

## 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 to 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                                                              | <ol style="list-style-type: none"> <li>1. Sub-decree</li> <li>2. Proclamation</li> <li>3. Joint Proclamation</li> <li>4. Circular</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                      |      |      |      |      |
| Translation of the five guidelines on harmonized pesticide registration and put in the regulation | <ol style="list-style-type: none"> <li>1. Guidelines for harmonization of pesticide registration requirements</li> <li>2. Guidelines for data requirements for the registration of biopesticide</li> <li>3. Guidelines for the preparation of efficacy test protocols</li> <li>4. Guidelines for harmonization of pesticide labelling</li> <li>5. Guidelines for pesticide residue monitoring system</li> </ol>                                                                                                                                                                                   |      |      |      |      |
| Adaptation                                                                                        | <ul style="list-style-type: none"> <li>– Adopt guidelines for minimum requirement for chemical pesticide and biopesticide</li> <li>– Adopt the guideline for labelling in line the harmonized Guideline</li> <li>– Adopt the guideline for information exchange in line the harmonized Guideline</li> <li>– Adoption of the 29 new efficacy test protocol and 40 modified FAO bio-efficacy test protocol</li> <li>– Adoption of guideline for pesticide residue monitoring system</li> </ul>                                                                                                      |      |      |      |      |
| Training                                                                                          | <ol style="list-style-type: none"> <li>1. Capacity building for pesticide registration Provide Training on pesticides formulation analysis, toxicology, risk assessment ...</li> <li>2. Training of relevant personnel who are direct involved in the evaluation of pesticide label</li> <li>3. Capacity building and up-gradation of skill of the men who are conducting efficacy evaluation of pesticides</li> <li>4. Training on advance analytical techniques, multi residue analysis and method</li> <li>5. Capacity building for residue laboratory: equipment, working place...</li> </ol> |      |      |      |      |
| Strengthening and monitoring                                                                      | <ol style="list-style-type: none"> <li>1. Law enforcement activities</li> <li>2. Law extension activities to wholesales and retailer as well as farmers</li> <li>3. Strengthen awareness raising activities on proper pesticides usage application to wholesalers retailers and farmer</li> <li>4. Monitor strictly for pesticide smuggling</li> <li>5. Collaboration with other related in the region on pesticide management</li> </ol>                                                                                                                                                         |      |      |      |      |

## 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                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| <b>1. Legislation and regulations</b> <ul style="list-style-type: none"><li>• Amend the Regulation of pesticide management</li><li>• Renew the Guidelines on data requirements for pesticide registration</li><li>• Set up the Guidelines for pesticide retail licensing management</li><li>• Combine and renew the Guidelines for accreditation of testing institutions for pesticide registration</li></ul> | 2013<br>2013-2014<br>2013<br>2013 |
| <b>2. Registration Application</b> <ul style="list-style-type: none"><li>• Extend the online submission and monitoring for pesticide registration</li></ul>                                                                                                                                                                                                                                                   | 2013-2014                         |
| <b>3. Technical evaluation</b> <ul style="list-style-type: none"><li>• Designate the administrative department of agriculture on provincial level to take charge of advertisement assessment</li></ul>                                                                                                                                                                                                        | 2013                              |
| <b>4. Registration</b> <ul style="list-style-type: none"><li>• Cancel the temporary registration option</li><li>• Set up re-registration option</li></ul>                                                                                                                                                                                                                                                     | 2013-2014<br>Unscheduled          |
| <b>5. Post-registration activities</b> <ul style="list-style-type: none"><li>• Built up the licensing system for pesticide retailers</li><li>• Enable the English version of notifications related to pesticide management issued by Ministry of Agriculture</li><li>• Set up a system for pesticide package and waste recovery and incinerate treatment</li></ul>                                            | 2013<br>2015<br>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 |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------|------|------|------|------|
| <b>a. REVIEW MOA DECREE ON GUIDELINES AND REQUIREMENTS FOR PESTICIDE REGISTRATION</b>                           |                                                                                          |      |      |      |      |      |
| • 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)<br>Establish data protection frame work                  | compliance with WTO-TRIPS agreement                                                      |      |      |      |      |      |
| • Technical criteria<br>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>b. REVIEW MINISTER OF AGRICULTURE DECREE ON PESTICIDE MONITORING</b>                                         |                                                                                          |      |      |      |      |      |
| • 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 |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------|------|------|------|------|
| <b>a. Procedures</b>                 |                                                                                                                                                 |      |      |      |      |      |
| • 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>b. Minimum data requirements</b>  |                                                                                                                                                 |      |      |      |      |      |
| • 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 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|------|------|------|------|------|
| <ul style="list-style-type: none"> <li>Licensing<br/>According to new MOA decree implementation on harmonized pesticide regulations</li> </ul>              | Better and harmonized regulation                                              |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Bio-efficacy<br/>According to new MOA decree implementation on harmonized pesticide regulations</li> </ul>           | Better and harmonized regulation                                              |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Quality and residue monitoring<br/>Develop guideline for monitoring pesticide quality</li> </ul>                     | SOP for pesticide monitoring                                                  |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Enforcement regulation with requirement of international treaties</li> </ul>                                         | Better and harmonized regulation                                              |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Information exchange<br/>Harmonize the criteria</li> </ul>                                                           | Better and harmonized regulation                                              |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Publish “green book” (annually)<br/>Distribute the products information which already approved by the MOA</li> </ul> | Transparency and publish the list of products which valid and approved by MOA |      |      |      |      |      |

## 6. Harmonization

| Yardstick                                                                                                                                                                                      |                                                                                            | 2013 | 2014 | 2015 | 2016 | 2017 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|------|------|------|------|------|
| <ul style="list-style-type: none"> <li>Harmonize the pesticide regulation based on the latest FAO code of conduct (FAO guidelines)</li> </ul>                                                  | Identify what are the gaps of the current guidelines compared to the latest FAO guidelines |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Regional Harmonization<br/>Identify what are the requirements need to regional harmonization<br/>Establish Asian information exchange portal</li> </ul> | Better regulation and harmonized                                                           |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>International treaties</li> </ul>                                                                                                                       | Strengthen compliance to commitment to international treaties                              |      |      |      |      |      |
| <ul style="list-style-type: none"> