Y						Y				
	Total:			**6**	**7**		**4**	**6**		**6**	**6**		**7**		**6**		
Botanical Pest Control Products																	
A. Identity and properties	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
B. Toxicology data	**Yes = 8**		Y	Y	Y	/		Y		Y	Y		Y		Y		
C. Bio-efficacy data	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
D. Residue data	**Yes = 7**		Y	Y	Y	/		Y			Y		Y		Y		
E. Human health/Environmental fate and effect data	**Yes = 7**		Y	Y		/		Y		Y	Y		Y		Y		
F. Labelling, packaging/storage data	**Yes = 8**		Y	Y	Y	/		Y		Y	Y		Y		Y		
G. Additional data requirements	**Yes = 3**				Y	/	Y						Y				
	Total:		**6**	**6**	**6**		**3**	**6**		**5**	**6**		**7**		**6**		
Biochemical Pest Control Products																	
A. Identity and properties	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
B. Toxicology data	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
C. Bio-efficacy data	**Yes = 8**		Y	Y	Y	/		Y		Y	Y		Y		Y		
D. Residue data	**Yes = 8**		Y	Y	Y	/		Y		Y	Y		Y		Y		
E. Human health/Environmental fate and effect data	**Yes = 7**		Y	Y		/		Y		Y	Y		Y		Y		
F. Labelling, packaging/storage data	**Yes = 8**		Y	Y	Y	/		Y		Y	Y		Y		Y		
G. Additional data requirements	**Yes = 3**				Y	/	Y						Y				
	Total:		**6**	**6**	**6**		**3**	**6**		**6**	**6**		**7**		**6**		
Microbial Pest Control Products																	
A. Identity and properties	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
B. Toxicology data	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
C. Bio-efficacy data	**Yes = 9**		Y	Y	Y	/	Y	Y		Y	Y		Y		Y		
D. Residue data	**Yes = 6**		Y		Y	/		Y			Y		Y		Y		
E. Human health/Environmental fate and effect data	**Yes = 6**		Y	Y		/		Y			Y		Y		Y		
F. Labelling, packaging/storage data	**Yes = 8**		Y	Y	Y	/		Y		Y	Y		Y		Y		
G. Additional data requirements:	**Yes = 4**				Y	/	Y				Y		Y				
	Total:		**6**	**5**	**6**		**4**	**6**		**4**	**7**		**7**		**6**		

Korea, DPR: Economic efficacy

Y = Yes

Observations

- Only half the countries have an option for provisional registration.
- Even though provisional registration may be granted on a limited set of data, most countries require the full set of registration folders.
- Most countries require the same set of registration dossiers for biological pest control agents as for chemical pesticides.

Conclusions

- More detailed information may be needed to assess the use of provisional registration in different countries;
- Regional harmonization of provisional registration requirements may have a lower priority since it is not an option in many countries.

Regular Registration

Background

Regular, full, proprietary registration is the normal type of pesticide registration to approve the sale and use of pesticides, with or without conditions. It usually requires the most complete set of registration data.

Survey Responses

Regular registration / Folder		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Chemical Pest Control Products																	
A. Identity and properties	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
B. Toxicology data	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
C. Bio-efficacy data	**Yes = 15**	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y
D. Residue data	**Yes = 15**	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y
E. Human health/Environmental fate and effect data	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
F. Labelling, packaging/storage data	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
G. Additional data requirements	**Yes = 7**		Y*		Y		Y	Y		Y			Y*	Y*			
	Total:	6	7	6	7	6	7	7	6	5	6	6	7	7	6	6	6
Botanical Pest Control Products																	
A. Identity and properties	**Yes = 15**	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
B. Toxicology data	**Yes = 15**	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
C. Bio-efficacy data	**Yes = 14**	Y		Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y
D. Residue data	**Yes = 13**	Y		Y	Y	Y		Y	Y		Y	Y	Y	Y	Y	Y	Y
E. Human health/Environmental fate and effect data	**Yes = 12**	Y		Y		Y		Y	Y		Y	Y	Y	Y	Y	Y	Y
F. Labelling, packaging/storage data	**Yes = 15**	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
G. Additional data requirements	**Yes = 7**	Y			Y		Y	Y		Y			Y	Y*			
	Total:	7		6	6	6	5	7	6	4	6	6	7	7	6	6	6
Biochemical Pest Control Products																	
A. Identity and properties	**Yes = 14**	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y
B. Toxicology data	**Yes = 13**	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y		Y
C. Bio-efficacy data	**Yes = 12**	Y		Y	Y	Y	Y	Y	Y		Y		Y	Y	Y		Y
D. Residue data	**Yes = 12**	Y		Y	Y	Y	Y	Y	Y		Y		Y	Y	Y		Y
E. Human health/Environmental fate and effect data	**Yes = 11**	Y		Y		Y	Y	Y	Y		Y		Y	Y	Y		Y
F. Labelling, packaging/storage data	**Yes = 14**	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y
G. Additional data requirements	**Yes = 6**				Y		Y	Y		Y			Y	Y*			
	Total:	6		6	6	6	7	7	6	4	6		7	7	6	2	6
Microbial Pest Control Products																	
A. Identity and properties	**Yes = 14**	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y
B. Toxicology data	**Yes = 14**	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y
C. Bio-efficacy data	**Yes = 13**	Y		Y	Y	Y	Y	Y	Y		Y		Y	Y	Y	Y	Y
D. Residue data	**Yes = 12**	Y			Y	Y*	Y	Y	Y		Y		Y	Y	Y	Y	Y
E. Human health/Environmental fate and effect data	**Yes = 12**	Y		Y		Y*	Y	Y	Y		Y		Y	Y	Y	Y	Y
F. Labelling, packaging/storage data	**Yes = 14**	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y
G. Additional data requirements	**Yes = 8**	Y*			Y		Y	Y		Y			Y	Y	Y		
	Total:	7		5	6	6	7	7	6	4	6		7	7	7	6	6

Additional data requirements:
Bangladesh/Cambodia: MSDS
Japan:
* Residue and environmental fate data are not necessary if no adverse effects on humans and non-target species are identified
Korea, DPR: Economic efficacy
Singapore: Method of Analysis
Philippines: Product Performance Data/Phytotoxicity

Observations

- Almost all countries require the full set of folders for chemical pesticides (exception: Myanmar)
- Except for Cambodia, all countries offer regular registration for biological pest control products; Cambodia and Pakistan do not offer regular registration for some types of biological products.
- Three countries require fewer folders for biological products as for chemical pesticides; except may be the bio-efficacy, residue and human health/environmental fate folders. In one instance, toxicological data were not required for biochemical pest control agents which generally have a non-toxic mode of action.

Conclusions

- Harmonization efforts should focus on regular registration requirements since it is the common type of registration in all countries;
- Folder requirements are largely harmonized in the APPPC region;
- Folder requirements for biological pest control products should reflect the inherent characteristics of these products which are different from chemical pesticides;
- The encouragement of low-risk and non-toxic pest control products should be reflected in the registration data requirements;
- More detailed information on the actual information required may be needed to assess the use of provisional registration in different countries.

Supplementary Registration

Background

A company may register a product that is identical to an already registered pesticide as a supplementary registrant for the company that has originally registered the product. The product would be marketed under its own brand name.

Survey Responses

Supplementary registration / Folder		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Chemical Pest Control Products																	
A. Identity and properties	**Yes = 5**				Y	/		Y		Y			Y		-		Y
B. Toxicology data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
C. Bio-efficacy data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
D. Residue data	**Yes = 5**				Y	/	Y	Y					Y		-		Y
E. Human health/Environmental fate and effect data	**Yes = 5**				Y	/	Y	Y					Y		-		Y
F. Labelling, packaging/storage data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
G. Additional data requirements	**Yes = 5**				Y	/	Y	Y				Y	Y				
	Total:				**7**		**6**	**7**		**4**		**1**	**7**				**6**
Botanical Pest Control Products																	
A. Identity and properties	**Yes = 5**				Y	/		Y		Y			Y		-		Y
B. Toxicology data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
C. Bio-efficacy data	**Yes = 5**				Y	/	Y	Y					Y		-		Y
D. Residue data	**Yes = 4**				Y	/		Y					Y		-		Y
E. Human health/Environmental fate and effect data	**Yes = 3**					/		Y					Y		-		Y
F. Labelling, packaging/storage data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
G. Additional data requirements	**Yes = 5**				Y	/	Y	Y				Y	Y				
	Total:				**6**		**4**	**7**		**3**		**1**	**7**				**6**
Biochemical Pest Control Products																	
A. Identity and properties	**Yes = 5**				Y			Y		Y			Y		-		Y
B. Toxicology data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
C. Bio-efficacy data	**Yes = 5**				Y	/	Y	Y					Y		-		Y
D. Residue data	**Yes = 5**				Y	/	Y	Y					Y		-		Y
E. Human health/Environmental fate and effect data	**Yes = 4**					/	Y	Y					Y		-		Y
F. Labelling, packaging/storage data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
G. Additional data requirements	**Yes = 4**				Y	/	Y	Y					Y				
	Total:				**6**		**6**	**7**		**3**			**7**				**6**
Microbial Pest Control Products																	
A. Identity and properties	**Yes = 5**				Y	/		Y		Y			Y		-		Y
B. Toxicology data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
C. Bio-efficacy data	**Yes = 5**				Y	/	Y	Y					Y		-		Y
D. Residue data	**Yes = 4**				Y	/		Y					Y		-		Y
E. Human health/Environmental fate and effect data	**Yes = 4**					/	Y	Y					Y		-		Y
F. Labelling, packaging/storage data	**Yes = 6**				Y	/	Y	Y		Y			Y		-		Y
G. Additional data requirements	**Yes = 4**				Y	/	Y	Y					Y				
	Total:				**6**		**5**	**7**		**3**			**7**				**6**

Observations

- Only 1/3 of the countries provide for supplementary registration.

Conclusions

- Regional harmonization of supplementary registration requirements may have a lower priority since not all countries offer this registration option.

Re-Registration

Background

Re-registration can have several forms from a complete new registration procedure to a mere renewal of the registration.

Survey Responses

Re-registration / Folder		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Chemical Pest Control Products																	
A. Identity and properties	**Yes = 7**				Y	/		Y	Y	Y			Y		Y	Y	
B. Toxicology data	**Yes = 7**				Y	/	Y	Y	*	Y			Y		Y	Y	
C. Bio-efficacy data	**Yes = 6**				Y	/	Y	Y	*				Y		Y	Y	
D. Residue data	**Yes = 6**				Y	/	Y	Y	*				Y		Y	Y	
E. Human health/Environmental fate and effect data	**Yes = 6**				Y	/	Y	Y	*				Y		Y	Y	
F. Labelling, packaging/storage data	**Yes = 9**				Y	/	Y	Y	Y	Y			Y		Y	Y	Y
G. Additional data requirements	**Yes = 4**				Y	/	Y	Y					Y				
	Total:				**7**		**6**	**7**	**2**	**3**			**7**		**6**	**6**	**1**
Botanical Pest Control Products																	
A. Identity and properties	**Yes = 7**				Y	/		Y	Y	Y			Y		Y	Y	
B. Toxicology data	**Yes = 7**				Y	/	Y	Y	*	Y			Y		Y	Y	
C. Bio-efficacy data	**Yes = 6**				Y	/	Y	Y	*				Y		Y	Y	
D. Residue data	**Yes = 5**				Y	/		Y	*				Y		Y	Y	
E. Human health/Environmental fate and effect data	**Yes = 4**					/		Y	*				Y		Y	Y	
F. Labelling, packaging/storage data	**Yes = 9**				Y	/	Y	Y	Y	Y			Y		Y	Y	Y
G. Additional data requirements	**Yes = 4**				Y	/	Y	Y					Y				
	Total:				**6**		**4**	**7**	**2**	**3**			**7**		**6**	**6**	**1**
Biochemical Pest Control Products																	
A. Identity and properties	**Yes = 7**				Y			Y	Y	Y			Y		Y	Y	
B. Toxicology data	**Yes = 6**				Y	/	Y	Y	*	Y			Y		Y		
C. Bio-efficacy data	**Yes = 5**				Y	/	Y	Y	*				Y		Y		
D. Residue data	**Yes = 5**				Y	/	Y	Y	*				Y		Y		
E. Human health/Environmental fate and effect data	**Yes = 4**					/	Y	Y	*				Y		Y		
F. Labelling, packaging/storage data	**Yes = 9**				Y	/	Y	Y	Y	Y			Y		Y	Y	Y
G. Additional data requirements	**Yes = 4**				Y	/	Y	Y					Y				
	Total:				**6**		**6**	**7**	**2**	**3**			**7**		**6**	**2**	**1**
Microbial Pest Control Products																	
A. Identity and properties	**Yes = 7**				Y	/		Y	Y	Y			Y		Y	Y	
B. Toxicology data	**Yes = 7**				Y	/	Y	Y	*	Y			Y		Y	Y	
C. Bio-efficacy data	**Yes = 6**				Y	/	Y	Y	*				Y		Y	Y	
D. Residue data	**Yes = 5**				Y	/		Y	*				Y		Y	Y	
E. Human health/Environmental fate and effect data	**Yes = 5**					/	Y	Y	*				Y		Y	Y	
F. Labelling, packaging/storage data	**Yes = 9**				Y	/	Y	Y	Y	Y			Y		Y	Y	Y
G. Additional data requirements	**Yes = 3**				Y	/	Y	Y									
	Total:				**6**		**5**	**7**	**2**	**3**			**6**		**6**	**6**	**1**

* Malaysia: New/additional data may be required upon re-registration if the pesticide has been shown/detected to exhibit previously unknown properties/effects during the course of its current registration.

Observations/Issues

- About 2/3 of the countries reported folder requirements for re-registration.

Conclusions

- More information is needed to determine how different countries handle re-registration.

Summary compilation of registration folder requirements

Comparison of Requirements		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Provisional Registration																	
Same as regular registration	**Yes = 6 N = 3 NA = 7**	NA	N	Y	Y	NA	N	Y	NA	N	Y	NA	Y	NA	Y	NA	NA
Same requirements for different pest control agents?	**Yes = 4 N = 5 NA = 7**	NA	N	N	N	NA	N	Y	NA	N	Y	NA	Y	NA	Y	NA	NA
Regular Registration																	
Same requirements for different pest control agents?	**Yes = 8 N = 8**	Y	N	N	N	N	N	Y	Y	N	Y	N	Y	Y	Y	N	Y
Supplementary Registration																	
Same as regular registration	**Yes = 4 N = 2 NA = 9**	-	NA	NA	Y	NA	N	Y	NA	N	NA	NA	Y	NA	NA	NA	Y
Same requirements for different pest control agents?	**Yes = 4 N = 3 NA = 9**	Y	NA	NA	N	NA	N	Y	NA	N	NA	NA	Y	NA	NA	NA	Y
Re-registration Registration																	
Same as regular registration	**Yes = 6 N = 4 NA = 5**	-	NA	NA	Y	NA	N	Y	N	N	Y	NA	Y	NA	Y	Y	N
Same requirements for different pest control agents?	**Yes = 8 N = 3 NA = 5**	Y	NA	NA	N	NA	N	Y	Y	Y	Y	NA	Y	NA	Y	N	Y
	Yes =	3		1	3	0	0	7	2	1	5	0	7	1	5	1	4
	No =		3	2	4	1	7	0	1	6	0	1	0	0	0	2	1
Y = Yes; N = No; NA = Not applicable																	

Observations

- Many countries have the same folder requirements for all registration options.
- Many countries always require the same folders for biological products as for chemical pesticides.
- Only a few countries have different registration folder requirements for the different groups of pest control products.

Conclusions

- One does not need different registration options and guidelines if the folder and data requirements are the same for different products and registration options.
- More differentiation in the folder and data requirements may help encourage the registration of low-risk and low-toxic biological products.
- More differentiation in the folder and data requirements may facilitate and expedite registration.

III. TECHNICAL EVALUATIONS OF APPLICATION DOSSIERS

1. General procedures

Background

The responsible authority of a country should specify clearly and comprehensively the types of data that are required for the registration of a pesticide. It is essential that all steps in the registration process are transparent and based on sound and published criteria and guidance documents. The same applies to the standards for acceptance of data and for the quality of data.

Survey responses

1. General procedures		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have written internal guidelines and evaluation criteria for the technical evaluation of application dossiers?	**Yes = 14** **No = 2**	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y
Do you accept data submissions (dossiers) in the OECD format?	**Yes = 9** **No = 5** **NR = 2**	Y	N	N	Y	N[1]		Y	Y	Y	N	Y	Y	Y	Y	N	
Do you accept evaluation reports (monographs) in the OECD format?	**Yes = 9** **No = 6** **NR = 1**	Y	N	N	Y	N[1]		Y	Y	Y	N	Y	Y	Y	Y	N	N
Do you verify analytical methods/test protocols?	**Yes = 14** **No = 2**	Y	Y	Y	Y	Y N[2]	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y
Do you accept field studies conducted in countries with similar ecological and epidemiological conditions?	**Yes = 12** **No = 4**	Y	Y	N	Y*	N	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Do you require laboratory data to be generated under Good Laboratory Practice (GLP) standards?	**Yes = 13** **No = 3**	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N
Do you require field tests to follow Good Experimentation Practices (GEP)?	**Yes = 12** **No = 4**	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	N
	Yes =	7	5	4	5	4	4	5	7	6	2	6	7	7	7	4	3

Indonesia: * = only for provisional registration.
Japan: *1 We will start accepting submissions in OECD format next year.
*2 Verification of analytical methods needs more attention in terms of the evaluation of uncertainty and variability of analytical results.

Y = Yes; N = No; NR = No response

Observations

- Almost all countries have internal guidelines for the evaluation of application dossiers and they verify analytical methods and test protocols;
- Most countries accept field studies conducted in other countries.

Conclusions

- There is already a high degree of similarities in the general procedures for the evaluation of dossiers.

2. Bio-efficacy assessment

Background

Bio-efficacy assessment is carried out to ensure that pesticides approved would be efficacious for its intended use. Responsible authorities should, where applicable, use the WHO peer-reviewed, generic models of assessment of certain public health pesticides in their assessment.

Survey responses

2. Bio-efficacy assessment		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have written internal guidelines and evaluation criteria for the assessment of the bio-efficacy data?	**Yes = 13** **No = 3**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**
Do you require test protocols to follow the FAO guidelines on efficacy evaluation of plant protection products (2006)?	**Yes = 11** **No = 4** **NR = 1**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**Y**	**Y**		**Y***	**N**	**Y**	**Y**	**N**
Do you have specific test protocols that are officially required for bio-efficacy testing?	**Yes = 9** **No = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**N**	**Y**	**N**	**N**	**Y**	**N**	**N**
Do you require efficacy trials to be carried out in your country?	**Yes = 13** **No = 3**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**Y**
Do you accept WHO efficacy assessments and evaluations for certain public health pesticides?	**Yes = 11** **NR = 5**	**Y**	**Y**	**Y**	**Y***	**/**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**NA**	**Y**		
	Yes =	**5**	**5**	**5**	**5**	**3**	**5**	**2**	**3**	**5**	**3**	**3**		**0**	**5**	**3**	**2**
Indonesia: * = only for provisional registration Philippines: May use either FAO bio-efficacy test protocol or regionally accepted protocol																	
Y = Yes; N = No; NR = No response																	
Number of official test protocols to be followed for bio-efficacy testing?	**low = 1** **hi = >100**	✓	**1**		**1**	**1**		**3**		**26**	NA	*		**-**	**>2**	**>100**	
Number of field trials required for major pests on major crops	**low = 1** **hi = 10**	✓	**1**	**10**	**1**	**6**	**10**	**3**	**1**	**6**	NA	**-**	**>3**	**-**	**>6**	**2**	**5***
Number of field trials required for minor used	**low = 1** **hi = 7**	✓	**1**	**6**	**1**	**4**	**5-7**	**3**	**1**	**3-4**	NA		**>3**	**-**	**?**	**2**	**2****
Number of growing seasons required for field trials	**low = 1** **hi = >3**	✓	**2**	**2**	**1**	**2**	**1-3**	**3**	**2**	**2**	NA		**>3**	**-**	**>2**	**1/2**	**2**
Pakistan: * 2 crops season data Thailand: Two field trials required, can be carried out in one season-two locations or two seasons-one location. Viet Nam: *4 small+1 large; ** 2 large																	

Observations

- Most of the countries (13) have written internal guidelines for the assessment of bio-efficacy data;
- About 2/3 of the countries require test protocols to follow FAO guidelines; half the countries also have country-specific test protocols;
- The majority of countries require efficacy trials to be carried out in the country; only 3 countries accept field trials from other countries;
- All responding countries accept WHO efficacy assessments and evaluations for certain public health pesticides;
- The number of required field trials ranges from 1-10 trials to be carried out over 1 to >3 seasons.

Conclusions

- There are substantial differences in the quality of bio-efficacy data due to the number of required field trials and growing seasons.

3. Quality assessment

Background

The quality of a pesticide submitted for registration is of prime importance and a quality assessment should be carried out. Applicants should provide certification to prove that their product is of good quality and where applicable, complies with international specifications such as those of FAO and WHO. Responsible authorities on the other hand should have access to analytical facilities to verify the quality of the pesticide prior to as well as post-registration. In the absence of such facilities, a certificate of analysis from an independent certified laboratory can be requested.

Survey responses

3. Quality assessment		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have written internal guidelines and evaluation criteria for the assessment of the pesticide quality?	**Yes = 12** **No = 4**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**
Do you require pesticides to conform to relevant FAO or WHO specifications?	**Yes = 15** **No = 1**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you accept a certificate of analysis from an independent qualified laboratory?	**Yes = 15** **No = 1**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y***	**Y**
		3	**3**	**2**	**3**	**2**	**3**	**2**	**3**	**2**	**2**	**3**	**3**	**2**	**3**	**3**	**3**
*Thailand: Certificate of analysis from other laboratory is accepted only if DOA laboratory's facility is not available.																	
Y = Yes; N = No; NR = No response																	

Observations

- Most of the countries (12) have written internal guidelines for the assessment of pesticide quality;
- Almost all countries require pesticides to conform to FAO/WHO specifications;
- All countries accept analyses from independent qualified laboratories.

Conclusions

- There is already a high degree of harmonization with regard to the assessment of pesticide quality;
- Not all countries have adequate analytical facilities to access the quality of pesticides.

4. Residue assessment

Background

For all uses of pesticides on food and feed crops, the applicant should provide the necessary residue data generated in accordance with *Codex Alimentarius* and FAO guidelines on good analytical practice and on crop residues data for assessment by the responsible authority. Residue assessments do not always need to be based on local residue trials, however. In some cases it may suffice to review the results of trials conducted in other countries on similar crops, using relevant agricultural practices under comparable climatic conditions. The use of maximum residue limits defined by the *Codex Alimentarius* is recommended whenever applicable to the national situation.

Survey responses

4. Residue assessment		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have written internal guidelines and evaluation criteria for the assessment of the pesticide residues?	**Yes = 12** **No = 4**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**	**Y**	**Y/1**	**Y**	**Y**	**Y**
Do you require residue data to be generated in accordance with *Codex Alimentarius?*	**Yes = 15** **No = 1**	**Y**	**Y**	**Y**	**Y**	**N[1]**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y/2**	**Y**	**Y**	**Y**
Do you require residue data to be generated in accordance with the FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed (2010)?	**Yes = 14** **No = 2**	**Y**	**Y**	**Y**	**N**	**Y[2]**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**
Do you require residue trials to be conducted in your country?	**Yes = 8** **No = 8**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**N**	**N**	**N**	**N**	**Y**	**Y**
Do you accept the results of trials conducted in other countries under comparable climatic conditions?	**Yes = 13** **No = 3**	**Y**	**Y**	**N**	**Y**	**N[3]**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you use maximum residue limits defined by the *Codex Alimentarius* when available?	**Yes = 16**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		5	6	5	4	4	6	4	5	5	5	3	5	5	5	6	5

Japan: *1 Guidelines on the generation of residue data for MRL setting are not provided in the Codex Alimentarius.
*2 Minimum number of residue trials for major crops will be increased from 2 to 6 from 2014.
*3 We accept data on indoor trials conducted in other countries.
Singapore: /1 Mostly following OECD
/2 Yes for setting national MRL; no for setting import tolerance
Thailand: Residue data generated in other countries is accepted provided that application dose rate different not exceed 25%

Y = Yes; N = No; NR = No response

Observations

- Most of the countries (12) have written internal guidelines for the assessment of pesticide residues;
- Almost all countries require residue data to be generated in accordance with the FAO Manual and the *Codex Alimentarius;*
- About half the countries require residue trials to be conducted in the country even though they indicated to accept trials from other countries;
- All countries use the MRL defined by the *Codex Alimentarius*.

Conclusions

- Except for the requirement that residue tests have to be conducted in the country, pesticide residue assessment procedures appear to be widely harmonized in APPPC countries.

5. Hazard assessment

Background

Applicants for registration of pesticides should submit a full assessment of hazards for human health and the environment. Such assessment should include acute oral, dermal and inhalation toxicity; skin and eye irritation, skin sensitization, as well as toxicity based on repeated administration (from sub-acute to chronic) and studies such as reproductive and developmental toxicity, genotoxicity, carcinogenicity, metabolism in animal and plants, etc. Ecotoxicological profile of the product based on toxicity to aquatic and terrestrial organisms as appropriate to the intended use, and information of persistence and bioaccumulation is also necessary.

Survey responses

5. Hazard assessment		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you carry out a health and environmental hazard assessment?	**Yes = 12 No = 4**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**N**	**Y**	**Y**
Do you have internal guidelines and evaluation criteria for the assessment of health and environmental hazards?	**Yes = 10 No = 6**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**	**Y**	**N**	**Y**	**Y**	**N**
Do you accept hazard assessments that have been carried out and published by reputable registration authorities in other countries?	**Yes = 15 No = 1**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you assess the hazard of the active substance?	**Yes = 15 No = 1**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you assess the hazard of the formulation?	**Yes = 15 No = 1**	**Y**	**Y**	**Y**	**Y**	**Y***	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		5	**5**	**5**	**5**	**4**	**5**	**3**	**5**	**4**	**1**	**3**	**5**	**4**	**4**	**5**	**4**
*Japan: Acute effects only																	
Y = Yes; N = No; NR = No response																	

Observations

- About 3/4 of the countries carry out health and environmental assessments; most of these countries have internal guidelines for making the assessments;
- All but one country (Japan) accepts hazard assessments carried out by registration authorities in other countries;
- Hazard assessments always include both the active substance and the formulation.

Conclusions

- Even though some countries do not carry out hazard assessments, there is generally a high degree of uniformity among APPPC countries.

6. Risk assessment

Background

Applicants for registration of pesticides should provide data on exposure resulting from the intended use under actual conditions of use. Applicants should also make an assessment of human health and environmental risks under the conditions the pesticide is proposed to be used and provide it to the responsible authority for evaluation.

Survey responses

6. Risk assessment		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you conduct country-specific risk assessments for…																	
occupational risks?	**Yes = 8 N/NR = 8**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**N**		**N**	**N**	**Y**	**N**	**N**	**Y**	**Y**
consumer risks?	**Yes = 10 No = 6**	**Y**	**Y**	**Y**	**Y***	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**N**	**N**	**N**	**N**	**Y**	**Y**
environmental risks?	**Yes = 8 N/NR = 8**	**Y**		**Y**	**Y***	**Y**	**Y**	**N**	**N**		**N**	**N**	**Y**	**N**		**Y**	**Y**
Do you have written internal guidelines and evaluation criteria for the assessment of health risks?	**Yes = 8 No = 8**	**Y**	**Y**	**Y**	**Y***	**Y**	**Y**	**N**	**N**	**N**	**N**	**N**	**Y**	**N**	**N**	**Y**	**N**
Do you have written internal guidelines and evaluation criteria for the assessment of environmental risks?	**Yes = 9 No = 7**	**Y**	**Y**	**Y**	**Y***	**Y**	**Y**	**N**	**N**	**N**	**N**	**N**	**Y**	**N**	**Y**	**Y**	**N**
Do you take into account the FAO *Revised guidelines on environmental criteria for the registration of pesticides* (1989)	**Yes = 12 No = 4**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**Y**	**Y**	**N***	**Y**
Do you collect information on the pesticide use practices in your country?	**Yes = 15 No = 1**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**
Do you have data on pesticides exposure in your country?	**Yes = 12 No = 4**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**N**	**Y**	**Y**	**N**
Do you take into account detailed toxicological data?	**Yes = 12 No = 4**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you take into account long-term dietary exposure?	**Yes = 12 No = 4**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you take into account exposure to very low levels of pesticides?	**Yes = 10 No = 6**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**N**	**N**	**N**	**N**	**Y**	**Y**	**Y**	**Y**
Do you require environmental effect studies?	**Yes = 15 No = 1**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you require environmental fate studies?	**Yes = 16**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you assess the risk for development of pest resistance?	**Yes = 13 No = 3**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you assess the risk for phytotoxicity?	**Yes = 14 No = 2**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		15	**14**	**15**	**12**	**13**	**14**	**5**	**11**	**7**	**3**	**7**	**13**	**8**	**11**	**14**	**12**
Indonesia: * = for GMO Thailand: *adopted EPA recommendation																	
Y = Yes; N = No; NR = No response																	

Observations

- Risks to consumers are assessed more often to consumers than to farmers or the environment;
- Slightly than half the countries (8-9) have written internal guidelines for the assessment of health or environmental risks;
- About 2/3 of the countries take the FAO guidelines into account and consider exposure information, toxicological data, and long-term dietary studies.
- All or almost all countries require environmental fate or environmental effect studies;
- Most countries assess the risk for the development of pest resistance and phytotoxicity.

Conclusions

- Even though most countries require health and environmental studies, many lack internal guidelines and decision-making criteria for the evaluation of health and environmental risks.

7. Risk-benefit analysis

Background

In considering the need for a pesticide, the responsible authority should weigh the benefits against the risks the pesticide would pose if it were to be used under local conditions. Relevant questions that should be considered are whether: the pest(s) for which the pesticide is to be used against is a problem; suitable (non-chemical) or lesser toxic and cost-effective chemical alternatives are available; there is a need for its use in resistance management; or the use of the pesticide is compatible with IPM or IVM. Besides human health and environmental risks there also may be economic risks, for instance if maximum residue limits for certain pesticides on export crops have been set at detection level in the country of destination.

Survey responses

7. Risk-benefit analysis		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you carry out a risk-benefit analysis?	**Yes = 10** **No = 6**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**	**Y**	**N**	**N**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you have written internal guidelines and evaluation criteria for a risk-benefit analysis?	**Yes = 6** **No = 10**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**	**N**	**N**	**N**	**N**	**Y**	**N**	**Y**	**N**	**N**
Do you consider whether the new product is actually needed?	**Yes = 12** **No = 4**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**N**	**Y**
Do you consider the availability of less-toxic alternatives?	**Yes = 15** **No = 1**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you consider the compatibility of the product with IPM or IVM?	**Yes = 14** **No = 2**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you consider economic risks?	**Yes = 13** **No = 2**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**		**Y**	**Y**	**Y**	**Y**
		6	**6**	**4**	**5**	**0**	**6**	**4**	**5**	**4**	**4**	**1**	**5**	**5**	**6**	**4**	**5**

Remarks:
Malaysia: Technical evaluations/analysis are carried out based on expert opinion.
Philippines: The FPA is having an interagency meetings with different stakeholders in conducting risk-benefit analysis prior to either approval of pesticide in question or banning of pesticide with economic importance.

Y = Yes; N = No; NR = No response

Observations

- About 2/3 of the countries carry out risk-benefit analysis, but not all of these countries have written internal guidelines;
- Less toxic alternatives compatible with IPM/IVM and economic risks are generally considered.

Conclusions

- Some considerations of risk-benefit seem to be considered in most of the APPPC countries, even though formal risk-benefit analyses still need to be introduced in a number of countries.

8. Labelling

Background

Draft labels submitted by applicants should be evaluated based on the requirements and criteria set for registration and should include clear information on the permitted use of the product, dosage and other use recommendations, warning and precautionary statements and description of required personal protection, hazard class, warning statement against the reuse of containers, and instructions on safe disposal or decontamination of empty containers. The responsible authority should also ensure that the approved labels are written in the major language(s) of the country and also include the registration number, lot or batch number, warning and precautionary statements, date of release of lot (month and year).

All products should be classified according to their hazard, in accordance with the Globally Harmonized System for Classification and Labelling (GHS). As long as this system is not fully implemented, products can be classified according to the WHO hazard classification or any national regulation. Responsible authorities particularly in developing countries should consider the use of colour bands, warning statements and pictograms to reflect the different hazard classes of pesticides to minimize risks posed by pesticides.

Survey responses

8. Labelling		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have written internal guidelines and evaluation criteria for the assessment of the pesticide labels?	**Yes = 15** **No = 1**	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
Do you require labels to follow the FAO Guidelines on good labelling practice for pesticides (1995)	**Yes = 15** **No = 1**	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Have you adopted the Global Harmonized System (GHS) for pesticides hazards evaluation and labelling?	**Yes = 6** **No = 9** **NR = 1**	Y	Y	N	Y	N		N	N	Y	N	N	N	N	Y	N	Y
Do you follow the WHO Recommended Classification of Pesticides by Hazard	**Yes = 15** **No = 1**	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Do you require bilingual labels (English and national language)?	**Yes = 10** **No = 6**	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N
		5	5	3	4	1	4	3	4	5	4	4	3	4	5	3	4
Y = Yes; N = No; NR = No response																	

Observations

- Almost all countries have internal guidelines for label evaluation, and follow FAO and WHO guidelines;
- About 1/3 of the countries have adopted the GHS system for hazard evaluation and labelling;
- About 2/3 of the countries require bilingual labels.

Conclusions

- Label assessment is probably the most harmonized aspect of registration management;
- Countries that have adopted the GHS have also adopted the WHO classification, which is a different system; it is not clear how these countries have resolved the conflicting guidelines.

IV. PESTICIDE REGISTRATION AND LICENSING

1. General Procedures

Background

This is one of the most important steps in the registration process and should be carried out by qualified experts and based on well-established criteria and procedures relevant to the intended use of the pesticide. It is important that applicants provide quality data to support their applications to enable the responsible authority to make informed decisions that would ensure that products registered would perform as intended and not cause unacceptable adverse effects to man and the environment. The pesticide board should take its decisions to register a pesticide, or refuse registration, based on criteria which have been legally defined. This will increase transparency and independence of decision-making. It is also important that registration can be cancelled if new information warrants such action.

Survey responses

1. General Procedures		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have legally defined criteria for making registration decisions?	**Yes = 16**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you have written internal guidelines and criteria for making registration decisions?	**Yes = 15** **No = 1**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you have procedures to cancel or restrict a valid registration?	**Yes = 16**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		3	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**2**	**3**	**3**	**3**	**3**	**3**	**3**	**3**
Y = Yes; N = No; NR = No response																	

Observations

- All countries have legally defined criteria for accepting or rejecting a registration application;
- All countries have procedures to cancel or restrict a valid registration if new evidence indicates previously unknown risks.

Conclusions

- The general procedures of registration decision making is largely harmonized among the responding APPPC countries

2. Please indicate who decides on pesticide registration and licensing?

Background

The pesticide registration body may be a government department or agency, or an independent national statuary body. A Pesticide Board (sometimes referred to as Pesticide Registration Board, Pesticide Council or Pesticide Committee) is the officially or legally appointed body that takes the final decision on the request for registration. Its independent members should be highly qualified experts from the sectors of agriculture, health and environment. The outcome of the registration process may be provisional or full registration, with or without restrictions or conditions, or refusal of registration.

Survey responses

2. Please indicate who decides on pesticide registration and licensing?		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Provisional registration			O	A	B	/	B	A		B		A	A	NA	A	-	
Full registration		A	O	A	B	A	A	A	B	B	A	A	A	A	A	R	B
Conditional registration with restrictions		-	O		B		A	A		B	A	A	A	NA	A	-	B
Renewal or re-registration		A	O	A	B	A	A	A	B	B	A	A	*	NA	A	R	A
Import/export licenses		A	O		B	A	ABO	A	AB	B	A	A	A	A*	A	HS	A
Sale and retail licenses		A	O			O*	ABO	A	B	O	A	O	A	A*	A	HS	A
Licensing of commercial pesticide applicators		A	O			/	ABO	A	B	B	A		A	A	A	HS	A
Cambodia: MAFF Japan: *Distributors of pesticides shall notify their place of business to respective prefectural governments. Pakistan: Provincial Govt. Philippines: *Region Singapore: For chemicals by NEA Thailand: R = Registration Sub-committee; HS = Hazardous Substances Regulatory group																	
A = National Authority; B = Pesticide Board; O = Other; NA = Not applicable																	

Observations

- In the majority of cases, the registration decision is taken by the responsible national regulatory agency; in about 1/3 of the countries, the registration decision is done by a pesticide board or similar committee;
- Licences are generally issued by the pesticide regulatory agency; in a few cases, the pesticide board decides on licences.

Conclusions

- While the FAO registration guidelines recommend a separation of dossier evaluation and final registration decision, in many countries both functions are carried out by the responsible national authority.

3. Please indicate the length of the validity period for the following types of registrations

Background

A registration would normally be granted for a limited period of time, the length of which depends on national circumstances and capacity for re-registration review. Before the end of the registration period, registrants should submit an application for re-registration. The applicant should include any new information that became available in the intervening period. The responsible authority should then evaluate the application for re-registration. If no request for re-registration is submitted, the pesticide should be removed from the pesticide register and not be allowed to be used.

Survey responses

3. Please indicate the length of the validity period for the following types of registrations		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Provisional registration	**low = 1 hi = 5**	-	1	1	1	/	1	-		5		1+	1	NA	1	-	
Full registration	**low = 2 hi = 10**	2	3	5	5	3	4-5	2	5	10	5	3	3	∞*	3	6	5
Conditional registration with restrictions	**low = 1 hi = 5**	-	1		-	/	1	-		2	1	*	1	NA	1	-	5
Renewal or re-registration	**low = 2 hi = 6**	3	3	1/5	5	3	4-5	2	5	5	5	3	3	NA	3	6	5

* Pakistan: No period defined
* Singapore: Life time

Observations

- A provisional registration is normally granted for 1 year except for Myanmar, where it is valid for 5 years;
- Normally, renewal or re-registration is for the same validity period as the full registration except for Bangladesh and Myanmar;
- The full registration is normally valid between 3 and 6 years (most often = 5 years), except for Bangladesh (2 years), Myanmar (10 years) and Singapore (life time);
- Conditional registration is usually for a shorter period than a full registration, except for Viet Nam (same period).

Conclusions

- Most countries have roughly similar registration validity periods with the notable exceptions of Bangladesh and Myanmar;
- In Bangladesh, the so-called full registration resembles a short-term provisional registration, which is followed by a longer-period renewal or re-registration;
- In Myanmar, the provisional registration resembles more a full registration in other countries;
- A common understanding of the functions of provisional, full and re-registration among APPPC countries would be desirable.

4. Please indicate the number of pesticide registrations

Background

The responsible authority should keep an up-to-date register of registered pesticides and make that information available to the public. The list should be updated on a regular basis, preferably at least once a month.

Survey responses

4. Please indicate the number of pesticide registrations		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Active Substances																	
Number or registered chemical pesticides	**low = 73 hi = 2 950**	2 950		580		470			449	201	92	236		-	141	93	400
Number or registered botanical pesticides	**low = 0 hi = 15**	**-**		15					**3**		**1**	**-**		**-**	**1**	**-**	
Number or registered biochemical pesticides	**low = 0 hi = 20**	**-**		20		33						**1**		**-**		**-**	
Number or registered microbial pesticides	**low = 2 hi = 13**	**-**		13		40			**1**		**5**	**-**	**5**	**-**	**1**	**-**	
Formulated Products																	
Number or registered chemical pesticides	**low = 73 hi = 20 000**	9	1 532	20 000	2 628	4 358		73	2 477	1 517	833	6 218	1 176	301	~800	1 943	3 500
Number or registered botanical pesticides	**low = 0 hi = 150**	-	0	150	66			0	6	4	10	1	2	3	1	2	
Number or registered biochemical pesticides	**low = 0 hi = 300**	-	0	300				0		60	x	1		0		-	
Number or registered microbial pesticides	**low = 0 hi = 1 800**	-	0	1 800				0	30	7	9	-	12	10	3	22	
hi = Highest number																	

Observations

- The total number of products registered in a country ranges widely from 73 to 20 000;
- About 99 percent of all registered pest control products are chemical pesticides; significant numbers of biological agents are only registered in China and Japan;
- Bangladesh indicated more registered active substances than formulated products (presumably an error?).

Conclusions

- It would need to be verified whether active substance registrations are only for the active substance or in combination with a formulated product;
- The low numbers of registered biological pest control products may be partially due to unreasonable or inappropriate registration requirements.

5. Banned or severely restricted pesticides

Background

A separate list containing the pesticide products that are banned or severely restricted in the country or region is desirable. The purpose of a list of banned pesticides is to indicate that certain pesticides will not be considered for registration. The purpose of severely restricting pesticides is to keep certain pesticides available for very specific purposes, only to be handled by specialists, while acknowledging that hazards are such that they should not be freely available.

Survey responses

5. Banned or severely restricted pesticides		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Number of banned/restricted highly toxic pesticides (WHO Class 1a and 1b)	**low = 3 hi = 54**	**12**	**42**	**26**	**42**	**7**		**46**	**3**	**10**	**5**	**26**	**28**	**-**	**4**	**6**	**29**
Number of banned/restricted Persistent Organic Pollutants (POPs)	**low = 0 hi = 15**	**9**	**12**	**8**		**15**	**8**	**9**	**9**	**9**	**9**	**9**	**9**	**-**	**all**	**12**	**0**
Number of other banned/restricted pesticides	**low = 0 hi = 116**	**CCA**	**116**	**26**		**6**	**32**	**0**	**19**	**7**			**19**	**-**	**1**	**84**	**0**
Total	**low = 14 hi = 170**	**21**	**170**	**60**	**42**	**28**	**40**	**55**	**31**	**26**	**14**	**35**	**56**		**26**	**102**	**29**
hi = Highest number																	

Observations

- There is a wide range of banned/restricted highly toxic pesticides ranging from 3 to 46 products
- The number of banned/restricted POP ranges from 0 to 15
- The total number of banned/restricted pesticides ranges from 14 to 170

Conclusions

- There are wide differences in the number of banned or restricted pesticides. Many countries may register pesticides that are banned in neighbouring countries;
- The Stockholm Convention currently regulates 21 chemicals, of which 9 are pesticides; in most reporting countries, the POP pesticides seem to be banned.

6. Please indicate the number of licenses issued for the following functions

Background

The number of issued licenses is an indicator for the size of the pesticide market and the level of enforcement of the pesticide legislation.

Survey responses

6. Please indicate the number of licenses issued for the following functions		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
• import of pesticides	**low = 8 hi = 2 639**	150	52			16		8	2 639	583	~60	136	318			848	
• manufacture of pesticides	**low = 0 hi = 4 342**	-	0			4 342		0		0	5	1	120			893	
• sale and retail shops	**low = 14 hi = 50 000**	~50 000	14			NA		15	5 000	2 684	~4 000		118		3 000	311	
• commercial pesticide applicators	**low = 1 hi = ~4 000**	80	14			/		1	3 937	1 560	8		302	154		58	
hi = Highest number																	

Observations

- Almost all reporting countries have issued import licences
- Only 5 countries have licensed local manufacture of pesticides
- Most reporting countries licence sale and retail shops; the number of licences per country ranges from 14 to about 50 000
- Most reporting countries licence commercial pest control operators; the number of licences per country ranges from 8 to almost 4 000.

Conclusions

- Licensing businesses is an important aspect of pesticide regulatory management in all responding countries.

V. POST-REGISTRATION ACTIVITIES

1. Please indicate the level of functionality of the following post-registration steps

Background

The responsible authority should ensure that all registration decisions and assessments are properly documented and stored for future reference. Furthermore, post-registration monitoring and evaluation provide a means of measuring the validity of predictions, based on registration data, regarding the efficacy, safety and environmental effects of a particular pesticide product. Post-registration monitoring and evaluation may reveal that a product is no longer effective as a result of the documented development of pesticide resistance to a level of field performance failure, that the product is of poor quality or that it has caused unacceptable risks to human health or the environment. Widespread abuse of the pesticide concerned or non-adherence to restrictions are factors that should also be taken into consideration. The responsible authority may make use of the findings of post-registration monitoring and evaluation to take the necessary corrective actions such as the amendment of recommendations on use and dosage, restriction on use or, if necessary, withdrawal of the registration of the product.

Survey responses

1. Please indicate the level of functionality of the following post-registration steps		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Archiving of all registration documents and correspondence and storage in a safe place	F = 10 P = 1 M = 3	F	P	F	F	F	F	M	FM = P	F	M		M	F	F	F	F
Post-registration monitoring of quality of pesticides	F = 8 P = 4 M = 4	F	P	F	P	F	F	M	P	M	M	F	P	M	F	F	F
Post-registration monitoring of pesticides in food	F = 6 P = 5 M = 5	F	M	F	M	F	P	M	F	P	M	M	P	F	P	F	P
Post-registration monitoring of poisoning cases of humans and livestock	F = 5 P = 8 M = 3	F	M	F	P	F	F	M	P	P	M	P	P	F	P	P	P
Post-registration monitoring of adverse effects on the environment	F = 3 P = 6 M = 7	F	M	F	M	F	P	M	P	M	M	P	P	M	P	P	M
Collection of data on the import, export, manufacture and use of pesticides	F = 11 P = 2 M = 3	F	M	F	F	F	F	M	P	F	F	F	F	M	F	F	P
Re-registration with complete or partial re-evaluation of dossiers	F = 7 P = 2 M = 5	F	M	F	F	M	P	M	F	P	M	F	F	NA	F	NA	PM = M
Unscheduled reviews when new information becomes available	F = 8 P = 3 M = 4	F	M	F	P	F	F	M	P	F	M	F	F	F	P	-	M
Appeals procedures against registration decision; Period for making an appeal:__days	low = 14 hi = 60				M	14		M	F	30	M	F	60	14	60	-	M
Full (F)		8	0	8		7	5	0	4	3	1	5	3	4	4	4	2
Partial (P)		0	2	0		0	3	0	6	3	0	2	4	0	4	2	4
More attention needed (M)		0	6	0		1	0	9	0	2	8	1	1	3	0	0	4

Observations

- Less than 2/3 of the countries are fully archiving all registration documents and correspondence;
- Most countries collect data on the import, export, manufacture and use of pesticides;
- About half the countries monitor the quality of pesticides and residues in food;
- Only a few countries monitor fully poisoning cases of humans and livestock, or adverse effects on the environment;
- About half the countries conduct unscheduled reviews when new information becomes available.

Conclusions

- All responsible agencies carry out post-registration activities;
- Post-registration monitoring and evaluation of adverse pesticide effects is still weak in half the countries;
- Without proper post-registration information, responsible authorities cannot take corrective actions.

2. Information management

Background

The FAO registration guidelines promote transparency and exchange of information in the pesticide registration process as well as in monitoring and evaluation post-registration. Governments should develop legislation and regulations to permit information exchange to the public about pesticide risks and benefits as well as to facilitate the participation of the public in the management of pesticides in the country. Governments should also facilitate exchange of information between responsible authorities through national institutions, international, regional and sub-regional organizations as well as public sector groups.

Survey responses

2. Information management		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you have regulations or guidelines for information sharing?	**Yes = 10 No = 5 NR = 1**	**Y**	**Y**	**Y**	**Y**	**N**		**N**	**N**	**N**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**
Do you have an information sharing system for pesticide regulations on …																	
• national level	**Yes = 11 No = 3 NR = 2**	**Y**	**Y**	**Y**	**Y**	**Y**		**N**	**N**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**Y**	
• regional level	**Yes = 9 No = 4 NR = 3**	**Y**	**Y**	**Y**	**Y**	**Y**		**N**	**N**	**Y**	**Y**	**N**	**Y**		**Y**	**N**	
• community level	**Yes = 9 No = 4 NR = 3**	**Y**	**Y**	**Y**	**N**	**Y**		**N**	**N**	**Y**	**Y**		**Y**		**Y**	**N**	**Y**
Do you use the FAORAP-APPPC website for information sharing?	**Yes = 5 No = 6 NR = 5**	**Y**	**N**			**N**		**N**	**Y**	**Y**	**Y**		**N**		**Y**	**N**	**N**
Have you reported the observance of the Code of Conduct to FAO according to Art. 12 of the Code?	**Yes = 5 No = 6 NR = 5**	**Y**	**N**			**Y**	**Y**	**N**		**N**	**N**	**N**			**Y**	**Y**	**N**
Do you have a published list/database on registered pesticides?	**Yes = 15 NR = 1**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Do you have a published list/database on banned/severely restricted pesticides?	**Yes = 14 No = 1 NR = 1**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**
Do you have reports of residues monitored in food?	**Yes = 12 No = 3 NR = 1**	**Y**	**Y**	**Y**		**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**N**	**N**	**Y***	**Y**	**Y**	**Y**
Do you have reports of residues monitored in the environment?	**Yes = 10 No = 5 NR = 1**	**Y**	**Y**	**Y**		**Y**	**Y**	**N**	**Y**	**Y**	**N**	**N**	**N**	**N**	**Y**	**Y**	**Y**
Do you have reports on monitoring the quality of pesticides?	**Yes = 11 No = 4 NR = 1**	**Y**	**Y**	**Y**		**Y**	**Y**	**N**	**N**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**Y**
Do you have reports on illegal trade of pesticides?	**Yes = 9 No = 7**	**Y**	**Y**	**Y**	**Y**	**N**	**N**	**Y**	**Y**	**Y**	**N**	**N**	**N**	**N**	**Y**	**Y**	**N**
Do you have reports on health and environmental incidences from exposure to pesticides	**Yes = 10 No = 5 NR = 1**	**Y**	**Y**	**Y**		**Y**	**Y**	**N**	**Y**	**Y**	**N**	**N**	**Y**	**N**	**Y**	**Y**	**N**
* Singapore: internal reports		13	11	11	6	10	5	3	7	11	9	4	7	4	13	10	6
NR = No response																	

Observations

- The majority of countries (10) have regulations or guidelines for information sharing;
- About 2/3 of the countries have information sharing systems that cover the national, regional and community level;
- Almost all countries have published lists on registered and banned/restricted pesticides;
- About 2/3 of the countries have reports on residues, quality, illegal trade and poisoning cases;
- Only few countries report the observance of the Code or conduct or use the FAORAP-APPPC website for information sharing.

Conclusions

- All countries have information and information exchange systems to promote transparency and the participation of the public in the management of pesticides in the country.

3. Please indicate the number of reports and notifications on the following matters

Background

The Code of Conduct and other international conventions provide a platform for reporting on pesticide regulatory management.

Survey responses

3. Please indicate the number of reports and notifications on the following matters		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Number of regular reports on observance of Code (Annex A)	**Yes = 2**	**-**				**>1** *1					**X**		**-**	**-**		**3** *1	
Number of ad-hoc reports on observance of Code (Annex B)	**Yes = 1**	**-**				**>1** *1					**X**		**-**	**-**		**-**	
Notifications of final regulatory actions (Rotterdam)	**Yes = 4**	**-**				**67** *2	**30**				**1**		**-**	**-**		**96**	
Notifications of PIC procedures (Rotterdam)	**Yes = 5**	**-**				**43**			**3**	**1**	**1**		**-**	**-**		**47** *2	
Notifications of MRLs established by the country	**Yes = 2**	**-**				**NA** *3		**0**			**X**		**-**	**0**		**50**	
Count =						**4**	**1**		**1**	**1**	**2**					**4**	

* Japan: *1 In 2009
*2 Including 35 final regulatory actions on pesticide regulation
*3 Notifications are regularly made, but no statistics available
Thailand: *1 In 2008, 2010 and 2011
*2 Number of Export Notification Acknowledged (2008–2012)

Observations

- Only two countries gave details on reports on the observance of Code of Conduct, even though 5 countries claimed to have issued reports
- Four countries have issued notifications under the Rotterdam Convention even though x countries have ratified the convention

Conclusions

- Most countries do not exchange information on pesticide regulatory management as requested by international treaties.

4. Do you have enforcement procedures against …

Background

Governments should make provision for effective monitoring and enforcement of pesticide regulations, including the establishment of licensing and inspection schemes for importers and retailers.

Survey responses

4. Do you have enforcement procedures against …		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
• low-quality pesticides	**Yes = 15** **No = 1**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
• unregistered use of pesticides	**Yes = 16**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
• unapproved use of pesticide	**Yes = 15** **No = 1**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y
• licensing violations concerning import, manufacture, storage, transport, distribution and use of banned pesticides	**Yes = 14** **No = 1** **NR = 1**	Y		Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y*	Y	Y	Y
• illegal trade in pesticides	**Yes = 14** **No = 2**	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y*	Y	Y	Y
• transport and marketing along with consumer goods	**Yes = 12** **No = 4**	Y	Y	Y	N	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y
• misleading advertisement	**Yes = 12** **No = 3** **NR = 1**	Y		Y	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y
		7	5	7	4	6	7	7	7	5	5	6	7	5	7	6	7
Singapore: By NEA																	

Observations

- Half countries have enforcement procedures for all violations listed;
- Except for unregistered use of pesticides, all other categories are not fully enforced in all countries;
- Certain enforcement procedures may not be applicable for some countries;
- Enforcement of proper transport, marketing and advertisement is still lacking in 6 countries.

Conclusions

- Even with enforcement procedures in place, actual enforcement depends on human and technical capacities that are still lacking in a number of countries.

5. Quality Control

Background

Monitoring the quality of pesticides sold protects farmers against counterfeit, adulterated, sub-standard and potentially hazardous products.

Survey responses

5. Quality Control		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Do you monitor the quality of pesticides sold in outlets?	**Yes = 13** **No = 3**	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y
Do you monitor imported active ingredients and formulations?	**Yes = 11** **No = 5**	Y	N	Y	N	Y[1]	Y	N	N	Y	Y	Y	Y	N	Y	Y	Y
Do you monitor imported intermediates and precursors for pesticide manufacture?	**Yes = 6** **N/NR = 10**	Y	N		N	N	Y	N	N	N	Y	N	Y	N	N	Y	Y
Do you monitor the flow of sub-standard and adulterated pesticides?	**Yes = 12** **No = 4**	Y	N	Y	N	Y[2]	Y	N*	Y	Y	Y	Y	Y	N	Y	Y	Y
		4	1	3	1	2	4	0	2	3	4	3	4	0	3	4	4

Japan:

*1 Pesticide formulations not registered in Japan are checked at customs and not allowed for import. Active ingredients of pesticides not registered in Japan cannot be imported unless the substance has successfully undergone safety assessment for other purposes (e.g. industrial chemical, medicine, etc.).

*2 There is no regular activities since sub-standard or adulterated pesticides are not commonplace. However, once such product is identified, the flow of the product will be traced based on a series of inspection of premises of manufactures, importers and distributors by the national authority as well as local governments. Responsible parties will be ordered to recall them and to report to the regulatory authority on its progress on a regular basis.

N = No; NR = No response

Observations

- More than 2/3 countries monitor the quality of pesticides and flow of substandard and adulterated pesticides.
- Less quality control monitoring focuses on imported chemicals.

Conclusions

- Some countries that monitor the quality of pesticides may not have sufficient personnel and technical capacity for an effective control.

6. Residue monitoring

Background

Pesticide residues in food, feed and the environment poses potential threats to consumers, livestock and wildlife. It is an important post-regulatory function to monitor the levels of residues in order to determine compliance with established MRL.

Survey responses

6. Residue monitoring		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Have you set up a system for monitoring pesticide residues in food?	**Yes = 11** **No = 5**	N	N	Y	N	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y
Have you set up a system for monitoring pesticide residues in feed?	**Yes = 4** **N/NR = 12**	N	N		N	Y	N	N	Y	N	Y	N	N	N	N	Y	N
Have you set up a system for monitoring pesticide residues in the environment?	**Yes = 6** **N/NR = 10**	N	N		N	Y	Y	N	Y	Y	N	N	N	N	Y	Y	N
		0	0	1	0	3	2	0	3	2	2	0	1	1	2	3	1
N = No; NR = No response																	

Observations

- Only 3 countries have set up a residue monitoring system that covers food, feed and the environment;
- 11 countries monitor pesticide residues in food;
- 4 counties monitor pesticide residues in feed;
- 6 countries include environmental samples.

Conclusions

- Residue monitoring is an essential part of post-registration monitoring and evaluation in order to assess risks to human health or the environment;
- Residue monitoring requires extensive resources that are not available in all countries. Five countries have no pesticide residue monitoring system, while 6 countries have only a partial one.

VI. INFRASTRUCTURE AND HUMAN CAPACITIES FOR PESTICIDE REGULATORY MANAGEMENT

1. National Authority for Pesticide Registration

Background

To enhance regional cooperation, the national authorities and contact persons should be known to other countries.

Survey responses

1. National Authority for Pesticide Registration		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Name		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Address			**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Contact			**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**

Bangladesh

Name of national authority for pesticide registration	Director Plant Protection Wing, DAE
Address	
Contact person	Name: Title: E-mail:

Cambodia

Name of national authority for pesticide registration	Department of Agricultural Legislation (DAL).
Address	Ministry of Agricultural, Forestry and Fisheries (MAFF) No. 200, Preah Norodom Bld., Sangkat Tonle Basak, Khan Chamkarmon, Phnom Penh, Cambodia
Contact person	Name: Mr Ouk Syphan Title: Director General of DAL. E-mail: osp.258@gmail.com

China

Name of national authority for pesticide registration	Department of Crop Production, Ministry of Agriculture, China
Address	No. 11 Nong ZhanGuan Nan Li, Chaoyang District, Beijing, China
Contact person	Name: Pesticide Management Division Title: E-mail: pmd@agri.gov.cn

Indonesia

Name of national authority for pesticide registration	Pesticide Commission
Address	Ministry of Agriculture Jl. Harsono. RM., No. 3. Building D, 8th Floor Ragunan Pasar-Minggu, South Jakarta
Contact person	Name: Dr Sumarjo Gatot Irianto Title: Chairman of Pesticide Committee/General Director of Facility and Infrastructure E-mail:

Japan

Name of national authority for pesticide registration	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Address	1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo, 100-8950 Japan
Contact person	Name: Masahiro SEGAWA Title: Director, Agricultural Chemicals Office, MAFF E-mail: Masahiro_Segawa@nm.maff.go.jp

Korea, DPR

Name of national authority for pesticide registration	Research Institute of Agro-chemicalization, Academy of Agricultural Sciences, DPR of Korea
Address	Chonggye-dong, Ryongsong District, Pyongyang
Contact person	Name: Kim Chi Yong Title: Director, Research Institute of Agro-chemicalization E-mail: aas1948@star-co.net.kp

Lao PDR

Name of national authority for pesticide registration	Department of Agriculture
Address	Ministry of Agriculture and Forestry Department of Agriculture B.O. Box 811, Vientiane, Lao PDR
Contact person	Name: Khamphoui Title: Director of Regulatory Division E-mail: phoui2@hotmail.com, doag@laotel.com

Malaysia

Name of national authority for pesticide registration	Pesticides Control Division, Department of Agriculture
Address	Floor 4-6, Wisma Tani, Jalan Sultan Salahuddin 50632 Kuala Lumpur, Malaysia
Contact person	Name: Nursiah Mohamad Tajol Aros Title: Director of Pesticides Control Division, Secretary to the Pesticides Board E-mail: nursiah@doa.gov.my

Myanmar

Name of national authority for pesticide registration	Pesticide registration Board Plant Protection Division
Address	Plant Protection Division, Department of Agriculture Bayintnaung Road, West Gyogone, Insein P.O. 11011, Yangon
Contact person	Name: U Aye Tun Title: Secretariat E-mail: ppmas.moai@mptmail.net.mm

Nepal

Name of national authority for pesticide registration	Pesticide registration & Management Division
Address	Hariharbhawan, Lalitpur, Nepal
Contact person	Name: Sabitri Baral Title: Pesticide Registrar E-mail: baral.sabitri@ymail.com

Pakistan

Name of national authority for pesticide registration	Plant Protection Adviser and Director General
Address	Department of Plant Protection, Jinnah Avenue, Malir Halt, Karachi.
Contact person	Name: Muhammad Sohail Shahzad Title: Deputy Director Registration E-mail: registration@plantprotection.gov.pk

Philippines

Name of national authority for pesticide registration	Fertilizer & Pesticide Authority
Address	FPA Building, BAI Compound, Visayas Avenue Diliman, Quezon City Philippines
Contact person	Name: Dr Norlito R. Gigana Title: Executive Director E-mail: nrgicana@yahoo.com, fpa_77@yahoo.com

Singapore

Name of national authority for pesticide registration	AVA
Address	Animal & Plant Health Centre, 6 Perahu Rd., S718827 Singapore
Contact person	Name: Ms Yap Mei Lai Title: Programme Chief (Plant Health) E-mail: yap_mei_lai@ava.gov.sg

Sri Lanka

Name of national authority for pesticide registration	Registrar of Pesticides (ROP)
Address	Office of the ROP, 1056, Getambe, Peradeniya
Contact person	Name: Dr G.A.W. Wijesekara Title: Registrar of Pesticides E-mail:

Thailand

Name of national authority for pesticide registration	Department of Agriculture
Address	50 Phaholyothin Rd., Ladyao Sub-District, Chatuchak District, Bangkok 10900
Contact person	Name: Mrs Supanon Sirichuaychoo Title: Senior Agricultural Scientist E-mail: ssupanon@yahoo.com

Viet Nam

Name of national authority for pesticide registration	Plant Protection Department (PPD) – MARD
Address	149 Ho Dac Di street, Dong Da, Hanoi, Viet Nam
Contact person	Name: Nguyen Xuan Hong Title: Director General E-mail: nxh4456@yahoo.com

2. Infrastructure

Background

The responsible authority should be sufficiently equipped to carry out its tasks. It should furthermore have access to technical support services such as laboratory facilities for pesticide quality and residue analysis, pesticide field-testing facilities, and post-registration monitoring mechanisms.

Survey responses

2. Infrastructure		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Number of quality control laboratories	low = 0 hi = 43	1	1	43	23	1	8	0	1	1	1	10	8	*	1	2	
Number of internationally accredited quality control laboratories	low = 0 hi = 6		1	6		0		0		-	1	2	3	*	0	1	5
Number of residue analysis laboratories	low = 0 hi = 73	-	1	73	3	*	6	1	4	3	1	2	4	*/2	1	9	
Number of internationally accredited residue analysis laboratories	low = 0 hi = 5		0			0		0			1	1	3	1	0	3	5
Number of toxicology laboratories	low = 0 hi = 35		1	35	8	0	2	0	1	NA	x	2	2	0	0	-	0
Singapore: * For QC unknown; local manufacturers have their own labs /2 For food safety control = 1; for environmental testing = 5																	
Instrumentation of quality control laboratories																	
Number of GC	low = 0 hi = 8	2	1			2	8	0	3	2	1	-	8	*	2	4	
Number of GC-MS	low = 0 hi = 3	-	1			1	2	0	1	-	x		3	*	1	1	
Number of LC-MS	low = 0 hi = 2	-				1	2	0		-	x		2	*	-	-	
Number of HPLC	low = 0 hi = 6	1	1			3	6	0	5	1	x		8	*	-	4	
		3	3			7	18	0	9	3	1		21		3	9	
* Singapore: for QC unknown																	
Instrumentation of residue analysis laboratories																	
Number of GC	low = - hi = 30	-	1			*	7		30	1	1	12	8	11	-	7	
Number of GC-MS	low = - hi = 5	-	1			*	2		3	-	x	2	3	5	-	4	
Number of LC-MS	low = - hi = 3	-				*	2		3	-	x	2	2	2	-	1	
Number of HPLC	low = - hi = 8	-	1			*	6			1	x	8	8	2	-	4	
			3				17		36	2	1	24	21	20		16	
Japan: * *Monitoring of pesticide residues is undertaken by health authorities of prefectural governments, National Institute of Health Science and private analytical laboratories registered by the Ministry of Health, Labour and Welfare.*																	

Observations

- Almost all countries have quality control and residue analysis laboratories; some of which are internationally accredited in 7 countries
- Only 7 countries have toxicology laboratories
- Not all laboratories are sufficiently equipped to carry out routine investigations

Conclusions

- Some countries may use the same instrumentation for formulation and residue analysis;
- Only a few countries have adequate capacities to carry out routine, post-registration investigations.

3. Personnel

Background

The FAO/WHO registration guidelines recommend that the responsible authority should be provided with adequate number of qualified staff for the tasks legally entrusted to it.

Survey responses

3. Personnel		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Number of registration officers	low = 1 hi = 70	1	1		13	~70	5	5	35	29	2	4	7	3	4	9	7
Number of enforcement officers	low = 1 hi = 660	1	1		13	*/1	12	2	13	72	1	660	25	14	60	245 *	558
Number of quality control laboratory personnel	low = 1 hi = 35	3	1			8	32	0	11	5	x		7*	-	3	23	35
Number of residue laboratory personnel	low = 0 hi = 42	-	0			*/2	42	4	25	5	x	30	3*	9	-	19	35
Number of toxicology laboratory personnel	low = 0 hi = 40	-	1			-	40	0	8	-	x	40	3*	-	0	-	
Total	low = 3 hi = 734	5	4		26	81	131	11	92	111	3	734	45	26	67	296	635

Japan:
*/1 Officers of the national and prefectural government working in the areas of agriculture, health and the environment are involved.
*/2 Monitoring of pesticide residues is undertaken by health authorities of prefectural governments, National Institute of Health Science and private analytical laboratories registered by the Ministry of Health, Labour and Welfare.
Philippines: min/lab
Thailand: Number of Agricultural inspector in the central and regional office, responsible for Fertilizer Act, Hazardous Substance Act and Seed Act.

Observations

- The number of registration officers ranged from 1 to about 70; three countries had only 1-2 officers;
- The number of enforcement officers ranged from 1 to 660; four countries had only 1-2 officers;
- Generally, there is more staff for technical support and enforcement than for registration.

Conclusions

- Several countries may have too few staff to carry out all the registration functions.
- In most countries, the number of enforcement staff may be inadequate for effective implementation of pesticide regulations.

4. Professional personnel involved in the review of pesticide dossiers

Background

The FAO/WHO registration guidelines recommend that if only limited permanent staff can be funded, provisions should be taken to assign or contract external experts for dossier evaluation.

Survey responses

4. Professional personnel involved in the review of pesticide dossiers		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Within agency																	
Agriculturalists	low = 3 hi = 78	7	Y	√	9	Y*	5	5	Y	34	78		3	Y		14	
Biologists	low = 2 hi = 9	-	Y	√	9	Y*	3		Y	2	x		0	Y			
Bio-efficacy specialist	low = 1 hi = 6	-	Y	√	3	Y*	6		Y	5	x		2	Y	1	64	
Pesticide chemists	low = 1 hi = 4	3	Y	√	2	Y*	4		Y	3	x	2	3	Y	1	9	
Toxicologists/medical doctor	low = 1 hi = 3	1	Y	√	2		3		Y	3	x	2	1		1		
Other (please specify)			Y	√	1*								0		2*		
Total	low = 4 hi = 87	11	Y	√	26	Y*	21	5	Y	47	78	4	9	Y	5	87	
China: Environmentalist Indonesia: Pesticide database Japan: Numbers unknown Sri Lanka: Research Officers																	
Outside agency																	
Agriculturalists	low = 4 hi = 20						4		Y				20				
Biologists	low = 1 hi = 10						3		Y		1		10				
Bio-efficacy specialist	low = 6 hi = 10						6		Y				10				
Pesticide chemists	low = 4 hi = 32						4		Y			32	8				
Toxicologists/medical doctor	low = 2 hi = 8					Y*	2		Y			8	4			3	
Other (please specify)													5*			-	
Total	low = 1 hi = 57					Y*	19		Y		1	40	57			3	
Japan: Numbers unknown Philippines: Entomologist Thailand: Office of Agricultural Regulation = 5; Agricultural Production Science Research and Development Office = 9																	

Observations

- The majority of personnel involved in the evaluation of dossiers come from agriculture; most of the responding countries have furthermore bio-efficacy specialists, pesticide chemists and toxicologists involved.
- Seven countries involve specialists from outside the agency in the review of dossiers; most of the outside personnel were pesticide chemists and bio-efficacy specialists.

Conclusions

- Half of the corresponding countries do not involve outside experts, even when the agency has only limited staff.

5. Please indicate the capacity building activities in the past three (3) years

Background

It is important that the regulatory staff has opportunities to further their education on pesticide regulatory management, analytical skills and assessment methodologies.

Survey responses

5. Please indicate the capacity building activities in the past three (3)		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Number of persons trained in bio-efficacy evaluation	low = 0 hi = 90 sum =	-				3[1]	90	1	3	12	x	2	2	3	0	64	
Number of persons trained in pesticide label evaluation	low = 1 hi = 54	1				3[1]		1	2	54	x	4	2	1	1	4	
Number of persons trained in pesticide residue analysis	low = - hi = 17	-				5[1]	5	1	17	3	2	-	2	7	1	19	
Number of persons trained in pesticide formulation analysis	low = 1 hi = 23	3				3[1]	12	1	10	5	x	2	2	0	1	23	
Number of persons trained in toxicology and risk assessment	low = - hi = 7 Sum = 26	-				7[1,2]	6	2	4	-	x	-	4	0	0	3	
Number of persons trained in ecotoxicology assessment	low = 0 hi = 5 Sum = 16	-				3[1]	5	0	4	-	x	-	2	0	0	2	
Number of persons trained in information management on pesticide regulatory matters	low = 0 hi = 14 Sum = 21	3				-		0	2	-	x	2	14	0	0	0	
	low = 2 hi = 118	7				24	118	6	42	74	2	10	28	11	3	115	

Japan:
*1 Number of capacity building *activities*
*2 Including training on residue evaluation

Observations

- The range of persons who have participated in capacity building ranged from 3 to 118.
- In 4 countries, fewer than 10 persons received further training.
- Most training opportunities were provided for bio-efficacy evaluation.
- The least training opportunities were provided for ecotoxicology assessment.

Conclusions

- Most of the countries provide capacity building training to their staff to enhance the pesticide management capabilities.

6. Pesticide use indicators

Background

Governments should collect and record data on the import, export, manufacture, formulation, quality, quantity and use of pesticides in order to assess the extent of any possible effects on human health or the environment and to follow trends in pesticide use for economic and other purposes.

Survey responses

6. Pesticide use indicators		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Pesticide Trade T	**Yes = 10**	Y	Y	Y		Y		Y	Y	Y	Y				Y	Y	
Pesticide Trade $	**Yes = 7**			Y		Y		Y	Y		Y				Y	Y	
Pesticide Use Profile T	**Yes = 9**	Y		(Y)	Y	Y		Y		Y	Y		Y		Y	Y	
Pesticide Use Profile $	**Yes = 6**					Y		Y	Y		Y				Y	Y	
		2	**1**	**2**	**1**	**4**	**0**	**4**	**3**	**2**	**4**	**0**	**1**	**0**	**4**	**4**	**0**

Observations

- Only 5 authorities had complete information about pesticide trade and domestic use.
- Half the countries had no or incomplete pesticide use information.
- Some countries were not clear whether the volume was of active ingredient or formulated product.

Conclusions

- Many regulatory agencies have insufficient information about the pesticide use in their country to assess potential adverse effects or to follow trends.

7. Progress and constraints with harmonization of pesticide regulatory matters

7. Progress and constraints with harmonization of pesticide regulatory matters		Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam
Main Progress	**Yes = 8**	**Y**				**Y**	**Y**		**Y**	**Y**	**Y**		**Y**			**Y**	
Main Constraints	**Yes = 7**	**Y**					**Y**		**Y**	**Y**	**Y**		**Y**			**Y**	

Main Progress

Bangladesh

- Updating of the Pesticide Ordinance, 1971 (amended in 2010)
- Updating of the Pesticide Rules, 1985 (amended in 2007)
- Procuring new GLC Machine GC 8610
- Training of chemists on Pesticide analysis and maintenance of lab equipments.

Japan

- We started to require GLP-compliance for supervised residue trials (since 2011).
- We will increase the minimum number of residue trials for major crops from 2 to 6 from 2014.
- We will soon start requiring the submission of livestock metabolism and livestock transfer study results for the registration of pesticide applied to feed crops or food crops whose by-products, inedible portion, etc. are fed to livestock.

Korea, DPR

- Adoption of legislations on Pesticides ("Law on Pesticides", "Regulation for enforcement", "Detailed Rules")
- Establishment of Pesticide Regulation and Quality Control System

Malaysia

- PMC 2 & 3 meetings, 2011
- ASEAN Labelling Harmonization meeting, 2010.

Myanmar

- Bio-efficacy Test Protocols workshop, 2011
- Policies action
- Training of chemists and inspectors on pesticide analysis, labelling practices and bio-efficacy evaluation.

Nepal

- IPM field studies have had significant impact on decision makers in determining policy regarding recommendations on pesticide management and application
- Impact of the IPM on rice and vegetable: Farmers reduced pesticides
- Deregistered methyl parathion, monocrotophos and endosulphan considering the list of PIC and POPs
- Updating of Pesticide Act and Rules is under way/progress, 2012
- Pesticide Consumption Survey in Nepal carried out, 2012
- Pest Risk Analysis (PRA) is done to protect the country's agriculture from damages that can be caused by harmful (quarantine) pests which can be brought in along with imported commodities.

Philippines

In year 2010, the Laboratory Services Division had been established for the monitoring and quality control of both pesticide and fertilizer formulated products. The fertilizer laboratory section is in fully functional while the pesticide formulation and residue laboratories are still waiting for budget on additional analytical instruments and budget for skilled personnel.

Sri Lanka

- Ratified with Rotterdam, Basel & Stockholm Conventions
- Follow PIC procedure
- Follow the Montreal Protocol
- WHO Class I chemicals banned (Use only 4 under restricted use)
- POP chemicals banned
- NVQ level 4 certificate required to sell pesticides.
- Restricted chemicals are issued only to registered pest control operators

Thailand

- No progress on harmonization of pesticide regulatory matters in Thailand.

Main constraints

Bangladesh

- Lack of machine/equipments like GC-MS, PCR, Microscope
- Lack of training on residue analysis and Biological/Microbial Pesticide analysis
- Lack of training on safe use of Pesticide

Korea, DPR

- No Information Service Centre for pesticide management information sharing
- Low capacity of Infrastructure including laboratories
- Shortage of investment for capacity building and training personnel

Malaysia

- Lack of human resources, expertise, financial resources & facilities

Myanmar

- Lack of expert (technician), financial support and operational
- Need to update the Procedures Relating to the Pesticide Law

Nepal

- There was not enough staff to provide timely technical guidance to farmers.
- Some IPM trainers retired or changed their positions
- No separate lab. Building for pesticide analytical works
- No trained staffs (manpower) for operating lab
- There is a trans-boundary issue, illegal import of pesticides and banned pesticides over Nepal's boarder are found into local markets. The use of banned or restricted pesticide cannot be prevented effectively because of illegal trans-boundary movement of pesticides. There is little or no information on such illegal movements regarding the name, quantities of chemicals sold
- Lacking of inter and intra cooperation and coordination (e.g. across ministries) for proper management of Basel Convention on the Control of Trans-boundary Movement of Hazardous Wastes and the Disposal, Rotterdam Convention on the Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade and Stockholm Convention on Persistent Organic Pollutants.

- No system and facility to monitor pesticide residues in the environment?
- Banning pesticide is based on available information such as DGDs and IPCS publications, etc. Most pesticide banning is not based on risk evaluation involving prevailing conditions within the country. As a result, most notifications of the final regulatory action submitted by Nepal do not meet criteria b (iii) of Annex 2 to the convention. Nepal needs assistance to conduct risk evaluation involving prevailing conditions within the country before banning a pesticide
- Limited financial and human resources present serious capacity constraints to implement and comply with treaty obligations
- Decision Guidance Document (DGDs) which is very technical
- Local Data not available because not much research has been done on PIC chemicals
- Lack of adequate knowledge on Risk Assessment
- Low awareness among stakeholders on chemical management issues and PIC procedure.

Philippines

- Lack of adequate trained personnel to fully implement the mandate on the national regulation and post-registration regulation of agrichemicals due to "freeze hiring" status of the national government.
- Pesticide Regulation guidelines has never been updated since 2001.

Sri Lanka

- Human resource not enough for evaluation of registrations
- Trainings for existing officers needed
- Pesticide residue testing lab and equipment needed
- Asst. Registrars has to be recruited according to the act. But not yet recruited
- Field enforcement officers are directly not controlled under Registrar of Pesticides and hence field enforcement is weak.

Thailand

- Harmonization of pesticide regulatory matters in Thailand has not started yet. Because registration under the previous Hazardous Substance Act has been expired on 22 August 2011, the regulation authority has to accelerate new registration. Therefore the task on harmonization has to be delayed.

B. Compilation of Questionnaire Supplement for TCP Countries Only

I. PESTICIDE LEGISLATION AND REGULATIONS

Background

The PMC meeting of the TCP project recommended that the adopted guidelines are translated, adopted and officially published to give them legal status.

Survey responses

	Please indicate the country status of the harmonized guidelines adapted by the PMC meeting of the TCP project		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
1a	**Guideline translated**								
	Guidelines for harmonization of pesticide registration requirements	**Yes = 2**		Y	*	~		-	Y
	Guidelines for harmonization of biopesticide registration requirements	**Yes = 2**		Y	*	-		-	Y
	Guidelines for the preparation of efficacy test protocols	**Yes = 2**			*	Y			Y
	Guidelines for harmonization of pesticide labelling	**Yes = 4**	Y	Y	*	Y			Y
	Guidelines for pesticide residue monitoring system	**Yes = 2**		Y	*	-			Y
	Recommendations for information exchange on pesticide regulatory matters	**Yes = 2**		Y	*	-			Y
		Sum = 14	**1**	**5**	*	**2**	**0**	**0**	**6**
b	**Guideline adopted**								
	Guidelines for harmonization of pesticide registration requirements	**Yes = 0**		-	*	-			
	Guidelines for harmonization of biopesticide registration requirements	**Yes = 1**		-	*	Y			
	Guidelines for the preparation of efficacy test protocols	**Yes = 1**		-	*	-		Y	
	Guidelines for harmonization of pesticide labelling	**Yes = 1**	Y	-	*	-			
	Guidelines for pesticide residue monitoring system	**Yes = 2**		-	*	Y		Y	
	Recommendations for information exchange on pesticide regulatory matters	**Yes = 1**		-	*	Y			
		Sum = 6	**1**	**0**	*	**3**	**0**	**2**	**0**
c	**Guideline officially published**								
	Guidelines for harmonization of pesticide registration requirements	**Yes = 1**		Y	*	-			
	Guidelines for harmonization of biopesticide registration requirements	**Yes = 1**		Y	*	-			
	Guidelines for the preparation of efficacy test protocols	**Yes = 0**			*	N			
	Guidelines for harmonization of pesticide labelling	**Yes = 1**		Y	*	N			
	Guidelines for pesticide residue monitoring system	**Yes = 1**		Y	*	-			
	Recommendations for information exchange on pesticide regulatory matters	**Yes = 1**		Y	*	-			
		Sum = 5	**0**	**5**	**0**	**0**	**0**	**0**	**0**

*Malaysia: In process of incorporating into current national guidelines
Y = Yes; N = No

Observations

- Four countries translated some or all the guidelines
- Three countries adopted between 1 and 3 of the guidelines. The guidelines on pesticide residue monitoring was adopted by 2 countries
- Only Lao PDP said that it officially published all guidelines

Conclusions

- Most TCP countries did not implement the recommendations of the PMC to adopt and officially publish all guidelines
- The recommendation to adopt and give legal status to the guideline documents may need to be reassessed and possibly revised

II. PESTICIDE REGISTRATION APPLICATION AND DATA REQUIREMENTS

1. Guidelines for harmonization of pesticide registration requirements

Background

The Guidelines for Harmonization of Pesticide Registration Requirements were adopted by the PMC meeting and contained 2 registration forms and 9 lists of registration data requirements that should be used by the countries to harmonize their pesticide management.

Survey responses

1.	**Guidelines for harmonization of pesticide registration requirements**		**Cambodia**	**Lao PDR**	**Malaysia**	**Myanmar**	**Philippines**	**Thailand**	**Viet Nam**
	Please indicate, which data requirements are already fully, partially or not yet adopted								
	Annex 1A: Application Form for Registration of Pesticides	Fully = 2 Partially = 0	**F**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 1B: Check Sheet (for official use only)	Fully = 2 Partially = 0	**F**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 2A: Chemical pesticide, proprietary registration, technical grade AI	Fully = 1 Partially = 1	**P**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 2B: Chemical pesticide, proprietary registration, formulated product	Fully = 2 Partially = 0	**F**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 2C: Chemical pesticide, supplementary registration, formulated product	Fully = 1 Partially = 1	**P**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 3A: Biochemical pesticide, proprietary registration, technical concentrate	Fully = 1 Partially = 0	**N**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 3B: Biochemical pesticide, proprietary registration, formulated product	Fully = 1 Partially = 0	**N**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 3C: Biochemical pesticide, supplementary registration, formulated product	Fully = 1 Partially = 0	**N**	**N**	**N**	**F**	**N**	**N**	**N**
	Annex 4A: Microbial pesticide, proprietary registration, active agent	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex 4B: Microbial pesticide, proprietary registration, formulated product	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex 4C: Microbial pesticide, supplementary registration, formulated product	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
		Fully =	**3**	**0**	**0**	**8**	**0**	**0**	**0**
		Partially =	**2**			**3**			
F = Fully; P = Partially; N = Not yet adopted									

Observations

- Two of the participating countries adopted parts of the guidelines
- The parts most often adopted were the registration forms and data requirements for chemical pesticides

Conclusions

- The contents of the guidelines were adopted even though the guideline was not officially adopted

2. Guidelines for harmonization of biopesticide registration requirements

Background

The Guidelines for Harmonization of Biopesticide Registration Requirements were adopted by the PMC meeting and contained 20 lists of registration data requirements that should be used by the countries to harmonize their pesticide management.

Survey responses

2.	Guidelines for harmonization of biopesticide registration requirements		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Please indicate, which data requirements are already fully, partially or not yet adopted								
	Annex A1. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF BOTANICALS (plant, plant extracts)	Fully = 1 Partially = 0	N	N	N	F	N	N	N
	Annex A2. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF PHYTO-CHEMICAL FORMULATED PEST CONTROL PRODUCTS	Fully = 1 Partially = 1	P	N	N	F	N	N	N
	Annex A3. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF PHEROMONE (semiochemicals)	Fully = 1 Partially = 1	P	N	N	F	N	N	N
	Annex A4. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF MICROBIAL PEST CONTROL AGENTS	Fully = 1 Partially = 0	N	N	N	F	N	N	N
	Annex BI. GUIDELINES/DATA REQUIREMENTS FOR REGIS-TRATION OF BOTANICAL PESTICIDES – provisional registration, technical concentrate	Fully = 1 Partially = 0	N	N	N	F	N	N	N
	Annex BI. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF BOTANICAL PESTICIDES – regular registration, formulated product	Fully = 1 Partially = 0	N	N	N	F	N	N	N
	Annex BII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PESTICIDE – Provisional Registration	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PESTICIDE – Regular Registration	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BIII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOTOXIC BACTERIA – Provisional Registration – Technical Concentrate	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BIII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOTOXIC BACTERIA – Provisional Registration – Formulated Product	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BIII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOTOXIC BACTERIA – Regular Registration – Technical Concentrate	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BIII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOTOXIC BACTERIA – Regular Registration – Formulated Product	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BIV. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF BACULOVIRUSES – NUCLEAR POLY-HEDROSIS VIRUS (NPV) & GRANULOSIS VIRUS (GV) – Provisional Registration	Fully = 0 Partially = 1	N	N	N	P	N	N	N
	Annex BIV. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF BACULOVIRUSES – NUCLEAR POLY-HEDROSIS VIRUS (NPV) & GRANULOSIS VIRUS (GV) – Regular Registration	Fully = 0 Partially = 1	N	N	N	P	N	N	N

2.	**Guidelines for harmonization of biopesiticide registration requirements**		**Cambodia**	**Lao PDR**	**Malaysia**	**Myanmar**	**Philippines**	**Thailand**	**Viet Nam**
	Please indicate, which data requirements are already fully, partially or not yet adopted								
	Annex BV. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOPATHOGENIC FUNGI – Provisional Registration	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex BV. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOPATHOGENIC FUNGI – Regular Registration	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex BVI. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC FUNGI – Provisional Registration	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex BVI. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC FUNGI – Regular Registration	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex BVII. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC BACTERIA – Provisional Registration	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
	Annex BVII. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC BACTERIA – Regular Registration	Fully = 0 Partially = 1	**N**	**N**	**N**	**P**	**N**	**N**	**N**
		Fully =				**6**			
		Partially =	**2**			**14**			
F = Fully; P = Partially; N = Not yet adopted									

Observations

- The Guidelines for *Harmonization of Biopesticide Registration Requirements* were used by three countries to harmonize the registration data requirements
- Myanmar adopted partially or fully all 20 proposed guidelines and data requirements

Conclusions

- The guidelines are still far from being a common standard for the harmonized registration of biopesticides
- It may be still premature to adopt the *Guidelines for Harmonization of Biopesticide Registration Requirements* and more consultations may be necessary

3. Data parameters required for registration

Background

The data requirements in the *Guidelines for Harmonization of Pesticide Registration Requirements* for the different folders of the pesticide registration dossier for the proprietary registration of the active ingredient and formulated, finished product in were compiled into a single list for easier reference. The data recommended for the particular types of pesticides were indicated by "R" in the first column and by shading of the respective rows. Since there was no corresponding list for botanical pesticides, the data requirements found in the *Guidelines for Harmonization of Biopesticide Registration Requirements* were marked in this list as recommended for harmonization.

A comparison of the actual requirements in the different countries with the recommended minimum data requirements allows it to assess the degree of existing harmonization in the region.

Survey responses

The following tables contain the data requirements in the TCP countries for different types of pesticides:

Folder A: Identity and Properties

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
A1	**Chemical identity of active ingredient/agent**								
R	1.1. Chemical Abstract Services Number (if any)	**Y = 5**	**Y**	**Y**	**Y**	**-**	**Y**		**Y**
R	1.2. Common name (proposed or accepted by ISO and synonyms)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Structural formula	**Y = 5**	**Y**	**-**	**Y**		**Y**	**Y**	**Y**
R	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.5. Empirical formula and molecular weight	**Y = 6**	**Y**	**-**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6. Specification together with method of analysis of active ingredient	**Y = 5**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**
		Sum = 36	**6**	**4**	**6**	**3**	**6**	**5**	**6**
A2	**Physical properties of pure active ingredient/agent**								
R	2.1. Appearance (physical state, colour, odour)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.2. Melting/decomposition/boiling point	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20–25 ºC, but only when above 10-3 Pascal)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20–25 ºC)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.6. Density (for liquids only)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.7. Hydrolysis rate under stated relevant conditions	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.8. Photolysis under stated relevant conditions	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	**Y = 5**	**Y**	**Y**	**Y**		**Y**	**Y**	
R	3.0. Methods of analysis of physico-chemical properties	**Y = 4**		**Y**	**Y**		**Y**	**Y**	
		Sum = 65	**9**	**10**	**10**	**8**	**10**	**10**	**8**
A3	**Technical grade product identity**								
R	3.1. Source; name and address of manufacturer and addresses where manufactured	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	3.2. Appearance (physical state, colour and odour)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	3.3. The minimum (and maximum) active ingredient content in g/kg	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	3.4. Identity and amount of isomers, impurities and other by-products	**Y = 6**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
R	3.5. Analytical test report of impurity profile	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	3.5. Outline of extraction process of active ingredient of BP	Y = 3	Y		Y	-	Y	-	
R	3.6. Analytical test report of specifications	Y = 6	Y	Y	Y	-	Y	Y	Y
R	3.6. Analytical test report	Y = 6	Y	Y	Y	Y	Y	Y	
R	3.7. Process of manufacturer	Y = 4	Y		Y	-	Y	-	Y
R	3.8. Shelf life	Y = 6	Y	Y	Y	-	Y	Y	Y
R	3.9. Specification together with methods of analysis (and physico-chemical properties)	Y = 5	Y	Y	Y	-	Y	Y	
		Sum = 63	11	9	11	6	11	9	7
A4	**Material Safety Data Sheet (MSDS)**								
R	4.1. Physical data (melting point, boiling point, flash point, etc.)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	4.2. Chemical toxicity	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	4.3. Health Effects	Y = 6	Y	Y	Y	-	Y	Y	Y
R	4.4. First aid	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	4.5. Reactivity	Y = 6	Y	Y	Y	-	Y	Y	Y
R	4.6. Storage	Y = 6	Y	Y	Y	-	Y	Y	Y
R	4.7. Disposal	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	4.8. Protective equipments	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	4.9. Spill-handling procedure	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	4.10. Label including hazard symbol	Y = 7	Y	Y	Y	Y	Y	Y	Y
		Sum = 67	10	10	10	7	10	10	10
A5	**Product identity of finished product**								
R	5.1. Formulator's name and address	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	5.2. Distinguishing name (proprietary name)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	5.3. Use category (herbicide, insecticide, etc.)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	Y = 7	Y	Y	Y	Y	Y	Y	Y
	5.4. Confidential statement of formula (this statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material)	Y = 6		Y	Y	Y	Y	Y	Y
		Sum = 34	4	5	5	5	5	5	5
A6	**Composition of finished product**								
R	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert components	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	6.3. Water/other solvent content (where relevant)	Y = 7	Y	Y	Y	Y	Y	Y	Y
	6.4. Specification together with method of analysis	Y = 5		Y	Y	Y	Y	Y	
	6.5. Analytical test report	Y = 6		Y	Y	Y	Y	Y	Y
	6.6. Shelf life	Y = 5		Y	Y	-	Y	Y	Y
		Sum = 37	3	6	6	5	6	6	5
A7	**Physical-chemical properties of finished product**								
R	7.1. Appearance (physical state, colour, odour)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	7.2. Storage stability (in respect to composition and physical properties related to use)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	7.3. Density (for liquids only)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	7.4 .Flammability: liquids – flash-point; solids – a statement must be made as to whether the product is flammable	Y = 7	Y	Y	Y	Y	Y	Y	Y

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
R	7.5. Acidity (where relevant)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	7.6. Alkalinity (where relevant)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	7.7. Other properties may in certain cases need evaluation	Y = 4	Y	Y	Y	-	Y		
		Sum = 46	7	7	7	6	7	6	6
A8	**Physical properties of the finished product related to use**								
R	8.1. Wettability (for dispersible powders)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.2. Persistent foam (for formulations applied in water)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.3. Suspendibility (for dispersible powders and suspension concentrates)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.5. Dry sieve test (for granules, dusts)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.6. Emulsion stability (for emulsifiable concentrates)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.7. Corrosiveness (when necessary)	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.9. Specification together with method of analysis	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.10. Analytical test report	Y = 7	Y	Y	Y	Y	Y	Y	Y
R	8.11. Shelf life	Y = 7	Y	Y	Y	Y	Y	Y	Y
		Sum = 77	11	11	11	11	11	11	11
Y = Yes; R = Required in the harmonization guidelines (shaded rows)									

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
A1	**Chemical identity of active ingredient/agent**								
R	1.1. Chemical Abstract Services Number (if any)	Y = 4		Y	Y	-	Y		Y
R	1.2. Common name (proposed or accepted by ISO and synonyms)	Y = 6		Y	Y	Y	Y	Y	Y
R	1.3. Structural formula	Y = 3		-			Y	Y	Y
R	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC)	Y = 6		Y	Y	Y	Y	Y	Y
	1.5. Empirical formula and molecular weight	Y = 4			Y		Y	Y	Y
	1.6. Specification together with method of analysis of active ingredient	Y = 5			Y	Y	Y	Y	Y
R	1.6. Plant species (common/scientific name) from which the active ingredient extracted	Y = 5		Y		Y	Y	Y	Y
		Sum = 33	0	4	5	4	7	6	7
A2	**Physical properties of pure active ingredient/agent**								
	2.1. Appearance (physical state, colour, odour)	Y = 6		Y	Y	Y	Y	Y	Y
	2.2. Melting/decomposition/boiling point	Y = 6		Y	Y	Y	Y	Y	Y
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20–25 °C, but only when above 10-3 Pascal)	Y = 6		Y	Y	Y	Y	Y	Y
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20–25 °C)	Y = 6		Y	Y	Y	Y	Y	Y
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Y = 6		Y	Y	Y	Y	Y	Y
	2.6. Density (for liquids only)	Y = 6		Y	Y	Y	Y	Y	Y
	2.7. Hydrolysis rate under stated relevant conditions	Y = 6		Y	Y	Y	Y	Y	Y
	2.8. Photolysis under stated relevant conditions	Y = 6		Y	Y	Y	Y	Y	Y

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	**Y = 3**			**Y**		**Y**	**Y**	
	3.0. Methods of analysis of physico-chemical properties	**Y = 3**			**Y**		**Y**	**Y**	
		Sum = 54	**0**	**8**	**10**	**8**	**10**	**10**	**8**
A3	**Technical grade product identity**								
R	3.1. Source; name and address of manufacturer and addresses where manufactured	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.2. Appearance (physical state, colour and odour)	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.3. The minimum (and maximum) active ingredient content in g/kg	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.4. Identity and amount of isomers, impurities and other by-products	**Y = 3**		**Y**	**Y**	-	**Y**	-	
	3.5. Analytical test report of impurity profile	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.5. Outline of extraction process of active ingredient of BP	**Y = 3**		**Y**	**Y**	-	**Y**	-	
	3.6 .Analytical test report of specifications	**Y = 4**		**Y**	**Y**	-	**Y**	-	**Y**
	3.6. Analytical test report	**Y = 4**		**Y**	**Y**	**Y**	**Y**	-	
R	3.7. Process of manufacturer	**Y = 3**		-	**Y**	-	**Y**	-	**Y**
R	3.8. Shelf life	**Y = 4**		**Y**	**Y**	-	**Y**	-	**Y**
R	3.9. Specification together with methods of analysis (and physico-chemical properties)	**Y = 3**		**Y**	**Y**	-	**Y**	-	
		Sum = 44	**0**	**10**	**11**	**5**	**11**	**0**	**7**
A4	**Material Safety Data Sheet (MSDS)**								
	4.1. Physical data (melting point, boiling point, flash point, etc.)	**Y = 4**		**Y**	**Y**	**Y**		-	**Y**
	4.2. Chemical toxicity	**Y = 3**		**Y**	**Y**			-	**Y**
	4.3. Health Effects	**Y = 4**		**Y**	**Y**	**Y**		-	**Y**
	4.4. First aid	**Y = 3**		**Y**	**Y**	-		-	**Y**
	4.5. Reactivity	**Y = 3**		**Y**	**Y**	-		-	**Y**
	4.6. Storage	**Y = 3**		**Y**	**Y**	-		-	**Y**
	4.7. Disposal	**Y = 3**		**Y**	**Y**	-		-	**Y**
	4.8. Protective equipments	**Y = 3**		**Y**	**Y**	-		-	**Y**
	4.9. Spill-handling procedure	**Y = 3**		**Y**	**Y**	-		-	**Y**
	4.10. Label including hazard symbol	**Y = 3**		**Y**	**Y**	-		-	**Y**
		Sum = 32		**10**	**10**	**2**			**10**
A5	**Product identity of finished product**								
R	5.1. Formulator's name and address	**Y = 4**		**Y**	**Y**	**Y**		-	**Y**
R	5.2. Distinguishing name (proprietary name)	**Y = 4**		**Y**	**Y**	**Y**		-	**Y**
R	5.3. Use category (herbicide, insecticide, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	5.4. Confidential statement of formula (this statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material)	**Y = 5**		**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 25	**0**	**5**	**4**	**5**	**3**	**3**	**5**
A6	**Composition of finished product**								
R	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert components	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	6.3. Water/other solvent content (where relevant)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	6.4. Specification together with method of analysis	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	6.5. Analytical test report	Y = 6		Y	Y	Y	Y	Y	Y
	6.6. Shelf life	Y = 6		Y	Y	Y	Y	Y	Y
		Sum = 35	0	6	6	6	6	6	5
A7	**Physical-chemical properties of finished product**								
R	7.1. Appearance (physical state, colour, odour)	Y = 6		Y	Y	Y	Y	Y	Y
R	7.2. Storage stability (in respect to composition and physical properties related to use)	Y = 6		Y	Y	Y	Y	Y	Y
R	7.3. Density (for liquids only)	Y = 6		Y	Y	Y	Y	Y	Y
	7.4. Flammability: liquids – flash-point; solids – a statement must be made as to whether the product is flammable	Y = 6		Y	Y	Y	Y	Y	Y
R	7.5. Acidity (where relevant)	Y = 5		Y	Y		Y	Y	Y
R	7.6. Alkalinity (where relevant)	Y = 4		Y	Y		Y	Y	
R	7.7. Other properties may in certain cases need evaluation	Y = 3		Y	Y		Y		
		Sum = 36	0	7	7	4	7	6	5
A8	**Physical properties of the finished product related to use**								
R	8.1. Wettability (for dispersible powders)	Y = 6		Y	Y	Y	Y	Y	Y
R	8.2. Persistent foam (for formulations applied in water)	Y = 6		Y	Y	Y	Y	Y	Y
R	8.3. Suspendibility (for dispersible powders and suspension concentrates)	Y = 6		Y	Y	Y	Y	Y	Y
R	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	Y = 6		Y	Y	Y	Y	Y	Y
R	8.5. Dry sieve test (for granules, dusts)	Y = 6		Y	Y	Y	Y	Y	Y
	8.6. Emulsion stability (for emulsifiable concentrates)	Y = 6		Y	Y	Y	Y	Y	Y
	8.7. Corrosiveness (when necessary)	Y = 6		Y	Y	Y	Y	Y	Y
	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	Y = 6		Y	Y	Y	Y	Y	Y
	8.9. Specification together with method of analysis	Y = 6		Y	Y	Y	Y	Y	Y
	8.10. Analytical test report	Y = 6		Y	Y	Y	Y	Y	Y
	8.11. Shelf life	Y = 6		Y	Y	Y	Y	Y	Y
		Sum = 66	0	11	11	11	11	11	11
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
A1	**Chemical identity of active ingredient/agent**								
R	1.1. Chemical Abstract Services Number (if any)	Y = 4		Y	Y	-	Y		Y
R	1.2. Common name (proposed or accepted by ISO and synonyms)	Y = 6		Y	Y	Y	Y	Y	Y
R	1.3. Structural formula	Y = 3		-			Y	Y	Y
R	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC)	Y = 5		Y		Y	Y	Y	Y
R	1.5. Empirical formula and molecular weight	Y = 3		-			Y	Y	Y
R	1.6. Specification together with method of analysis of active ingredient	Y = 5		-	Y	Y	Y	Y	Y
R	1.6. Plant species (common/scientific name) from which the active ingredient extracted	Y = 5		Y		Y	Y	Y	Y
		Sum = 31	0	4	3	4	7	6	7
A2	**Physical properties of pure active ingredient/agent**								
R	2.1. Appearance (physical state, colour, odour)	Y = 6		Y	Y	Y	Y	Y	Y
R	2.2. Melting/decomposition/boiling point	Y = 6		Y	Y	Y	Y	Y	Y

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
R	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20–25 ºC, but only when above 10-3 Pascal)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20–25 ºC)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.6. Density (for liquids only)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.7. Hydrolysis rate under stated relevant conditions	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.8. Photolysis under stated relevant conditions	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	**Y = 3**			**Y**		**Y**	**Y**	
R	3.0. Methods of analysis of physico-chemical properties	**Y = 3**			**Y**		**Y**	**Y**	
		Sum = 54		**8**	**10**	**8**	**10**	**10**	**8**
A3	**Technical grade product identity**								
R	3.1. Source; name and address of manufacturer and addresses where manufactured	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.2. Appearance (physical state, colour and odour)	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.3. The minimum (and maximum) active ingredient content in g/kg	**Y = 5**		**Y**	**Y**	**Y**	**Y**	-	**Y**
R	3.4. Identity and amount of isomers, impurities and other by-products	**Y = 4**		**Y**	**Y**	**Y**	**Y**	-	
	3.5. Analytical test report of impurity profile	**Y = 4**		-	**Y**	**Y**	**Y**	-	**Y**
R	3.5. Outline of extraction process of active ingredient of BP	**Y = 2**		-	**Y**	-	**Y**	-	
	3.6. Analytical test report of specifications	**Y = 4**		-	**Y**	**Y**	**Y**	-	**Y**
R	3.6. Analytical test report	**Y = 3**		**Y**	**Y**	-	**Y**	-	
	3.7. Process of manufacturer	**Y = 3**		-	**Y**	-	**Y**	-	**Y**
R	3.8. Shelf life	**Y = 4**		**Y**	**Y**	-	**Y**	-	**Y**
R	3.9. Specification together with methods of analysis (and physico-chemical properties)	**Y = 3**		**Y**	**Y**	-	**Y**	-	
		Sum = 42	**0**	**7**	**11**	**6**	**11**	**0**	**7**
A4	**Material Safety Data Sheet (MSDS)**								
	4.1. Physical data (melting point, boiling point, flash point, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.2. Chemical toxicity	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.3. Health Effects	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.4. First aid	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.5. Reactivity	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.6. Storage	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.7. Disposal	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.8. Protective equipments	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.9. Spill-handling procedure	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	4.10. Label including hazard symbol	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 60	**0**	**10**	**10**	**10**	**10**	**10**	**10**
A5	**Product identity of finished product**								
R	5.1. Formulator's name and address	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	5.2. Distinguishing name (proprietary name)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	5.3. Use category (herbicide, insecticide, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	5.4. Confidential statement of formula (this statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material)	**Y = 5**		**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 29	**0**	**5**	**4**	**5**	**5**	**5**	**5**

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
A6	**Composition of finished product**								
R	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert components	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.3. Water/other solvent content (where relevant)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.4. Specification together with method of analysis	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	
R	6.5. Analytical test report	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.6. Shelf life	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
		Sum = 34	**0**	**6**	**6**	**5**	**6**	**6**	**5**
A7	**Physical-chemical properties of finished product**								
R	7.1. Appearance (physical state, colour, odour)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	7.2. Storage stability (in respect to composition and physical properties related to use)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	7.3. Density (for liquids only)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	7.4. Flammability: liquids – flash-point; solids – a statement must be made as to whether the product is flammable	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	7.5. Acidity (where relevant)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	7.6. Alkalinity (where relevant)	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	
R	7.7. Other properties may in certain cases need evaluation	**Y = 3**		**Y**	**Y**	**-**	**Y**		
		Sum = 38	**0**	**7**	**7**	**6**	**7**	**6**	**5**
A8	**Physical properties of the finished product related to use**								
R	8.1. Wettability (for dispersible powders)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.2. Persistent foam (for formulations applied in water)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.3. Suspendibility (for dispersible powders and suspension concentrates)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.5. Dry sieve test (for granules, dusts)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.6. Emulsion stability (for emulsifiable concentrates)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.7. Corrosiveness (when necessary)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.9. Specification together with method of analysis	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.10. Analytical test report	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.11. Shelf life	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 66	**0**	**11**	**11**	**11**	**11**	**11**	**11**

Y = Yes; R = As required in the harmonization guidelines (shaded rows)

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
A1	**Chemical identity of active ingredient/agent**								
R	1.1. Chemical Abstract Services Number (if any)	**Y = 2**			**Y**			-	**Y**
R	1.2. Common name (proposed or accepted by ISO and synonyms)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Scientific Name	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.4. Synonyms	**Y = 4**			**Y**	**Y**	**Y**		**Y**
R	1.5. Taxonomical Position (Class/Order/Family/Sub-family)	**Y = 4**			**Y**	**Y**	**Y**		**Y**
R	1.6. Strain/serotype/biotype	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 28	**0**	**3**	**6**	**5**	**5**	**3**	**6**
	For microbial pest control agents: Identification characteristics	**Y =**							
R	2.1. Morphological characteristics	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
R	2.2. Cultural characteristics	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
R	2.3. Biochemical properties	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
R	2.4. Serological identification (where appropriate)	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
R	2.5. Molecular diagnosis (where appropriate)	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
R	2.6. Analytical methods for identification & characterization of MCPA	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
R	2.7. Identification of plasmids or other extra chromosomal genetic material responsible for pesticide activity or pathogenicity or toxicity, etc., where appropriate	**Y = 2**			**Y**	-	**Y**		
R	2.8. Whether wild type or genetically altered organism?	**Y = 3**			**Y**	**Y**	**Y**		
R	2.9. Natural occurrence of organism and its relation to other related species	**Y = 3**			**Y**	**Y**	**Y**		
		Sum = 32	**0**	**6**	**9**	**8**	**9**	**0**	**0**
A3	**Technical grade product identity**								
	3.1. Source; name and address of manufacturer and addresses where manufactured	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
	3.2. Appearance (physical state, colour and odour)	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
	3.3. The minimum (and maximum) active ingredient content in g/kg	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
	3.4. Identity and amount of isomers, impurities and other by-products	**Y = 3**		**Y**	**Y**	-	**Y**		
	3.5. Analytical test report of impurity profile	**Y = 4**		**Y**	**Y**	-	**Y**		**Y**
	3.5. Outline of extraction process of active ingredient of BP	**Y = 3**		**Y**	**Y**	-	**Y**		
	3.6. Analytical test report of specifications	**Y = 4**		**Y**	**Y**	-	**Y**		**Y**
	3.6. Analytical test report	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
	3.7. Process of manufacturer	**Y = 3**		-	**Y**	-	**Y**		**Y**
	3.8. Shelf life	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
	3.9. Specification together with methods of analysis (and physico-chemical properties)	**Y = 3**			**Y**	**Y**	**Y**		
		Sum = 44	**0**	**9**	**11**	**6**	**11**	**0**	**7**
A3	**Biological properties of microbial pest control agent**								
R	3.1. Biological properties of active agent (target pest, microbial agent host range, life cycle, and mode of action of microbial agent, potential hazards (such as infectivity) to mammals (including human beings), environment and other non-targeted species, if any	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	
R	3.2. Description of morphological types of MCPA and any unusual morphological, biochemical, resistance characteristics of the organism that is different from classic description of organism	**Y = 4**		**Y**	**Y**	**Y**	**Y**	-	
R	3.3. Determination of toxin content & potency of toxin by bioassay method	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	
R	3.4. Specification together with method of analysis and shelf life	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
R	3.5. If the organism in question is genetically altered one, method of DNA finger printing and identification of inserted or deleted transcripts, identification of gene control regions, identification of genetic markers, etc.), where appropriate	**Y = 4**		**Y**	**Y**	**Y**	**Y**	**-**	
		Sum = 23	**0**	**5**	**5**	**5**	**5**	**3**	**0**
A4	**Source of microbial pest control agent**								
R	4.1. Name & Address of Supplier(s)	**Y = 5**		**Y**		**Y**	**Y**	**Y**	**Y**
R	4.2. Suppliers' Code Number	**Y = 3**		**Y**		**Y**	**Y**		
		Sum = 8	**0**	**2**	**0**	**2**	**2**	**1**	**1**
A4	**Material Safety Data Sheet (MSDS)**								
	4.1. Physical data (melting point, boiling point, flash point, etc.)	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.2. Chemical toxicity	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.3. Health Effects	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.4. First aid	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.5. Reactivity	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.6. Storage	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.7. Disposal	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.8. Protective equipments	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.9. Spill-handling procedure	**Y = 3**		**Y**	**Y**	**-**			**Y**
	4.10. Label including hazard symbol	**Y = 3**		**Y**	**Y**	**-**			**Y**
		Sum = 30	**0**	**10**	**10**	**0**	**0**	**0**	**10**
A5	**Product identity of finished product**								
R	5.1. Formulator's name and address	**Y = 4**		**Y**	**Y**	**Y**			**Y**
R	5.2. Distinguishing name (proprietary name)	**Y = 4**		**Y**	**Y**	**Y**			**Y**
R	5.3. Use category (herbicide, insecticide, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	5.4. Confidential statement of formula (this statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material)	**Y = 5**		**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 25	**0**	**5**	**4**	**5**	**3**	**3**	**5**
A6	**Composition of finished product**					**-**			
	6.1. Content of technical grade active ingredien(s) (where more than one active ingredient, information should be given on each ingredient separately)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g., technical grade, adjuvants and inert components	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	6.3. Water/other solvent content (where relevant)	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
	6.4. Specification together with method of analysis	**Y = 4**		**Y**	**Y**	**-**	**Y**	**Y**	
R	6.5. Analytical test report	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.6. Shelf life	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.1. Percentage composition (by weight) of each ingredient; the number of units per unit volume or weight is needed for microbial impurities; viability data in terms of PFU, CFU, etc., per unit weight or volume of product	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	
R	6.2. Identity of other ingredients included in the formulation, e.g. stickers, spreaders, etc.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.3. Certification of composition limits for each ingredient	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	6.4. Analysis of contaminants, if any	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
R	6.5. Specification together with method of analysis	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
		Sum = 60	**0**	**11**	**11**	**9**	**11**	**10**	**8**
A7	**Physical-chemical properties of finished product**								
	7.1. Appearance (physical state, colour, odour)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	7.2. Storage stability (in respect to composition and physical properties related to use)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	7.3. Density (for liquids only)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	7.4. Flammability: liquids – flash-point; solids – a statement must be made as to whether the product is flammable	**Y = 3**			**Y**	**-**		**Y**	**Y**
	7.5. Acidity (where relevant)	**Y = 3**			**Y**	**-**		**Y**	**Y**
	7.6. Alkalinity (where relevant)	**Y = 2**			**Y**	**-**		**Y**	
	7.7. Other properties may in certain cases need evaluation	**Y = 4**		**Y**	**Y**	**Y**	**Y**		
		Sum = 30	**0**	**4**	**7**	**4**	**4**	**6**	**5**
A8	**Physical properties of the finished product related to use**								
	8.1. Wettability (for dispersible powders)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.2. Persistent foam (for formulations applied in water)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.3. Suspendibility (for dispersible powders and suspension concentrates)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.5. Dry sieve test (for granules, dusts)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.6. Emulsion stability (for emulsifiable concentrates)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.7. Corrosiveness (when necessary)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.8. Known incompatibilities with other products, e.g. pesticides fertilizers	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.9. Specification together with method of analysis	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.10. Analytical test report	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	8.11. Shelf life	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 66	**0**	**11**	**11**	**11**	**11**	**11**	**11**

Y = Yes; R = As required in the harmonization guidelines (shaded rows)

Summary percent harmonization with regard to overall list of data requirements

		Data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
A1	Chemical identity of active ingredient/agent	6	6	4	6	3	6	5	6	**36**	**86%**
A2	Physical properties of pure active ingredient/agent	10	9	10	10	8	10	10	8	**65**	**93%**
A3	Technical grade product identity	11	11	8	11	6	11	9	7	**63**	**82%**
A4	Material Safety Data Sheet (MSDS)	10	10	10	10	7	10	10	10	**67**	**96%**
A5	Product identity of finished product	5	4	5	5	5	5	5	5	**34**	**97%**
A6	Composition of finished product	6	3	6	6	5	6	6	5	**37**	**88%**
A7	Physical-chemical properties of finished product	7	7	7	7	6	7	6	6	**46**	**94%**
A8	Physical properties of the finished product related to use	11	11	11	11	11	11	11	11	**77**	**100%**
	Sum	**66**	**61**	**61**	**66**	**51**	**66**	**62**	**58**	425	
% harmonized			**92%**	**62%**	**100%**	**77%**	**100%**	**94%**	**88%**		**92%**
Botanical Pesticides											
A1	Chemical identity of active ingredient/agent	7	0	4	5	4	7	6	7	**33**	**67%**
A2	Physical properties of pure active ingredient/agent	10	0	8	10	8	10	10	8	**54**	**77%**
A3	Technical grade product identity	11	0	10	11	5	11	0	7	**44**	**57%**
A4	Material Safety Data Sheet (MSDS)	10	0	10	10	2	0	0	10	**32**	**46%**
A5	Product identity of finished product	5	0	5	4	5	3	3	5	**25**	**71%**
A6	Composition of finished product	6	0	6	6	6	6	6	5	**35**	**83%**
A7	Physical-chemical properties of finished product	7	0	7	7	4	7	6	5	**36**	**73%**
A8	Physical properties of the finished product related to use	**11**	**0**	**11**	**11**	**11**	**11**	**11**	**11**	**66**	**86%**
	Sum	67	0	61	64	**45**	**55**	**42**	**58**	**325**	
% harmonized			**0%**	**91%**	**96%**	**67%**	**82%**	**63%**	**87%**		**69%**
Biochemical Pesticides											
A1	Chemical identity of active ingredient/agent	7	0	4	3	4	7	6	7	**31**	**63%**
A2	Physical properties of pure active ingredient/agent	10	0	8	10	8	10	10	8	**54**	**77%**
A3	Technical grade product identity	11	0	7	11	6	11	0	7	**42**	**55%**
A4	Material Safety Data Sheet (MSDS)	10	0	10	10	10	10	10	10	**60**	**86%**
A5	Product identity of finished product	5	0	5	4	5	5	5	5	**29**	**83%**
A6	Composition of finished product	6	0	6	6	5	6	6	5	**34**	**81%**
A7	Physical-chemical properties of finished product	7	0	7	7	6	7	6	5	**38**	**78%**
A8	Physical properties of the finished product related to use	11	0	11	11	11	11	11	11	**66**	**86%**
	Sum	**67**	**0**	**58**	**62**	**55**	**67**	**54**	**58**	**354**	
% harmonized			**0%**	**87%**	**93%**	**82%**	**100%**	**81%**	**87%**		**75%**
Microbial Pesticides											
A1	Chemical identity of active ingredient/agent	6	0	3	6	5	5	3	6	**28**	**67%**
	Identification characteristics for microbial PCA	9	0	6	9	8	9	0	0	**32**	**51%**
A3	Technical grade product identity	11	0	9	11	6	11	0	7	**44**	**57%**
A3	Biological properties of microbial PCA	5	0	5	5	5	5	3	0	**23**	**66%**
A4	Source of microbial pest control agent	2	0	2	0	2	2	1	1	**8**	**57%**
A4	Material Safety Data Sheet (MSDS)	10	0	10	10	0	0	0	10	**30**	**43%**
A5	Product identity of finished product	5	0	5	4	5	3	3	5	**25**	**71%**
A6	Composition of finished product	11	0	11	11	9	11	10	8	**60**	**78%**
A7	Physical-chemical properties of finished product	7	0	4	7	4	4	6	5	**30**	**67%**
A8	Physical properties of the finished product related to use	11	0	11	11	11	11	11	11	**66**	**86%**
	Sum	**77**	**0**	**66**	**74**	**55**	**61**	**37**	**53**	**346**	
% harmonized			**0%**	**86%**	**96%**	**71%**	**79%**	**48%**	**69%**		**64%**
Overall % harmonized		277	**22%**	**67%**	**73%**	**58%**	**70%**	**55%**	**61%**		

Summary percent harmonization with regard to recommended data requirements

		Required Data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
A1	Chemical identity of active ingredient/agent	6	6	4	6	3	6	5	6	**36**	**86%**
A2	Physical properties of pure active ingredient/agent	10	9	10	10	8	10	10	8	**65**	**93%**
A3	Technical grade product identity	11	11	8	11	6	11	9	7	**63**	**79%**
A4	Material Safety Data Sheet (MSDS)	10	10	10	10	7	10	10	10	**67**	**89%**
A5	Product identity of finished product	4	4	4	4	4	4	4	4	**28**	**100%**
A6	Composition of finished product	3	3	3	3	3	3	3	3	**21**	**100%**
A7	Physical-chemical properties of finished product	7	7	7	7	6	7	6	6	**46**	**94%**
A8	Physical properties of the finished product related to use	**11**	**11**	**11**	**11**	**11**	**11**	**11**	**11**	77	**100%**
	Sum	**62**	**61**	**57**	**62**	**48**	**62**	**58**	**55**	**403**	
% harmonized			**98%**	**92%**	**100%**	**77%**	**100%**	**94%**	**89%**		**91%**
Botanical Pesticides											
A1	Chemical identity of active ingredient/agent	5	0	4	3	3	5	4	5	**24**	**69%**
A3	Technical grade product identity	8	0	7	8	3	8	0	5	**31**	**55%**
A5	Product identity of finished product	4	0	4	4	4	2	2	4	**20**	**71%**
A6	Composition of finished product	2	0	2	2	2	2	2	2	**12**	**86%**
A7	Physical-chemical properties of finished product	6	0	6	6	3	6	5	4	**30**	**71%**
A8	Physical properties of the finished product related to use	5	0	5	5	5	5	5	5	**30**	**86%**
	Sum	**30**	**0**	**28**	**28**	**20**	**28**	**18**	**25**	**147**	
% harmonized			**0%**	**93%**	**93%**	**67%**	**93%**	**60%**	**83%**		**70%**
Biochemical Pesticides											
A1	Chemical identity of active ingredient/agent	7	0	4	3	4	7	6	7	**31**	**63%**
A2	Physical properties of pure active ingredient/agent	10	0	8	10	10	10	10	8	**56**	**80%**
A3	Technical grade product identity	8	0	8	8	4	8	0	4	**32**	**57%**
A5	Product identity of finished product	4	0	4	4	4	4	4	4	**24**	**86%**
A6	Composition of finished product	6	0	6	6	5	6	6	5	**34**	**81%**
A7	Physical-chemical properties of finished product	7	0	7	7	6	7	6	5	**38**	**78%**
A8	Physical properties of the finished product related to use	8	0	8	8	8	8	8	8	**48**	**86%**
	Sum	**50**	**0**	**45**	**46**	**41**	**50**	**40**	**41**	**263**	
% harmonized			**0%**	**90%**	**92%**	**82%**	**100%**	**80%**	**82%**		**75%**
Microbial Pesticides											
A1	Chemical identity of active ingredient/agent	6	0	3	6	5	5	3	6	**28**	**67%**
	Identification characteristics for microbial PCA	9	0	6	9	8	9	0	0	**32**	**51%**
A3	Biological properties of microbial PCA	5	0	5	5	5	5	3	0	**23**	**66%**
A4	Source of microbial pest control agent	2	0	2	0	2	2	1	1	**8**	**57%**
A5	Product identity of finished product	3	0	3	3	3	1	1	3	**14**	**67%**
A6	Composition of finished product	7	0	7	7	7	7	6	5	**39**	**80%**
	Sum	**32**	**0**	**26**	**30**	**30**	**29**	**14**	**15**	**144**	
% harmonized			**0%**	**94%**	**94%**	**94%**	**91%**	**44%**	**47%**		**64%**
Overall % harmonized		174	**35%**	**74%**	**80%**	**69%**	**82%**	**65%**	**64%**		

Observations

- The Folder A data requirements for chemical pesticides are already harmonized to 84 percent among the countries. In 4 countries, the degree of harmonization is between 94 and 100 percent.
- The Folder A data requirements for botanical, biochemical and microbial pesticides are harmonized to a lesser degree between 60 and 69 percent.
- All responding countries require also data that were not listed as required in the guidelines.

Conclusions

- Folder A data requirements for all types of biological pest control products may need to be upgraded in most countries

Folder B: Toxicity Data

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
B1	**Acute Toxicity tests**								
R	1.1. Acute oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Acute dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Acute inhalation toxicity (LC_{50} in mg/l)	**Y = 6**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**
		Sum = 20	**3**	**3**	**3**	**3**	**2**	**3**	**3**
B2	**Irritation tests**								
R	2.1. Primary skin irritation	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.2. Eye irritation	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	Allergy/sensitization test	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	Sub-chronic toxicity tests in (minimum of oral test of 90 days duration in rats)	**Y = 6**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**
R	Reproduction Effects studies (minimum of two generations in rats)	**Y = 6**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**
R	Teratogenicity studies (in two species, one in rats and other in non-rodents)	**Y = 6**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**
R	Neurotoxicity studies in hens (for organophosphorus compounds)	**Y = 6**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**
R	Mutagenicity studies (minimum of Ames test and in vivo micronucleus Test)	**Y = 6**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**
R	Carcinogenicity tests and chronic (long term) toxicity studies in rats	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	Medical Data/Poisoning symptoms/Antidote	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 64	**9**	**10**	**10**	**5**	**10**	**10**	**10**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
B1	**Acute Toxicity tests**								
R	1.1. Acute oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Acute dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Acute inhalation toxicity (LC_{50} in mg/l)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
		Sum = 17	**0**	**3**	**3**	**3**	**2**	**3**	**3**
B2	**Irritation tests**								
R	2.1. Primary skin irritation	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.2. Eye irritation	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	Allergy/sensitization test	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Sub-chronic toxicity tests in (minimum of oral test of 90 days duration in rats)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Reproduction Effects studies (minimum of two generations in rats)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Teratogenicity studies (in two species, one in rats and other in non-rodents)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Neurotoxicity studies in hens (for organophosphorus compounds)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Mutagenicity studies (minimum of Ames test and in vivo micronucleus Test)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Carcinogenicity tests and chronic (long term) toxicity studies in rats	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Medical Data/Poisoning symptoms/Antidote	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 60	**0**	**10**	**10**	**10**	**10**	**10**	**10**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
B1	**Acute Toxicity tests**								
R	1.1. Acute oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Acute dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Acute inhalation toxicity (LC_{50} in mg/l)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
		Sum = 17	**0**	**3**	**3**	**3**	**2**	**3**	**3**
B2	**Irritation tests**								
R	2.1. Primary skin irritation	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	2.2. Eye irritation	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	Allergy/sensitization test	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Sub-chronic toxicity tests in (minimum of oral test of 90 days duration in rats)	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Reproduction Effects studies (minimum of two generations in rats)	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Teratogenicity studies (in two species, one in rats and other in non-rodents)	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Neurotoxicity studies in hens (for organophosphorus compounds)	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Mutagenicity studies (minimum of Ames test and in vivo micronucleus Test)	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Carcinogenicity tests and chronic (long term) toxicity studies in rats	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Medical Data/Poisoning symptoms/Antidote	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 54	**0**	**10**	**10**	**4**	**10**	**10**	**10**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
B1	**Acute Toxicity tests**								
R	1.1. Acute oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Acute dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Acute inhalation toxicity (LC_{50} in mg/l)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 18	**0**	**3**	**3**	**3**	**3**	**3**	**3**
B2	**Irritation tests**								
R	2.1. Primary skin irritation	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
R	2.2. Eye irritation	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
R	Allergy/sensitization test	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	Sub-chronic toxicity tests in (minimum of oral test of 90 days duration in rats)	**Y = 4**		**Y**			**Y**	**Y**	**Y**
	Reproduction Effects studies (minimum of two generations in rats)	**Y = 4**		**Y**			**Y**	**Y**	**Y**
	Teratogenicity studies (in two species, one in rats and other in non-rodents)	**Y = 4**		**Y**			**Y**	**Y**	**Y**
	Neurotoxicity studies in hens (for organophosphorus compounds)	**Y = 4**		**Y**			**Y**	**Y**	**Y**
	Mutagenicity studies (minimum of Ames test and in vivo micronucleus Test)	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
	Carcinogenicity tests and chronic (long term) toxicity studies in rats	**Y = 4**		**Y**			**Y**	**Y**	**Y**
	Medical Data/Poisoning symptoms/Antidote	**Y = 4**		**Y**			**Y**	**Y**	**Y**
		Sum = 45	**0**	**10**	**4**	**1**	**10**	**10**	**10**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

Summary percent harmonization with regard to overall list of data requirements

	Data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides										
B1 Acute Toxicity tests	3	3	3	3	3	2	3	3	20	**95%**
B2 Irritation tests	10	9	9	10	5	10	10	10	63	**90%**
Sum	13	12	12	13	8	12	13	13	83	
% harmonized		**92%**	**92%**	**100%**	**62%**	**92%**	**100%**	**100%**		**91%**
Botanical Pesticides										
B1 Acute Toxicity tests	3	0	3	3	3	2	3	3	17	**81%**
B2 Irritation tests	10	0	10	10	10	10	10	10	60	**86%**
Sum	13	0	13	13	13	12	13	13	77	
% harmonized		**0%**	**100%**	**100%**	**100%**	**92%**	**100%**	**100%**		**85%**
Biochemical Pesticides										
B1 Acute Toxicity tests	3	0	3	3	3	2	3	3	17	**81%**
B2 Irritation tests	10	0	10	10	4	10	10	10	54	**77%**
Sum	13	0	13	13	7	12	13	13	71	
% harmonized		**0%**	**100%**	**100%**	**54%**	**92%**	**100%**	**100%**		**78%**
Microbial Pesticides										
B1 Acute Toxicity tests	3	0	3	3	3	3	3	3	18	**86%**
B2 Irritation tests	10	0	10	4	1	10	10	10	45	**64%**
Sum	13	0	13	7	4	13	13	13	63	
% harmonized		**0%**	**100%**	**54%**	**31%**	**100%**	**100%**	**100%**		**69%**
Overall Sum	52	12	52	46	32	49	52	52		
Overall % harmonized		**23%**	**98%**	**88%**	**62%**	**94%**	**100%**	**100%**		**81%**

Summary percent harmonization with regard to recommended data requirements

	Data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides										
B1 Acute Toxicity tests	3	3	3	3	3	2	3	3	20	**95%**
B2 Irritation tests	10	9	9	10	5	10	10	10	63	**90%**
Sum	13	12	12	13	8	12	13	13	83	
% harmonized		**92%**	**92%**	**100%**	**62%**	**92%**	**100%**	**100%**		**91%**
Botanical Pesticides										
B1 Acute Toxicity tests	3	0	3	3	3	2	3	3	17	**81%**
B2 Irritation tests	3	0	3	3	3	3	3	3	18	**86%**
Sum	6	0	6	6	6	5	6	6	35	
% harmonized		**0%**	**100%**	**100%**	**100%**	**83%**	**100%**	**100%**		**83%**
Biochemical Pesticides										
B1 Acute Toxicity tests	3	0	3	3	3	2	3	3	17	**81%**
B2 Irritation tests	3	0	3	3	3	3	3	3	18	**86%**
Sum	6	0	6	6	6	5	6	6	35	
% harmonized		**0%**	**100%**	**100%**	**100%**	**83%**	**100%**	**100%**		**83%**
Microbial Pesticides										
B1 Acute Toxicity tests	3	0	3	3	3	3	3	3	18	**86%**
B2 Irritation tests	3	0	3	3	1	3	3	3	16	**76%**
Sum	6	0	6	6	4	6	6	6	34	
% harmonized		**0%**	**100%**	**100%**	**67%**	**100%**	**100%**	**100%**		**81%**
Overall Sum	31	12	30	31	19	28	31	31		
Overall % harmonized		**39%**	**97%**	**100%**	**77%**	**90%**	**100%**	**100%**		

Observations

- The Folder B data requirements for chemical pesticides are already harmonized to 92 percent among the countries. In 4 countries, the degree of harmonization is 100 percent.
- The Folder B data requirements for botanical, biochemical and microbial pesticides are harmonized to a lesser degree between 60 and 69 percent (without Cambodia: 81–88 percent)
- With regard to the recommended minimum data requirements, the degree of harmonization is between 76 and 92 percent (without Cambodia: 89–94 percent)
- In 4 countries, the degree of harmonization is 100 percent.
- All responding countries require more data than listed as required in the guidelines.

Conclusions

- Only three countries need to upgrade their Folder B data requirements.

Folder C: Bio-efficacy Data and Pest information

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
C1	**Bio-efficacy and Pest information**								
R	1.1. Pest (Common/Scientific name)	**Y = 6**		Y	Y	Y	Y	Y	Y
R	1.2. Dosage/rate of application	**Y = 6**		Y	Y	Y	Y	Y	Y
R	1.3. No. of applications	**Y = 6**		Y	Y	Y	Y	Y	Y
R	1.4. Application Method (e.g. dusting/spraying (high volume/ low volume/ultra low volume, etc.)/Appliances	**Y = 6**		Y	Y	Y	Y	Y	Y
		Sum = 24	**0**	**4**	**4**	**4**	**4**	**4**	**4**
C2	**Crop/Commodity information**								
R	2.1. Crop/Commodity (Common/Scientific name)	**Y = 5**		Y	Y	Y		Y	Y
R	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	**Y = 5**		Y	Y	Y		Y	Y
R	2.3. Pre-harvest intervals	**Y = 5**		Y	Y	Y		Y	Y
R	Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)	**Y = 5**		Y	Y	Y		Y	Y
R	Evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)	**Y = 5**		Y	Y	Y		Y	Y
R	Method of Sampling	**Y = 5**		Y	Y	Y		Y	Y
R	Recording field data	**Y = 5**		Y	Y	Y		Y	Y
R	Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence	**Y = 5**		Y	Y	Y		Y	Y
		Sum = 40	**0**	**8**	**8**	**8**	**0**	**8**	**8**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
C1	**Bio-efficacy and Pest information**								
R	1.1. Pest (Common/Scientific name)	**Y = 6**		Y	Y	Y	Y	Y	Y
R	1.2. Dosage/rate of application	**Y = 6**		Y	Y	Y	Y	Y	Y
R	1.3. No. of applications	**Y = 6**		Y	Y	Y	Y	Y	Y
R	1.4. Application Method (e.g. dusting/spraying (high volume/ low volume/ultra low volume, etc.)/Appliances	**Y = 6**		Y	Y	Y	Y	Y	Y
		Sum = 24	**0**	**4**	**4**	**4**	**4**	**4**	**4**
C2	**Crop/Commodity information**								
R	2.1. Crop/Commodity (Common/Scientific name)	**Y = 5**		Y	Y	Y		Y	Y
R	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	**Y = 5**		Y	Y	Y		Y	Y
R	2.3. Pre-harvest intervals	**Y = 5**		Y	Y	Y		Y	Y
R	Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)	**Y = 5**		Y	Y	Y		Y	Y
R	Evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)	**Y = 5**		Y	Y	Y		Y	Y
R	Method of Sampling	**Y = 5**		Y	Y	Y		Y	Y
R	Recording field data	**Y = 5**		Y	Y	Y		Y	Y
R	Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence	**Y = 5**		Y	Y	Y		Y	Y
		Sum = 40	**0**	**8**	**8**	**8**	**0**	**8**	**8**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
C1	**Bio-efficacy and Pest information**								
R	1.1. Pest (Common/Scientific name)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Dosage/rate of application	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. No. of applications	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.4. Application Method (e.g. dusting/spraying (high volume/ low volume/ultra low volume, etc.)/Appliances	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 24		**4**	**4**	**4**	**4**	**4**	**4**
C2	**Crop/Commodity information**								
R	2.1. Crop/Commodity (Common/Scientific name)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	2.3. Pre-harvest intervals	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Method of Sampling	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Recording field data	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
		Sum = 40		**8**	**8**	**8**	**0**	**8**	**8**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
C1	**Bio-efficacy and Pest information**								
R	1.1. Pest (Common/Scientific name)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Dosage/rate of application	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. No. of applications	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.4. Application Method (e.g. dusting/spraying (high volume/ low volume/ultra low volume, etc.)/Appliances	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 24	**0**	**4**	**4**	**4**	**4**	**4**	**4**
C2	**Crop/Commodity information**								
R	2.1. Crop/Commodity (Common/Scientific name)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	2.3. Pre-harvest intervals	**Y = 4**		**Y**	**Y**	**-**		**Y**	**Y**
R	Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Method of Sampling	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Recording field data	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
R	Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence	**Y = 5**		**Y**	**Y**	**Y**		**Y**	**Y**
		Sum = 39	**0**	**8**	**8**	**7**	**0**	**8**	**8**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

Summary percent harmonization with regard to all as well as recommended data requirements

		Data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
C1	Bio-efficacy and Pest information	4	0	4	4	4	4	4	4	24	**86%**
C2	Crop/Commodity information	8	0	8	8	8	0	8	8	40	**71%**
	Sum	12	0	12	12	12	4	12	12	64	
% harmonized			**0%**	**100%**	**100%**	**100%**	**33%**	**100%**	**100%**		**76%**
Botanical Pesticides											
C1	Bio-efficacy and Pest information	4	0	4	4	4	4	4	4	24	**86%**
C2	Crop/Commodity information	8	0	8	8	8	0	8	8	40	**71%**
	Sum	12	0	12	12	12	4	12	12	64	
% harmonized			**0%**	**92%**	**100%**	**100%**	**33%**	**100%**	**100%**		**75%**
Biochemical Pesticides											
C1	Bio-efficacy and Pest information	4	0	4	4	4	4	4	4	24	**86%**
C2	Crop/Commodity information	8	0	8	8	8	0	8	8	40	**71%**
	Sum	12	0	12	12	12	4	12	12	64	
% harmonized			**0%**	**100%**	**100%**	**100%**	**33%**	**100%**	**100%**		**75%**
Microbial Pesticides											
C1	Bio-efficacy and Pest information	4	0	4	4	4	4	4	4	24	**86%**
C2	Crop/Commodity information	8	0	8	8	7	0	8	8	39	**70%**
	Sum	12	0	12	12	11	4	12	12	63	
% harmonized			**0%**	**100%**	**100%**	**92%**	**33%**	**100%**	**100%**		**75%**
	Overall Sum	48	0	48	48	47	16	48	48		
Overall % harmonized			**0%**	**100%**	**100%**	**98%**	**33%**	**100%**	**100%**		

Observations

- The same Folder C data was listed as required for all types of pesticides
- The Folder C data requirements are already highly harmonized in most countries between 92 and 100 percent (except for Cambodia and Philippines); in 3 countries, the degree of harmonization was 100 percent.
- Cambodia does not require any bio-efficacy data for registration, while the Philippines, does not require crop/commodity information

Conclusions

- Only two countries need to harmonize their Folder C data requirements

Folder D: Residue Data

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
D1	**Plant metabolism:**								
R	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	**Y = 6**	**Y**	**Y**	**Y**	-	**Y**	**Y**	**Y**
R	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	**Y = 5**	**Y**	**Y**		-	**Y**	**Y**	**Y**
R	1.3. Crop groupings	**Y = 5**	**Y**	**Y**		-	**Y**	**Y**	**Y**
R	1.1. Use of radio labelling material (C-14, P-32, S-35)	**Y = 5**	**Y**	**Y**	**Y**	-	**Y**		**Y**
R	1.1. Dosage rate (at least equal to intended use)	**Y = 6**	**Y**	**Y**	**Y**	-	**Y**	**Y**	**Y**
R	1.2. Identification & characterization of residues	**Y = 6**	**Y**	**Y**	**Y**	-	**Y**	**Y**	**Y**
R	1.3. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	**Y = 4**	**Y**	**Y**	**Y**	-			**Y**
		Sum = 37	**7**	**7**	**5**	**0**	**6**	**5**	**7**
D2	**Farm Animal Metabolism:**								
R	2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken	**Y = 3**	**Y**		**Y**	-			**Y**
R	2.2. Duration of dosing (dosed daily for 3 consecutive days)	**Y = 3**	**Y**		**Y**	-			**Y**
R	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)	**Y = 3**	**Y**		**Y**	-			**Y**
R	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	**Y = 3**	**Y**		**Y**	-			**Y**
R	2.5. Parental compounds should be used	**Y = 2**	**Y**			-			**Y**
		Sum = 14	**5**	**0**	**4**	**0**	**0**	**0**	**5**
D3	**Farm Animal Feeding Studies:**								
R	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	**Y = 2**	**Y**		**Y**	-			
R	3.2. Number of animals and duration of dosing (a minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	**Y = 1**	**Y**			-			
R	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	**Y = 2**	**Y**		**Y**	-			
R	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X)) and control group)	**Y = 1**	**Y**			-			
R	3.5. Material used: usually parent compound	**Y = 2**	**Y**		**Y**	-			
		Sum = 8	**5**	**0**	**3**	**0**	**0**	**0**	**0**
D4	**Processing Studies**								
R	4.1. Data on transfer of residues into processed commodities	**Y = 1**	**Y**			-			
R	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup), Peas and beans (without pods), Oil seeds (meal, oil), Olive (virgin oil), Tea (brewed)	**Y = 2**	**Y**			-			**Y**
R	4.3. Residue trials carried out over different years (at least minimum of 3 trials)	**Y = 2**	**Y**			-		**Y**	
R	4.4. Glasshouse trials (protected crops)	**Y = 1**	**Y**			-			
R	4.5. Post-harvest treatment studies (wheat, potato)	**Y = 2**	**Y**			-		**Y**	
R	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	**Y = 2**	**Y**			-	**Y**		

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
R	4.7. Decline Studies (4 sampling intervals, i.e., five samples) Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	**Y = 4**	**Y**		**Y**	**-**		**Y**	**Y**
R	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	**Y = 5**	**Y**		**Y**	**-**	**Y**	**Y**	**Y**
		Sum = 19	**8**	**0**	**2**	**0**	**2**	**4**	**3**
D5	**Analytical Methods/standards for residue determination:**								
R	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
R	5.2. Analytical standards/reference chemicals	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
		Sum = 10	**0**	**2**	**2**	**0**	**2**	**2**	**2**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
D1	**Plant metabolism:**								
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	**Y = 3**		**Y**		**-**	**Y**	**Y**	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	**Y = 3**		**Y**		**-**	**Y**	**Y**	
	1.3. Crop groupings	**Y = 2**				**-**	**Y**	**Y**	
	1.1. Use of radio labelling material (C-14, P-32, S-35)	**Y = 1**				**-**	**Y**		
	1.1. Dosage rate (at least equal to intended use)	**Y = 4**		**Y**	**Y**	**-**	**Y**	**Y**	
	1.2. Identification & characterization of residues	**Y = 3**		**Y**		**-**	**Y**	**Y**	
	1.3. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	**Y = 1**		**Y**		**-**			
		Sum = 17	**0**	**5**	**1**	**0**	**6**	**5**	**0**
D2	**Farm Animal Metabolism:**					**-**			
	2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken								
	2.2. Duration of dosing (dosed daily for 3 consecutive days)					**-**			
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)					**-**			
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg					**-**			
	2.5. Parental compounds should be used					**-**			
		Sum = 0	**0**	**0**	**0**	**0**	**0**	**0**	**0**
D3	**Farm Animal Feeding Studies:**								
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)					**-**			
	3.2. Number of animals and duration of dosing (a minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)					**-**			

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)					-			
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X)) and control group)					-			
	3.5. Material used: usually parent compound					-			
		Sum = 0	**0**	**0**	**0**	**0**	**0**	**0**	**0**
D4	**Processing Studies**								
	4.1. Data on transfer of residues into processed commodities					-			
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup), Peas and beans (without pods), Oil seeds (meal, oil), Olive (virgin oil), Tea (brewed)					-			
	4.3. Residue trials carried out over different years (at least minimum of 3 trials)					-			
	4.4. Glasshouse trials (protected crops)					-			
	4.5. Post-harvest treatment studies (wheat, potato)					-			
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	**Y = 1**				-	**Y**		
	4.7. Decline Studies (4 sampling intervals, i.e., five samples) Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue					-			
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	**Y = 1**				-	**Y**		
		Sum = 2	**0**	**0**	**0**	**0**	**2**	**0**	**0**
D5	**Analytical Methods/standards for residue determination:**								
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	**Y = 1**				-	**Y**		
	5.2. Analytical standards/reference chemicals	**Y = 1**				-	**Y**		
		Sum = 2	**0**	**0**	**0**	**0**	**2**	**0**	**0**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
D1	**Plant metabolism:**								
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	**Y = 4**		Y	Y	-	Y	Y	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	**Y = 3**		Y		-	Y	Y	
	1.3. Crop groupings	**Y = 2**				-	Y	Y	
	1.1. Use of radio labelling material (C-14, P-32, S-35)	**Y = 2**			Y	-	Y		
	1.1. Dosage rate (at least equal to intended use)	**Y = 4**		Y	Y	-	Y	Y	
	1.2. Identification & characterization of residues	**Y = 4**		Y	Y	-	Y	Y	
	1.3. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	**Y = 2**		Y	Y	-			
		Sum = 21	**0**	**5**	**5**		**6**	**5**	**0**
D2	**Farm Animal Metabolism:**								
	2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken	**Y = 1**			Y	-			
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	**Y = 1**			Y	-			
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)	**Y = 1**			Y	-			
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	**Y = 1**			Y	-			
	2.5. Parental compounds should be used					-			
		Sum = 4	**0**	**0**	**4**	**0**	**0**	**0**	**0**
D3	**Farm Animal Feeding Studies:**								
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	**Y = 1**			Y	-			
	3.2. Number of animals and duration of dosing (a minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)					-			
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	**Y = 1**			Y	-			
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X)) and control group)					-			
	3.5. Material used: usually parent compound	**Y = 1**			Y	-			
		Sum = 3	**0**	**0**	**3**	**0**	**0**	**0**	**0**
D4	**Processing Studies**								
	4.1. Data on transfer of residues into processed commodities.					-			
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup), Peas and beans (without pods), Oil seeds (meal, oil), Olive (virgin oil), Tea (brewed)					-			
	4.3. Residue trials carried out over different years (at least minimum of 3 trials)					-			
	4.4. Glasshouse trials (protected crops)					-			
	4.5. Post-harvest treatment studies (wheat, potato)					-			
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	**Y = 1**				-	Y		

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	4.7. Decline Studies (4 sampling intervals, i.e., five samples) Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	**Y = 1**			**Y**	-			
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	**Y = 1**				-	**Y**		
		Sum = 3	**0**	**0**	**1**	**0**	**2**	**0**	**0**
D5	**Analytical Methods/standards for residue determination:**								
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	**Y = 1**				-	**Y**		
	5.2. Analytical standards/reference chemicals	**Y = 2**			**Y**	-	**Y**		
		Sum = 3	**0**	**0**	**1**	**0**	**2**	**0**	**0**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
D1	**Plant metabolism:**								
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	**Y = 3**		**Y**		-	**Y**	**Y**	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	**Y = 3**		**Y**		-	**Y**	**Y**	
	1.3. Crop groupings	**Y = 2**				-	**Y**	**Y**	
	1.1. Use of radio labelling material (C-14, P-32, S-35)	**Y = 1**				-	**Y**		
	1.1. Dosage rate (at least equal to intended use)	**Y = 4**		**Y**	**Y**	-	**Y**	**Y**	
	1.2. Identification & characterization of residues	**Y = 3**		**Y**		-	**Y**	**Y**	
	1.3. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	**Y = 1**		**Y**		-			
		Sum = 17	**0**	**5**	**1**	**0**	**6**	**5**	**0**
D2	**Farm Animal Metabolism:**								
	2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken					-			
	2.2. Duration of dosing (dosed daily for 3 consecutive days)					-			
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)					-			
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg					-			
	2.5. Parental compounds should be used					-			
		Sum = 0	**0**	**0**	**0**	**0**	**0**	**0**	**0**
D3	**Farm Animal Feeding Studies:**								
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)					-			
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs					-			

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)					-			
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X)) and control group)					-			
	3.5. Material used: usually parent compound					-			
		Sum = 0	**0**	**0**	**0**	**0**	**0**	**0**	**0**
D4	**Processing Studies**								
	4.1. Data on transfer of residues into processed commodities					-			
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup), Peas and beans (without pods), Oil seeds (meal, oil), Olive (virgin oil), Tea (brewed)					-			
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)					-			
	4.4. Glasshouse trials (protected crops)					-			
	4.5. Post-harvest treatment studies (wheat, potato)					-			
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	**Y = 1**				-	**Y**		
	4.7. Decline Studies (4 sampling intervals, i.e., five samples) Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue					-			
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	**Y = 1**				-	**Y**		
		Sum = 2	**0**	**0**	**0**	**0**	**2**	**0**	**0**
D5	**Analytical Methods/standards for residue determination:**								
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	**Y = 1**				-	**Y**		
	5.2. Analytical standards/reference chemicals	**Y = 1**				-	**Y**		
		Sum = 2	**0**	**0**	**0**	**0**	**2**	**0**	**0**
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

Summary percent harmonization with regard to overall list of data requirements

		Nr. of data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
D1	Plant metabolism	7	7	7	5	0	6	5	7	37	**76%**
D2	Farm Animal Metabolism	5	5	0	4	0	0	0	5	14	**40%**
D3	Farm Animal Feeding Studies	5	5	0	3	0	0	0	0	9	**23%**
D4	Processing Studies	8	8	0	2	0	2	4	3	19	**34%**
D5	Methods/standards for residue determination	2	0	2	2	0	2	2	2	10	**71%**
	Sum	27	25	9	16	0	10	11	17	88	
% harmonized			**93%**	**33%**	**59%**	**0%**	**37%**	**41%**	**63%**		**47%**
Botanical Pesticides											
D1	Plant metabolism	7	0	5	1	0	6	5	0	17	**35%**
D2	Farm Animal Metabolism	5	0	0	0	0	0	0	0	0	**0%**
D3	Farm Animal Feeding Studies	5	0	0	0	0	0	0	0	0	**0%**
D4	Processing Studies	8	0	0	0	0	2	0	0	2	**4%**
D5	Methods/standards for residue determination	2	0	0	0	0	2	0	0	2	**14%**
	Sum	27	0	5	1	0	10	5	0	21	
% harmonized			**0%**	**19%**	**4%**	**0%**	**37%**	**19%**	**0%**		**11%**
Biochemical Pesticides											
D1	Plant metabolism	7	0	5	5		6	5	0	21	**43%**
D2	Farm Animal Metabolism	5	0	0	4	0	0	0	0	4	**11%**
D3	Farm Animal Feeding Studies	5	0	0	3	0	0	0	0	3	**9%**
D4	Processing Studies	8	0	0	1	0	2	0	0	3	**5%**
D5	Methods/standards for residue determination	2	0	0	1	0	2	0	0	3	**21%**
	Sum	27	0	5	14	0	10	5	0	34	
% harmonized			**0%**	**19%**	**52%**	**0%**	**37%**	**19%**	**0%**		**18%**
Microbial Pesticides											
D1	Plant metabolism	7	0	5	1	0	6	5	0	17	**35%**
D2	Farm Animal Metabolism	5	0	0	0	0	0	0	0	0	**0%**
D3	Farm Animal Feeding Studies	5	0	0	0	0	0	0	0	0	**0%**
D4	Processing Studies	8	0	0	0	0	2	0	0	2	**4%**
D5	Methods/standards for residue determination	2	0	0	0	0	2	0	0	2	**14%**
	Sum	27	0	5	1	0	10	5	0	21	
% harmonized			**0%**	**19%**	**4%**	**0%**	**37%**	**19%**	**0%**		**11%**
	Overall Sum	108	25	24	32	0	40	26	17		
Overall % harmonized			**23%**	**22%**	**30%**	**0%**	**37%**	**24%**	**16%**		**22%**

Summary percent harmonization with regard to recommended data requirements

		Nr. of data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
D1	Plant metabolism	3	**3**	3	**3**	**0**	**3**	**3**	**3**	18	**86%**
D2	Farm Animal Metabolism	5	5	0	4	0	0	0	5	14	**40%**
D3	Farm Animal Feeding Studies	3	**3**	0	**2**	**0**	**0**	**0**	**0**	5	**24%**
D4	Processing Studies	2	**2**	0	**2**	**0**	**1**	**2**	**2**	9	**64%**
D5	Analytical Methods/standards for residue determination	2	0	2	2	0	2	2	2	10	**71%**
	Sum	15	13	5	13	0	6	7	12	56	**53%**
% harmonized			**87%**	**33%**	**87%**	**0%**	**40%**	**47%**	**80%**		
Botanical Pesticides											
D	No residue folder required	0	0	0	0	0	0	0	0	0	**0%**
	Sum	0	0	0	0	0	0	0	0	0	**0%**
% harmonized			**0%**	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**		
Biochemical Pesticides											
D	No residue folder required	0	0	0	0	0	0	0	0	0	**0%**
	Sum	0	0	0	0	0	0	0	0	0	**0%**
% harmonized			**0%**	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**		
Microbial Pesticides											
D	No residue folder required	0	0	0	0	0	0	0	0	0	**0%**
	Sum	0	0	0	0	0	0	0	0	0	**0%**
% harmonized			0%	0%	0%	0%	0%	0%	0%		
	Overall Sum	28	26	26	16	0	10	11	17		
Overall % harmonized			**87%**	**33%**	**87%**	**0%**	**40%**	**47%**	**80%**		

Observations

- The Folder D data requirements for chemical pesticides are already harmonized to only 54 percent with regard to the recommended data requirements
- No Folder D was required according the harmonization guidelines for biological pest control products, but four countries nevertheless require residue data for registration

Conclusions

- Several countries may review their residue data requirements for biological pest control products, and upgrade their residue study requirements for chemical pesticides

Folder E: Human Health Exposure/Environmental Data

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
E1	**Human Health Exposure Effects:**								
R	Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring)	**Y = 6**	**Y**	**Y**	**Y**	**-**	**Y**	**Y**	**Y**
R	Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring)	**Y = 4**	**Y**	**Y**		**-**	**Y**	**-**	**Y**
		Sum = 10	**2**	**2**	**1**	**0**	**2**	**1**	**2**
E2	**Evaluation of Environmental Fate & Effects:**								
R	3.1. Data on translocation of pesticides in soil and water	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	**Y = 6**	**Y**	**Y**	**Y**	**-**	**Y**	**Y**	**Y**
R	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators, etc.)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	3.3. Primary data on aquatic toxicity (e.g. fish and other aquatic animals)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	2.4. Primary data on phytotoxicity effects	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
R	3.4. Primary data on persistence/translocation in plants	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
	2.6. Primary data on treatment of effluents & disposal	**Y = 4**		**Y**		**-**	**Y**	**Y**	**Y**
		Sum = 47	**4**	**8**	**7**	**4**	**8**	**8**	**8**
E4	**Monitoring of environmental effects:**								
	4.1. Monitoring of substantial change in use/application pattern	**Y = 1**				**-**		**Y**	
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	**Y = 2**				**Y**		**Y**	
R	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	**Y = 2**	**Y**					**Y**	
		Sum = 5	**1**	**0**	**0**	**1**	**0**	**3**	**0**
E5	**Post-registration data generation**								
	Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence/resistance)	**Y = 5**		**Y**	**Y**	**Y**	**Y**	**Y**	
		Sum = 5	**0**	**1**	**1**	**1**	**1**	**1**	

Y = Yes; R = As required in the harmonization guidelines (shaded rows)

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
E1	**Human Health Exposure Effects:**								
	Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring)	**Y = 2**				-	Y	-	Y
	Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring)	**Y = 2**				-	Y	-	Y
		Sum = 4	**0**	**0**	**0**	**0**	**2**	**0**	**2**
E2	**Evaluation of Environmental Fate & Effects:**								
	3.1. Data on translocation of pesticides in soil and water	**Y = 2**				-	Y	-	Y
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	**Y = 3**				-	Y	Y	Y
	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators, etc.)	**Y = 4**			Y	-	Y	Y	Y
	3.3. Primary data on aquatic toxicity (e.g. fish and other aquatic animals)	**Y = 3**				-	Y	Y	Y
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	**Y = 3**				-	Y	Y	Y
	2.4. Primary data on phytotoxicity effects	**Y = 4**			Y	-	Y	Y	Y
	3.4. Primary data on persistence/translocation in plants	**Y = 3**				-	Y	Y	Y
	2.6. Primary data on treatment of effluents & disposal	**Y = 3**				-	Y	Y	Y
		Sum = 25	**0**	**0**	**2**	**0**	**8**	**7**	**8**
E4	**Monitoring of environmental effects:**								
	4.1. Monitoring of substantial change in use/application pattern	**Y = 2**				Y		Y	
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	**Y = 2**				Y		Y	
	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate					-		-	
		Sum = 4	**0**	**0**	**0**	**2**	**0**	**2**	**0**
E5	**Post-registration data generation**								
	Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence/resistance)	**Y = 1**				-	Y	-	
		Sum = 1					**1**		

Y = Yes; R = As required in the harmonization guidelines (shaded rows)

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
E1	**Human Health Exposure Effects:**								
R	Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring)	**Y = 4**			**Y**	**Y**	**Y**	-	**Y**
R	Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring)	**Y = 3**				**Y**	**Y**	-	**Y**
		Sum = 7	**0**	**0**	**1**	**2**	**2**	**0**	**2**
E2	**Evaluation of Environmental Fate & Effects:**								
	3.1. Data on translocation of pesticides in soil and water	**Y = 4**		**Y**	**Y**	-	**Y**	-	**Y**
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	**Y = 5**		**Y**	**Y**	-	**Y**	**Y**	**Y**
	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators, etc.)	**Y = 5**		**Y**	**Y**	-	**Y**	**Y**	**Y**
	3.3. Primary data on aquatic toxicity (e.g. fish and other aquatic animals)	**Y = 5**		**Y**	**Y**	-	**Y**	**Y**	**Y**
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	**Y = 4**		**Y**		-	**Y**	**Y**	**Y**
	2.4. Primary data on phytotoxicity effects	**Y = 5**		**Y**	**Y**	-	**Y**	**Y**	**Y**
	3.4. Primary data on persistence/translocation in plants	**Y = 5**		**Y**	**Y**	-	**Y**	**Y**	**Y**
	2.6. Primary data on treatment of effluents & disposal	**Y = 4**		**Y**		-	**Y**	**Y**	**Y**
		Sum = 37	**0**	**8**	**6**	**0**	**8**	**7**	**8**
E4	**Monitoring of environmental effects:**								
	4.1. Monitoring of substantial change in use/application pattern	**Y = 1**				-		**Y**	
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	**Y = 1**				-		**Y**	
	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate					-		-	
		Sum = 2	**0**	**0**	**0**	**0**	**0**	**2**	**0**
E5	**Post-registration data generation**								
	Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence/resistance)	**Y = 3**		**Y**	**Y**	-	**Y**	-	
		Sum = 3	0	**1**	**1**		**1**		
Y = Yes; R = As required in the harmonization guidelines (shaded rows)									

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
E1	**Human Health Exposure Effects:**								
R	Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring)	**Y = 4**		**Y**		**Y**	**Y**	-	**Y**
R	Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring)	**Y = 4**		**Y**		**Y**	**Y**	-	**Y**
		Sum = 8	**0**	**2**	**0**	**2**	**2**	**0**	**2**
E2	**Evaluation of Environmental Fate & Effects:**								
	3.1. Data on translocation of pesticides in soil and water	**Y = 2**				-	**Y**	-	**Y**
R	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	**Y = 3**				-	**Y**	**Y**	**Y**
R	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators, etc.)	**Y = 3**				-	**Y**	**Y**	**Y**
	3.3. Primary data on aquatic toxicity (e.g. fish and other aquatic animals)	**Y = 3**				-	**Y**	**Y**	**Y**
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	**Y = 3**				-	**Y**	**Y**	**Y**
R	2.4. Primary data on phytotoxicity effects	**Y = 5**		**Y**	**Y**	-	**Y**	**Y**	**Y**
	3.4. Primary data on persistence/translocation in plants	**Y = 4**		**Y**		-	**Y**	**Y**	**Y**
	2.6. Primary data on treatment of effluents & disposal	**Y = 4**		**Y**		-	**Y**	**Y**	**Y**
		Sum = 27	**0**	**3**	**1**	**0**	**8**	**7**	**8**
E4	**Monitoring of environmental effects:**								
	4.1. Monitoring of substantial change in use/application pattern	**Y = 2**		**Y**		-		**Y**	
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	**Y = 2**		**Y**		-		**Y**	
	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	**Y = 1**		**Y**		-		-	
		Sum = 5	**0**	**3**	**0**	**0**	**0**	**2**	**0**
E5	**Post-registration data generation**								
	Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence/resistance)	**Y = 2**		**Y**		-	**Y**	-	
		Sum = 2		**1**			**1**		

Y = Yes; R = As required in the harmonization guidelines (shaded rows)

Summary percent harmonization with regard to overall list of data requirements

		Nr. of data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
E1	Human Health Exposure Effects	2	2	2	1	0	2	1	2	10	**71%**
E2	Evaluation of Environmental Fate & Effects	8	4	8	7	4	8	8	8	47	**84%**
E4	Monitoring of environmental effects	3	1	0	0	1	0	3	0	5	**24%**
E5	Post-registration data generation	1	0	1	1	1	1	1	0	5	**71%**
	Sum	14	7	11	9	6	11	13	10	67	
% harmonized			**50%**	**79%**	**64%**	**43%**	**79%**	**93%**	**71%**		**68%**
Botanical Pesticides											
E1	Human Health Exposure Effects	2	0	0	0	0	2	0	2	4	**29%**
E2	Evaluation of Environmental Fate & Effects	8	0	0	2	0	8	7	8	25	**45%**
E4	Monitoring of environmental effects	3	0	0	0	2	0	2	0	4	**19%**
E5	Post-registration data generation	1	0	0	0	0	1	0	0	1	**14%**
	Sum	14	0	0	2	2	11	9	10	34	
% harmonized			**0%**	**0%**	**14%**	**14%**	**79%**	**64%**	**71%**		**35%**
Biochemical Pesticides											
E1	Human Health Exposure Effects	2	0	0	1	2	2	0	2	7	**50%**
E2	Evaluation of Environmental Fate & Effects	8	0	8	6	0	8	7	8	37	**66%**
E4	Monitoring of environmental effects	3	0	0	0	0	0	2	0	2	**10%**
E5	Post-registration data generation	1	0	1	1	0	1	0	0	3	**43%**
	Sum	14	0	9	8	2	11	9	10	49	
% harmonized			**0%**	**64%**	**57%**	**14%**	**79%**	**64%**	**71%**		**50%**
Microbial Pesticides											
E1	Human Health Exposure Effects	2	0	2	0	2	2	0	2	8	**57%**
E2	Evaluation of Environmental Fate & Effects	8	0	3	1	0	8	7	8	27	**48%**
E4	Monitoring of environmental effects	3	0	3	0	0	0	2	0	5	**24%**
E5	Post-registration data generation	1	0	1	0	0	1	0	0	2	**29%**
	Sum	14	0	9	1	2	11	9	10	42	
% harmonized			**0%**	**64%**	**7%**	**14%**	**79%**	**64%**	**71%**		**43%**
	Overall Sum	56	7	29	20	12	44	40	40		
Overall % harmonized			**13%**	**52%**	**36%**	**21%**	**79%**	**71%**	**71%**		**49%**

Summary percent harmonization with regard to recommended data requirements

	Nr. of data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides										
E1 Human Health Exposure Effects	2	2	2	1	0	2	1	2	10	**71%**
E2 Evaluation of Environmental Fate & Effects	4	3	4	4	3	4	4	4	26	**93%**
E4 Monitoring of environmental effects	1	1	0	0	0	0	1	0	2	**43%**
Sum	7	6	6	5	3	6	6	6	38	
% harmonized		**86%**	**86%**	**71%**	**43%**	**86%**	**86%**	**86%**		**78%**
Botanical Pesticides										
E1 Human Health Exposure Effects	0	0	0	0	0	0	0	0	0	**0%**
Sum	0	0	0	0	0	0	0	0	0	
% harmonized		**0%**	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**		**0%**
Biochemical Pesticides										
E1 Human Health Exposure Effects	2	0	0	1	2	2	0	2	7	**50%**
Sum	2	0	0	1	2	2	0	2	7	
% harmonized		**0%**	**0%**	**50%**	**100%**	**100%**	**0%**	**100%**		**50%**
Microbial Pesticides										
E1 Human Health Exposure Effects	2	0	2	0	2	2	0	2	8	**57%**
E2 Evaluation of Environmental Fate & Effects	3	0	1	1	0	3	3	3	11	**52%**
Sum	5	0	3	1	2	5	3	5	19	
% harmonized		**0%**	**60%**	**20%**	**40%**	**100%**	**60%**	**100%**		**54%**
Overall Sum	14	6	9	7	7	13	9	13		
Overall % harmonized		**43%**	**69%**	**50%**	**50%**	**93%**	**64%**	**93%**		**65%**

Observations

- The Folder E data requirements for chemical pesticides are harmonized to 80 percent with regard to the recommended data.
- The Folder E data requirements for biochemical and microbial pesticides are harmonized to a lesser degree between 60 and 64 percent (without Cambodia: 70–75 percent); no data requirements were recommended for botanical pesticides.
- Three countries require all (100%) recommended Folder E data for biological products.
- All responding countries require more data than listed as required in the guidelines.

Conclusions

- Five countries require less than 2/3 of the recommended human health and environmental data and should review their requirements.

Folder F: Labelling/Packaging/Storage Data

	Chemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
F1	**Labelling**								
R	1.1. Chemical name/Common name of MPCA	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.2. Product Name	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Formulation/contents of the product	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.4. Quantity (Wt/Vol.)	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6. Manufacturer & Licensing Number/date of issue	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6.1. Batch Number	**Y = 6**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**
R	1.6.2. Manufacturing date	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6.3. Date of expiry of product	**Y = 6**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**
R	1.7. Precautions & Directions for use	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.8. Warning phrases & Symbols	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.9. Storage conditions	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.10. Recommended crop/commodity	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.11. Pre-harvest intervals	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.12. Restrictions, if any	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.13. Signs/symptoms of pesticide poisoning & treatment	**Y = 7**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 104	**10**	**16**	**16**	**16**	**16**	**14**	**16**
F2	**Packaging**								
R	2.1. Specification of primary package	**Y = 4**		**Y**	**Y**	**-**	**Y**	**Y**	
R	2.2. Specification of secondary package	**Y = 3**		**Y**	**Y**	**-**	**Y**		
R	2.3. Specification of bulk package for transport	**Y = 3**	**Y**	**Y**		**-**	**Y**		
	2.3. Sterile packing condition	**Y = 2**				**Y**	**Y**		
		Sum = 12	**1**	**3**	**2**	**1**	**4**	**1**	**0**
F3	**Storage tests (Shelf life)**								
R	Storage tests (Shelf life)		**Y**	**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 6	**1**	**1**		**1**	**1**	**1**	**1**

	Botanical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
F1	**Labelling**								
	1.1. Chemical name/Common name of MPCA	**Y = 3**			**Y**	**Y**			**Y**
	1.2. Product Name	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.3. Formulation/contents of the product	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.4. Quantity (Wt/Vol.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.6. Manufacturer & Licensing Number/date of issue	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.6.1. Batch Number	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
	1.6.2. Manufacturing date	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.6.3. Date of expiry of product	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
R	1.7. Precautions & Directions for use	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.8. Warning phrases & Symbols	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.9. Storage conditions	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.10. Recommended crop/commodity	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.11. Pre-harvest intervals	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.12. Restrictions, if any	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.13. Signs/symptoms of pesticide poisoning & treatment	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
		Sum = 90		**15**	**16**	**15**	**15**	**13**	**16**
F2	**Packaging**								
R	2.1. Specification of primary package	**Y = 4**		**Y**	**Y**		**Y**	**Y**	
	2.2. Specification of secondary package	**Y = 3**		**Y**	**Y**		**Y**		
	2.3. Specification of bulk package for transport	**Y = 2**		**Y**			**Y**		
	2.3. Sterile packing condition	**Y = 2**				**Y**	**Y**		
		Sum = 11	**0**	**3**	**2**	**1**	**4**	**1**	**0**
F3	**Storage tests (Shelf life)**								
R	Storage tests (Shelf life)			**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 5		**1**		**1**	**1**	**1**	**1**

	Biochemical Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
F1	**Labelling**								
R	1.1. Chemical name/Common name of MPCA	**Y = 4**		**Y**	**Y**	**Y**			**Y**
R	1.2. Product Name	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Formulation/contents of the product	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.4. Quantity (Wt/Vol.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6. Manufacturer & Licensing Number/date of issue	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6.1. Batch Number	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
R	1.6.2. Manufacturing date	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6.3. Date of expiry of product	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
R	1.7. Precautions & Directions for use	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.8. Warning phrases & Symbols	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.9. Storage conditions	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.10. Recommended crop/commodity	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.11. Pre-harvest intervals	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.12. Restrictions, if any	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.13. Signs/symptoms of pesticide poisoning & treatment	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
		Sum = 92		**16**	**16**	**16**	**15**	**13**	**16**
F2	**Packaging**								
R	2.1. Specification of primary package	**Y = 4**		**Y**	**Y**	**-**	**Y**	**Y**	
R	2.2. Specification of secondary package	**Y = 3**		**Y**	**Y**	**-**	**Y**		
R	2.3. Specification of bulk package for transport	**Y = 2**		**Y**		**-**	**Y**		
	2.3. Sterile packing condition	**Y = 3**		**Y**		**Y**	**Y**		
		Sum = 12	**0**	**4**	**2**	**1**	**4**	**1**	**0**
F3	**Storage tests (Shelf life)**								
R	Storage tests (Shelf life)	**Y = 5**		**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 5	**0**	**1**	**0**	**1**	**1**	**1**	**1**

	Microbial Pesticides		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
F1	**Labelling**								
R	1.1. Chemical name/Common name of MPCA	**Y = 4**		**Y**	**Y**	**Y**			**Y**
R	1.2. Product Name	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.3. Formulation/contents of the product	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.4. Quantity (Wt/Vol.)	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6. Manufacturer & Licensing Number/date of issue	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6.1. Batch Number	**Y = 5**		**Y**	**Y**	**Y**	**Y**		**Y**
R	1.6.2. Manufacturing date	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.6.3. Date of expiry of product	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.7. Precautions & Directions for use	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.8. Warning phrases & Symbols	**Y = 5**		**Y**	**Y**		**Y**	**Y**	**Y**
R	1.9. Storage conditions	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
R	1.10. Recommended crop/commodity	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
	1.11. Pre-harvest intervals	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
	1.12. Restrictions, if any	**Y = 6**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
	1.13. Signs/symptoms of pesticide poisoning & treatment	**Y = 5**		**Y**	**Y**	**-**	**Y**	**Y**	**Y**
		Sum = 89	**0**	**16**	**16**	**12**	**15**	**14**	**16**
F2	**Packaging**								
R	2.1. Specification of primary package	**Y = 4**		**Y**	**Y**	**-**	**Y**	**Y**	
R	2.2. Specification of secondary package	**Y = 3**		**Y**	**Y**	**-**	**Y**		
	2.3. Specification of bulk package for transport	**Y = 2**		**Y**		**-**	**Y**		
R	2.3. Sterile packing condition	**Y = 3**		**Y**		**Y**	**Y**		
		Sum = 12	**0**	**4**	**2**	**1**	**4**	**1**	**0**
F3	**Storage tests (Shelf life)**								
R	Storage tests (Shelf life)	**Y = 5**		**Y**		**Y**	**Y**	**Y**	**Y**
		Sum = 5	**0**	**1**	**0**	**1**	**1**	**1**	**1**

Summary percent harmonization with regard to overall list of data requirements

		Nr. of data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
F1	Labelling	16	10	16	16	16	16	14	16	104	**93%**
F2	Packaging	4	1	3	2	1	4	1	0	12	**43%**
F3	Storage tests (Shelf life)	1	1	1		1	1	1	1	6	**86%**
	Sum	21	12	20	18	18	21	16	17	122	
% harmonized			**57%**	**95%**	**86%**	**86%**	**100%**	**76%**	**81%**		**83%**
Botanical Pesticides											
F1	Labelling	16		16	16	15	15	13	16	91	**81%**
F2	Packaging	4	0	3	2	1	4	1	0	11	**39%**
F3	Storage tests (Shelf life)	1		1		1	1	1	1	5	**71%**
	Sum	21	0	20	18	17	20	15	17	107	
% harmonized			**0%**	**95%**	**86%**	**81%**	**95%**	**71%**	**81%**		**73%**
Biochemical Pesticides											
F1	Labelling	16		16	16	16	15	13	16	92	**82%**
F2	Packaging	4	0	4	2	1	4	1	0	12	**43%**
F3	Storage tests (Shelf life)	1	0	1	0	1	1	1	1	5	**71%**
	Sum	21	0	21	18	18	20	15	17	109	
% harmonized			**0%**	**100%**	**86%**	**86%**	**95%**	**71%**	**81%**		**74%**
Microbial Pesticides											
F1	Labelling	16	0	16	16	12	15	14	16	89	**79%**
F2	Packaging	4	0	4	2	1	4	1	0	12	**43%**
F3	Storage tests (Shelf life)	1	0	1	0	1	1	1	1	5	**71%**
	Sum	21	0	21	18	14	20	16	17	106	
% harmonized			**0%**	**100%**	**86%**	**67%**	**95%**	**76%**	**81%**		**72%**
	Overall Sum	84	12	82	72	67	81	62	68		
Overall % harmonized			**14%**	**100%**	**86%**	**80%**	**96%**	**74%**	**81%**		**73%**

Summary percent harmonization with regard to recommended data requirements

		Nr. of data	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam	Sum	% Harmonized
Chemical Pesticides											
F1	Labelling	16	10	16	16	16	16	14	16	104	**93%**
F2	Packaging	3	1	3	2	0	3	1	0	10	**48%**
F3	Storage tests (Shelf life)	1	1	1		1	1	1	1	6	**86%**
	Sum	20	12	20	18	17	20	16	17	120	
% harmonized			**60%**	**100%**	**90%**	**85%**	**100%**	**80%**	**85%**		**86%**
Botanical Pesticides											
F1	Labelling	7	0	7	7	6	7	7	7	41	**84%**
F2	Packaging	1	0	1	1	0	1	1	0	4	**57%**
F3	Storage tests (Shelf life)	1		1		1	1	1	1	5	**71%**
	Sum	9	0	9	8	7	9	9	8	50	
% harmonized			**0%**	**100%**	**89%**	**78%**	**100%**	**100%**	**89%**		**79%**
Biochemical Pesticides											
F1	Labelling	16		16	16	16	15	13	16	92	**82%**
F2	Packaging	3	0	3	2	0	3	1	0	9	**43%**
F3	Storage tests (Shelf life)	1	0	1	0	1	1	1	1	5	**71%**
	Sum	20	0	20	18	17	19	15	17	106	
% harmonized			**0%**	**100%**	**90%**	**85%**	**95%**	**75%**	**85%**		**76%**
Microbial Pesticides											
F1	Labelling	13	0	13	13	12	12	11	13	74	**81%**
F2	Packaging	3	0	3	2	1	3	1	0	10	**48%**
F3	Storage tests (Shelf life)	1	0	1	0	1	1	1	1	5	**71%**
	Sum	17	0	17	15	14	16	13	14	89	
% harmonized			**0%**	**100%**	**88%**	**82%**	**94%**	**76%**	**82%**		**75%**
	Overall Sum	66	12	66	59	55	64	53	56		
Overall % harmonized			**18%**	**100%**	**89%**	**83%**	**97%**	**80%**	**85%**		**79%**

Observations

- The Folder F data requirements for chemical pesticides are already harmonized between 60 and 100 percent with regard to the recommended data.
- The Folder F data requirements for botanical, biochemical and microbial pesticides are already fairly harmonized to 87–93 percent (without Cambodia; with Cambodia: 75–79 percent).
- Some countries require more data than listed as required in the guidelines.

Conclusions

- Most country's labelling and packaging data requirements are already reasonably harmonized and only minor upgrades are required for full harmonization.

III. OTHER AREAS OF HARMONIZATION

Background

The TCP project also developed *Guidelines for the preparation of efficacy test protocols, Guidelines for harmonization of pesticide labelling, Guidelines for pesticide residue monitoring system*, and *Recommendations for information exchange on pesticide regulatory matters*, risk assessment and formulation analysis. The country status on the harmonization of these matters is summarized below.

1. Guidelines for the preparation of efficacy test protocols

Background

The guidelines gave an updated format for efficacy test protocols for chemical pesticides and presented 25 specific efficacy test protocols to supplement those already developed earlier by FAO. It was recommended that the countries adopt the guidelines and the new test protocols, and to bring their existing test protocols in line with international/harmonized guidelines.

Survey responses

1.	Guidelines for the preparation of efficacy test protocols		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Do you require bio-efficacy registration data to follow the 40 modified FAO bio-efficacy test protocols?	**Y = 4**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**
	Do you require bio-efficacy registration data to follow the 29 new harmonized bio-efficacy test protocols?	**Y = 4**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**
	Do you accept bio-efficacy registration data generated in other ASEAN countries according to the harmonized bio-efficacy test protocols?	**Y = 4**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**
	Have you modified other existing test protocols in accordance with the new modality guidelines for the preparation of efficacy test protocols If yes, please indicate the number of modified test protocols: _____	**Y = 2**	**Y**	**N**	**N**	**N**	**N**	**Y** 187	**N**
		Sum = 14	**4**	**3**	**0**	**3**	**0**	**4**	**0**

Observations

- Four countries have adopted parts of the guidelines
- Cambodia has adopted all parts of the guidelines even though it reported not to require bio-efficacy data for any type of pesticides.

Conclusions

- A partial harmonization of efficacy test protocols has been achieved
- The actual situation in some countries may need to be verified

2. Guidelines for harmonization of pesticide labelling

Background

The guidelines proposed to harmonize label information and design. It was recommended that labels should include all elements proposed in the guidelines and that their design should be similar except for the language.

Survey responses

2.	Guidelines for harmonization of pesticide labelling		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Have you revised the national legislation to accommodate the harmonized labelling guidelines?	**Y = 3**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**
	Do you require the same contents of the following label sections to as listed in the harmonized guidelines?								
	– Information to identify the product	**Y = 5**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**N**
	– Hazard and safety information	**Y = 5**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**N**
	– Use instructions	**Y = 5**	**Y**	**Y**	**N**	**Y**	**Y**	**Y**	**N**
	– Other information	**Y = 3**	**Y**	**Y**	**N**	**-**	**Y**		**N**
		Sum = 21	**5**	**5**	**0**	**4**	**4**	**3**	**0**

Observations

- Three countries have revised their national legislation to accommodate the harmonized labelling requirements
- The majority of the countries (5) have already harmonized the label sections on: information to identify the product; hazard and safety information; and use instructions

Conclusions

- A partial harmonization of pesticide labelling has been achieved

3. Recommendations for risk assessment

Background

The TCP project provided recommendations to strengthen risk assessment in those countries that are already fairly advanced (Malaysia, Thailand, Philippines) and those that still need to build up their risk assessment capacities.

Survey responses

3.	Recommendations for risk assessment		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Have you adopted the harmonized toxicology testing protocols	**Y = 2**	**N**	**Y**	**N**	**Y**	**N**	**N**	**N**
	Have you adopted the FAO guidelines/procedures for ecotoxicology assessment?	**Y = 3**	**N**	**Y**	**N**	**Y**	**N**	**Y**	**N**
		Sum = 5	**0**	**2**	**0**	**2**	**0**	**1**	**0**

Observations

- Only two countries have adopted the harmonized toxicology testing protocols, while 3 countries have adopted the FAO procedures for ecotoxicology assessment
- The majority of the countries have not adopted the recommendations for risk assessment

Conclusions

- Risk assessment is an area that still needs to be improved in most countries in Southeast Asia

4. Recommendations for formulation analysis

Background

The TCP project provided a list of recommendations to strengthen pesticide quality control and formulation analysis. This included the recommendation to standardize test methodologies and procedures to monitor the quality of pesticides.

Survey responses

4.	Recommendations for formulation analysis		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Have you adopted the harmonized pesticide testing protocols?	**Y = 4**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**
		Sum = 4	**1**	**1**		**1**		**1**	

Observations

- Four countries have adopted the harmonized pesticide testing protocols

Conclusions

- A partial harmonization of formulation analysis has been achieved

5. Guidelines for pesticide residue monitoring system

Background

The guidelines for pesticide residue monitoring included infrastructure and human resource requirements, sampling plan, analytical pesticide standards, analytical methods, validation, reporting and interpretation of results. It was recommended that countries with an established residue monitoring system should provide assistance to those countries that are in the process of building one. All countries should use the same extraction and clean-up methods.

Survey responses

5.	Guidelines for pesticide residue monitoring system		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Have you set up a pesticide residue monitoring system according the harmonized guidelines?	**Y = 2**	**Y**	**N**	**N**	**N**	**N**	**Y**	**N**
	Have you adopted the harmonized testing protocols for residue determination?	**Y = 4**	**Y**	**Y**	**N**	**Y**	**N**	**Y**	**N**
		Sum = 6	**2**	**1**		**1**		**2**	

Observations

- Four countries have adopted the harmonized testing protocols for residue determination
- Only two countries have set up a residue monitoring system according to the harmonized guidelines

Conclusions

- Implementation of the harmonized guidelines for residue monitoring

6. Recommendations for information exchange on pesticide regulatory matters

Background

The guidelines for information exchange contained formats for the reporting of legislation and regulations national guidelines, standards, testing protocols, registration data requirements, registered, restricted and banned pesticides, maximum residue limits (MRL), publications, videos, projects, workshops, news. It was recommended that the countries establish specific legislation and regulations for information exchange, designate responsible authority, develop national information management system, provide training in information exchange, establish a regional internet portal and pesticide database, adopt harmonized formats for information exchange.

Survey responses

6.	Recommendations for information exchange on pesticide regulatory matters		Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Viet Nam
	Do you have a list of Pesticide Act/Rules/Regulations/Amendments prepared in the format recommended in the harmonized guidelines?	**Y = 3**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**
	Do you have a list of national guidelines/standards/testing protocols prepared in the format recommended in the harmonized guidelines?	**Y = 2**	**Y**	**N**	**N**	**Y**	**N**	**N**	**N**
	Do you have a list of registered pesticides prepared in the format recommended in the harmonized guidelines?	**Y = 3**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**
	Do you have a list of banned and/or severely restricted pesticides prepared in the format recommended in the harmonized guidelines?	**Y = 3**	**Y**	**Y**	**N**	**Y**	**N**	**N**	**N**
	Do you have a list national maximum residue limits (MRL) prepared in the format recommended in the harmonized guidelines?	**Y = 1**	**Y**	**N**	**N**	**N**	**N**	**N**	**N**
		Sum = 12	**5**	**3**	**0**	**4**	**0**	**0**	**0**
	Countries that submitted list of banned and registered pesticides								

Observations

- Three countries reported to use the format recommended in the harmonized guidelines
- Even though some countries reported to use the recommended information exchange format, none of the countries submitted their lists of registered and banned/severely restricted pesticides in the recommended format

Conclusions

- There is little evidence that the information exchange recommendation have been implemented.
- The recommended formats may have been to complicated and extensive to be seen as helpful

ANNEX 2

Lists of banned and restricted pesticides

List of banned and restricted pesticides

PIC or POP	Chemical Name	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
	2, 3-dichlorphenol				■													1
	2, 4-dichlorphenol				■													1
	2, 5-dichlorphenol				■													1
PIC	2, 4, 5-T and its salts and esters	■	■		■	■	■	■	■	■			■		■	■	■	12
	2, 4, 5-TCP															■		1
	2, 4, 5-TP		■													■		2
	2, 4, 6-T (TCP)				■													1
	2, 4, 6-tribromophenol (TBP)				■													1
	4-Bromo-2, 5-dichlorphenol				■													1
	4-aminodiphenyl															■		1
	4-nitrodiphenyl															■		1
	Acrolein		▒															1
PIC	Alachlor		▒				■											2
PIC	Aldicarb		■		■		■						▒		■			5
	Aldoxycarb		■															1
POP, PIC	Aldrin		■	■	■	■	■	■	■	■	■		■	■	■	■	■	14
	Allyl alcohol		▒															1
	Al-phosphide		▒		▒												■	3
	Aminocarb		■													■		2
	Amitraz		■															1
	Amitrole															■		1
	ANTU (1-naphthylthiourea)		■										■					2
	Aramite		■													■		2
	Asbestos-amosite															■		1
	Arsenic compound (AS)		■	■	■			■					▒		■	■	■	8
	Arsenic Trioxide												■					1
	Calcium arsenate		■					■								■		3
	Copper arsenate hydroxide															■		1
	Copper acetoarsenic (Paris Green)												■			■		2
	Sodium Arsenite							■								■		2
	Azinphos ethyl		▒										■			■		3
	Azinphos methyl		■													■		2
	Azocyclotin		▒															1
	Benomyl						▒											1
	Benzidine															■		1
PIC	Binapacryl		■				■	■	■			■				■		6
	bis (chloromethyl) ether															■		1
	Blasticidin-S		▒															1
	Brodifacoum		▒							▒								2
	Bromadiolone		▒							▒								2
	Bromophos		■													■		2
	Bromophos ethyl		■									■				■		3
	BromoxynilIoxynil		■															1
	Butocarboxim		▒															1
	Cadmium compound (Cb)		■													■	■	3

PIC or POP	Chemical Name	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
	Cadusafos		■															1
	Calcium cyanide		■															1
	Calcium phosphide			■														1
	Camphechlor		■	■														2
PIC	Captafol		■		■	■	■	■	■	■		■			■	■	■	11
	Captan		■														■	2
	Carbofuran		■				■										■	3
	Carbon disulfide						■						■					2
	Carbon tetrachloride												■			■		2
	Carbophenothion		■															1
POP, PIC	Chlordane	■	■		■	■	■	■	■	■	■		■	■	■	■	■	14
POP	Chlordecone		■		■	■					■					■		5
PIC	Chlordimeform		■	■	■		■	■	■	■		■	■		■	■	■	12
	Chlorfenvinphos		■					■										2
	Chlormephos (?)		■															1
	Chlornitrofen					■												1
PIC	Chlorobenzilate						■	■	■			■	■			■		6
	Chloroform												■					1
	Chloropicrin		■															1
	Chlorophenols															■		1
	Chlorthiophos		■					■				■				■		4
	Coumaphos		■	■														2
	Crimidine		■															1
	Crotoxyphos		■															1
	Cyanthoate		■															1
	Cycloheximide		■					■								■		3
	Cyhexatin		■		■	■		■		■		■				■		7
	Cytokinin (Zeatin)		■															1
	Dalapon											■						1
	Daminozide		■					■								■		3
	DBCP (Dibromochloropropane)		■	■	■			■				■	■		■	■		8
	DDD															■		1
POP, PIC	DDT	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	16
	Demephion		■													■		2
	Demeton		■					■								■		3
	Demeton-S-methyl		■															1
	Diamidafos		■															1
	Dichlorvos	■	■														■	3
	Dicofol		■			■											■	3
	Dicrotophos		■									■						2
POP, PIC	Dieldrin	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	15
	Dimefox		■					■								■		3
	Dimetilan		■															1
	Dimethoate														■			1
	Dinitrocresol							■										1
PIC	Dinoseb and its salts and esters		■		■		■	■	■	■						■		7

PIC or POP	Chemical Name	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
	Dinoterb		■													■		2
	Dinoterb acetate/Dinitrobutyphenol							■										1
	Dioxathion		■															1
	Diphacinone		▒															1
	Disulfoton		■									■				■		3
PIC	Dinitro-ortho-cresol (DNOC) and its salts		■				■		■							■		4
	Edifenphos		■															1
PIC	EDB				■		■	■	■	■			■			■		7
POP, PIC	Endosulfan		■		■	■	■	■	■		■	■	▒		■	▒	■	12
POP	Endrin		■		■	■	■	■		■	■	■	■	■	■	■	■	13
	Endothion		■														■	2
	Ethoprophos		■										▒					2
	EPN		■		■			■		■			■					5
	Ethyl formate												▒					1
	Ethyl hexylene glycol															■		1
	Ethylene dibromide		■	■														2
PIC	Ethylene dichloride		■				■		■							■		4
PIC	Ethylene oxide		■				■	■	■							■		5
	Ethylthiodemeton		■															1
	Fenamiphos		■	■														2
	Fensulfothion		■	■												■		3
	Fenthion		▒							▒					■			3
	Fentin		■													■		2
	Flocoumafen		▒															1
	Flucythrinate		■															1
PIC	Fluoroacetamide		■	■			■	■	■							■		6
	Fonofos		■	■												■		3
	Formaldehyda				■													1
	Formetanate		▒															1
	Fosthietan		■															1
	Gliftor			■														1
	Gophacide												■					1
POP, PIC	HCH/BHC (mixed isomers)	■	■		■		■	■	■	■	■	■	■		■	■	■	13
POP	α-HCH					■					■							2
POP	β-HCH					■					■					■		3
POP, PIC	Heptachlor	■	■		■	■	■	■	■		■	■	■	■	■	■	■	14
POP, PIC	Hexachlorobenzene HCB		■	■		■	■		■		■		■	■		■	■	10
POP	Hexabromobiphenyl (HBB)										■							1
	Heptenophos		▒															1
	Hydrogen cyanide												▒					1
	IPSP		■															1
	Isazofos		▒															1
	Isobenzan		■														■	2
	Isodrin (Isomer of Aldrine)		■														■	2
	Isofenphos		▒															1
	Isoxathion		■															1

PIC or POP	Chemical Name	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
	Lead arsenate		■			■										■		3
	Lead compound (Pb)		■	■													■	3
	Leptophos		■		■			■				■	■		■	■		7
POP, PIC	Lindane (gamma-HCH)		■		■	■	■	■	■		■		■		■	■	■	11
	MAFA		■															1
	Magnesium phosphide		■	■	■												■	4
	MCPB		■													■		2
	Mecarbam		■															1
	Mecoprop															■		1
	Mephosfolan															■		1
	Medinoterb acetate		■															1
	Mephosphoslan		■															1
	Mercaptophos		■															1
PIC	Mercury compound (Hg)		■	■	■	■	■	■	■	■		■			■	■	■	12
PIC	Mercuric Fungicides										■		■					2
	Methacarbate		■															1
	Methamidophos	■	■	■			■	■	■	■		■			■	■	■	11
	Methidathion		■										■					2
	Methomyl		■					■									■	3
	Methoxychlor				■													1
	Methoxyethyl mercury chloride (MEMC)							■										1
	Methyl bromide	■	■		■		■	■		■			■				■	8
	Mevinfos		■		■							■						3
	MGK repellent-11															■		1
POP	Mirex		■		■	■	■				■		■	■		■		8
PIC	Monocrotophos	■	■	■			■	■	■	■	■	■	■		■	■	■	13
	Methanediamine			■														1
	Monosodium methanearsonate/MSMA				■													1
	Naphthylamine															■		1
	Nicotine		■															1
	Nitrilacarb		■															1
	Nitrofen		■	■									■			■		4
	ODCB															■		1
	Omethoate		■															1
	Organotin												■					1
	Oxamyl		■					■										2
	Oxydemeton-methyl		■															1
	Oxydeprofos (ESP)		■															1
	Paraquat		■		■			■					■					4
PIC	Parathion		■	■		■	■	■	■	■			■		■	■	■	11
	Parathion-methyl		■	■	■	■	■	■	■		■	■	■		■	■	■	13
	PCNB quintozene					■									■			2
POP	Pentachlorobenzene (PeCB)				■	■					■							3
	Pentachlorophenate sodium		■								■					■		3
PIC	Pentachlorophenol/PCP and its salts and esters		■		■	■	■		■				■		■	■	■	9
	Phenamiphos												■					1

PIC or POP	Chemical Name	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
	Phenothiol		■													■		2
	Phenylmercuric acetate (PMA)																	0
	Phorate		■					■								■		3
	Phosfolan		■															1
	Phosfolan-methyl			■														1
	Phosphamidon	■	■	■			■	■	■		■				■	■	■	10
	Phosphine									■			■					2
	Phosphorus (white & yellow)				■								■			■		3
	Pirimiphos-ethyl		■															1
	Polybrominated biphenyls (PBBs)															■		1
POP	Polychlorinated biphenyls (PCB)										■			■				2
	Polychlorinated triphenyls (PCTs)															■		1
	Polychlorocamphene		■					■										2
	Propaphos		■															1
	Propetamphos		■															1
	Prothoate		■															1
	Prothoate															■		1
	Pyrinuron (piriminil)															■		1
	Safrole															■		1
	Salmonella pesticides				■													1
	Schardan		■					■								■		3
	Scilliroside		■															1
	Selenium compound (Se)							■									■	2
	Silatrane			■					■									1
	Sodium Pentachlorophenate monohydrate								■								■	2
	Sodium compound		■															1
	Sodium chlorate		■		■			■								■		4
	Sodium fluoroacetate		■	■			■	■					■			■		6
	Strobane (tepene polychlorinated)		■							■						■		3
	Strychnine		■		■								■					3
	Sulfotep															■		1
	Sulfuric acid (Asam sulfur)				■													1
	Sulfuril floride				■													1
	Talinum compound		■					■					■		■	■	■	6
	Telodrin				■											■		2
	TEPP		■			■		■								■		4
	Terbufos		■	■														2
	Tetrachloroethane		■															1
	Tetramine			■														1
	Thiram						■											1
	Thiofanox		■															1
	Thiometon		■															1
	Thionazin		■															1
POP, PIC	Toxaphene				■	■	■	■	■	■	■	■	■	■		■	■	12
	Triamiphos		■															1
	Triazophos		■															1

PIC or POP	Chemical Name	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
	Tributyltin oxide (TBTO)		■				■		■									3
	Trichloronat		■															1
	Tris (2, 3-dibromopropyl) phosphate															■		1
	Vamidothion		▒															1
	Vinyl chloride monomer															■		1
	Zineb											■						1
	Zinc phosphide		▒	■	▒					▒							▒	5
Mixtures																		
	Na2SiF6 80% + ZnCl2 20%																▒	1
	Methylene bis thiocyanate 10% + 2-(thiocyanomethylthio) benzothiazole 10%																▒	1
	Methylene bis Thiocyanate 5% + Quaternary ammonium compounds 25%																▒	1
	Sodium Tetraborate decahydrate 54% + Boric acid 36%																▒	1
	CuSO4 50% + K2Cr2O7 50%																▒	1
Total	243	11	158	32	49	27	39	54	30	25	23	24	48	10	27	97	44	

■ = Banned ▒ = Restricted

Note: No ban or restriction does not imply that the chemical is registered in the country

List of banned and restricted
Rotterdam Convention pesticides

List of PIC pesticides	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
2, 4, 5-T and its salts and esters	■	■		■	■	■	■	■	■			■		■	■	■	12
Alachlor		▒				■											2
Aldicarb		■		■		■						▒		■			5
Aldrin		■	■	■	■	■	■	■	■	■		■	■	■	■	■	14
Binapacryl		■				■	■	■			■				■		6
Captafol		■		■	■	■	■	■	■		■			■	■	■	11
Chlordane	■	■		■	■	■	■	■	■	■		■	■	■	■	■	14
Chlordimeform		■	■	■		■	■	■	■		■	■		■	■	■	12
Chlorobenzilate						■	■	■			■	▒			■		6
DDT	■	■	■	■	■	■	■	■	▒	■	■	▒	■	■	■	■	16
Dieldrin	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	15
Dinoseb and its salts and esters		■		■		■	■	■	■						■		7
Dinitro-ortho-cresol (DNOC) and its salts		■				■	■	■							■		4
EDB				■		■	■	■	■			■			■		7
Endosulfan		■		■	■	■	■	■		■	■	▒		■	▒	■	12
Ethylene dichloride		■				■	■	■			■				■		5
Ethylene oxide		■				■	■	■							■		5
Fluoroacetamide		■	■			■	■	■							■		6
HCH/BHC (mixed isomers)	■	■		■		■	■	■	■	■	■	■		■	■	■	13
Heptachior	■	■		■	■	■	■	■		■	■	■	■	■	■	■	14
Hexachlorobenzene HCB		■	■		■	■	■			■	■	■	■		■	■	10
Lindane (gamma-HCH)		■		■	■	■	■	■		■		▒		■	■	■	11
Mercury compounds (Hg), fungicides		■	■	■	■	■	■	■	■	■	■	■		■	■	■	14
Monocrotophos	■	■	■			■	■	■	■	■	■	▒		▒	■	■	13
Parathion		■	■		■	■	■	■	■			■		■	■	■	11
Pentachlorophenol/PCP and its salts and esters		■		■	■	■		■		■	■	▒		■	■	■	9
Toxophene				■	■	■	■	■	■	■	■	■	■		■	■	12
27	7	24	9	17	14	27	21	25	14	12	12	19	7	16	25	17	0

■ = Banned ▒ = Restricted

Note: No ban or restriction does not imply that the chemical is registered in the country

List of banned and restricted
Stockholm Convention pesticides

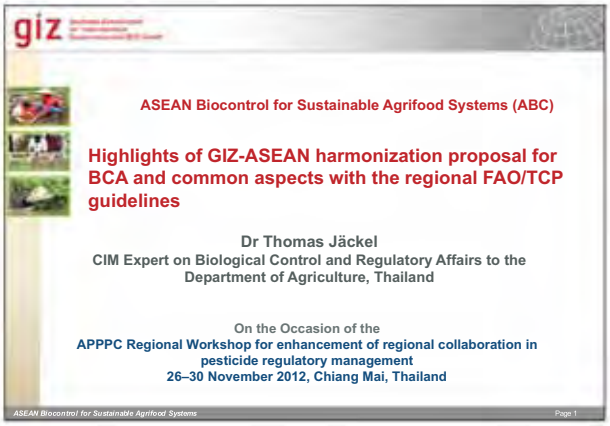
List of POP pesticides	Bangladesh	Cambodia	China	Indonesia	Japan	Korea, DPR	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Philippines	Singapore	Sri Lanka	Thailand	Viet Nam	No. Countries
Aldrin		■	■	■	■	■	■	■	■	■		■	■	■	■	■	14
Chlordane	■	■		■	■	■	■	■	■	■		■	■	■	■	■	14
Chlordecone		■		■	■					■					■		5
DDT	■	■	■	■	■	■	■	■	▒	■	■	▒	■	■	■	■	16
Dieldrin	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	15
Endosulfan		■		■	■	■	■	■		■	■	▒		■	▒	■	12
Endrin		■		■	■	■	■		■	■	■	■	■	■	■	■	13
α-HCH	■	■		■	■	■	■	■	■	■	■	■		■	■	■	14
β-HCH	■	■		■	■	■	■	■	■	■	■	■		■	■	■	14
Heptachlor	■	■		■	■	■	■	■		■	■	■	■	■	■	■	14
Hexachlorobenzene HCB		■	■		■	■		■		■		■	■		■	■	10
Lindane (gamma-HCH)		■		■	■	■	■	■		■		▒		■	■	■	11
Mirex		■		■	■	■				■		■	■		■		8
Pentachlorobenzene (PeCB)				■	■					■							3
Toxophene				■	■	■	■	■	■	■	■	■	■		■	■	12
15	6	13	4	14	15	13	11	11	8	15	7	13	9	10	14	12	

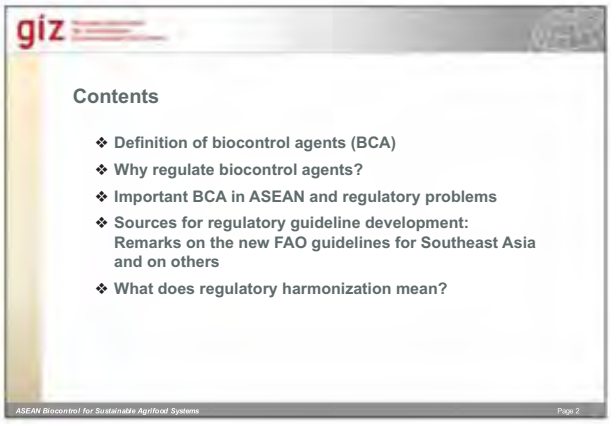
■ = Banned ▒ = Restricted

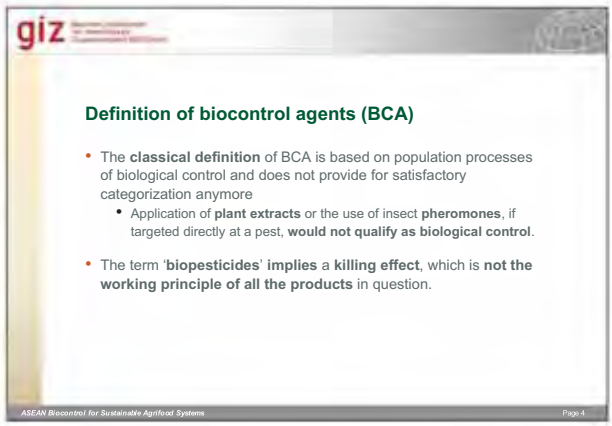
Note: No ban or restriction does not imply that the chemical is registered in the country

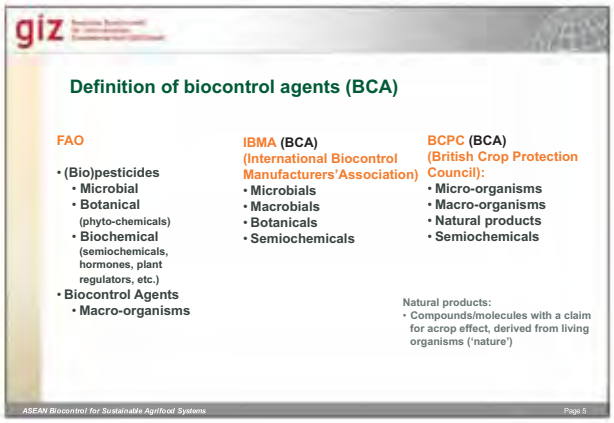
Highlights of GIZ-ASEAN harmonization proposal for BCA and common aspects with the regional FAO/TCP guidelines

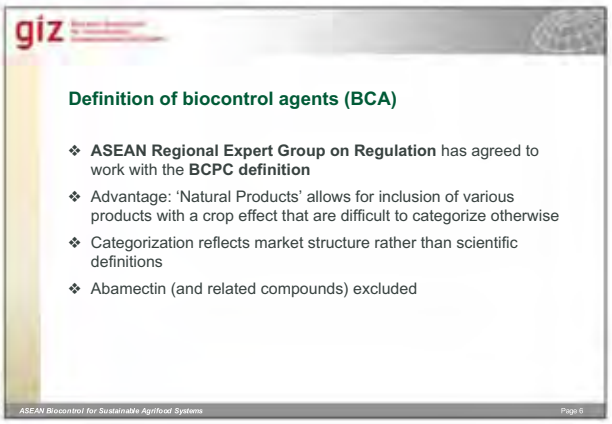
by Dr Thomas Jäckel











Why regulate biocontrol agents?

1. If product sold with intention to control pest, then effectiveness should be demonstrated
   - However, BCAs often lower (short-term) efficacy than synthetic chemistry
     - » Systems of pest control need to be developed to allow for this variation; in particular no direct comparison BCA vs. synthetics
     - » BCA more responding to environmental variation, therefore, level of pest control varies
     - » Users/customers have to be educated about this by companies

Why regulate biocontrol agents?

2. Regulatory authorities need to determine whether a BCA has the potential to cause negative effects to humans and the environment
   - However, most BCA **low or no risk active agents/ingredients**
   - Many **not based on toxic principle,** not hazardous substances
     - » **Adherence to 'toxic paradigm' can lead regulators to wrong conclusions**: E.g. US EPA regards any isolate of micro-organisms passaged through live hosts as new active ingredient, because in their opinion passage could trigger activation of new' toxin genes'
   - Macrobials, Semiochemicals: Would they need regulation at all?
   - Macrobials: environmental aspects relevant (exotic vs. native; how within-ASEAN trade?)

Current BCA all *low risk* to *no risk* products (EU, US)

- Non carcinogenic
- Non mutagenic
- Non toxic to reproduction
- Non sensitizing
- No growth > 34°C
- Genetically stable

BT	Long history of safe use – well documented (WHO)
Granulovirus	Biodegradable NPV accumulation (See specific paper OECD N° 20) Well documented safe use
Nematodes (EPN)	Background population in nature Long time experience with no problems Low risk for spreading (aggregation)
SCLP Pheromones	Short-chained lepidopteran pheromones, substantially reduced data requirements (OECD): Non-toxic, target specific, naturally occuring
Macrobials	No toxins produced No allergic reaction

Why regulate biocontrol agents?

3. Need to be able to characterize the BCA product
   - Regulators have to ensure that BCA companies are selling products that **contain the ingredients that are stated on the product label** and are free from harmful contaminants

Quality Control

(Company)

- Specifications
- No human pathogen/toxin
- Controlling production in a way that the desired components of a BCA are obtained in a **consistent quantity and quality**
- Ensuring that **virulence/ effectiveness is maintained constant** over production cycles
- Making sure that the **concentration of the a.i.** in the formulation varies within certain limits (of error) only.

Monitoring Regulatory Compliance

(Regulator)

- For registration: Analysis of samples to **verify claims** regarding the ingredients of a plant protection product
- Post-registration: check whether a.i. and formulation remain the same during permitted sales period (contamination, alterations of formulation, etc.)

Important BCA in ASEAN and regulatory problems

Importance (market size) of BCA in ASEAN and regulatory problems (according to ASEAN Biocontrol assessment)

BCA Category	Importance and regulatory problems
	Leading users of BCA in ASEAN: Indonesia, Thailand, Viet Nam
1. Microbials	• Most important group (*Bt.* market leader) • Significant taxonomic and analytical problems • Post-registration quality check needed
2. Botanicals	• Market size second to microbials in ASEAN (Neem most abundant product) • Significant analytical problems due to complex mixture of ingredients
3. Semiochemicals	• Use patchy (e.g. plantations), many not registered • No field testing protocols • Large future potential, pheromones could become useful and economic tools if requirements were relaxed
4. Macrobials	• Rarely produced and traded (by local companies); mainly used by government programmes • Most ASEAN countries do not regulate macrobials; import and release covered by international guidelines (e.g. FAO)

Sources for regulatory guideline development

Current Guidelines on biopesticides of FAO:

Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia

- Tremendous effort to harmonize overall pesticide regulation in the region
- Very useful (simplified) data requirements for **harmonized registration** of microbials, botanicals and semiochemicals (Attachment 2, pp. 159)
- Helpful instructions on analytical and testing procedures

Sources for regulatory guideline development

Current Guidelines on biopesticides of FAO:

Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia

- Points to consider with regard to BCA:
  - Definition: term 'biopesticides' should be discontinued
  - Formulation (finished product) versus active ingredient (technical grade) registration: Often two sets of data requirements (also OECD and others)
    - » To simplify, follow 'mosaic' approach for data requirements (e.g. FAO harmonized registration); one data set addressing formulation or a.i. where appropriate in a one-stop requirement list.

Sources for regulatory guideline development

Current Guidelines on biopesticides of FAO:

Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia

- Points to consider with regard to BCA:
  - Microbials (e.g. infectious organisms) Guidelines focus on toxicity/ pathogenicity testing;
    - » Better, 'infectivity' and 'host specificity' as the starting parameter for human and non-targed safety (infectious organisms that do not infect would not necessarily need a tox-study)
    - » Common skin-, inhalation-, injection-tox inappropriate for many microbials

Sources for regulatory guideline development

Current Guidelines on biopesticides of FAO:

Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia

- Points to consider with regard to BCA:
  - Microbials:
    - "***Undertaking should be submitted that strain is indigenous, naturally occurring, not exotic in origin***" (e.g. p. 204, entomotoxic bacteria)
    - » Statement problematic: Most products to date imported, originally non-native, exotic in origin.
    - » Useful BCAs exist **outside and within** a certain country
    - » Problematic with regard to trade. Within ASEAN?
    - » Clear guidelines needed!

Sources for regulatory guideline development

Current Guidelines on biopesticides of FAO:

Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia

- Points to consider with regard to BCA:
  - Microbials: Strain/biotype/isolate characterization Characterization recommendable, but principle/requirement of genetic '**uniformity**' and '**stability**' problematic. Which genes to look at?
    - » Mutation rates of traits related to mode of action? What is the exact mode of action and genes linked to it? Experts recommend to erase this point.
    - » A certain degree of **variability is necessary for effectiveness** of various BCA (e.g. baculoviruses, protozoan agents, fungi)

Sources for regulatory guideline development

In a nutshell: Special data recommended for improvement of regulatory management of BCA by expert panels (e.g. REBEKA 2007, OECD)

BCA Category	Points of Consideration
Microbials	▸ More emphasis on existing scientific information than on prescribed tests; non-target saf ety well documented ▸ Environmental fate and behaviour minor concern in risk assessment of regulatory authorities worldwide ▸ Genetic 'stability' problematic, erase
Macrobials	▸ Harmonize import and release of non-native species ▸ Harmonize environmental risk assessment (ERA)
Natural Products (here: Botanicals)	▸ Plant extracts complex mixtures, analytical methods should be focusing on active substances or substances of concern ▸ Waiving of data based on history of safe use
Semiochemicals	▸ Rationales for relaxation of data requirements available; exemption from registration could be considered ▸ Protocols for efficacy testing need to be adapted for semiochemicals (and for other BCA as well)

What does regulatory harmonization mean?

- ASEAN Biocontrol and Regional Expert Group on Regulation are focusing on the following areas:
  - Minimum data **requirements (sources: FAO, OECD, REBEKA etc.)**
  - **Proprietary (original)** versus supplemental (me-too) registration (see FAO, p. 240)
    - » Useful concept, but many questions arise
    - » How is data of applicant protected across various countries?
    - » Would that imply formation of a 'positive list' of proprietary active agents across the region? Monitoring by a regional body (expert group)?
    - » How to tell the difference between 'same' and 'similar' active ingredients/agents?
      - Strongly depends on analytical capabilities (and interpretation) of regulator: taxonomy, molecular typing, biochemical composition (botanicals? mix of a.i.)
      - Analytical capacity building needed

What does regulatory harmonization mean?

- ASEAN Biocontrol and Regional Expert Group on Regulation are focusing on the following areas:
  - Incorporating trade aspects (import, export) in regulatory management (role of quarantine, etc.)
  - Development of regional annotated database on BCAs
  - Post-registration monitoring (ensuring 'quality')
  - Field trial protocols for BCA

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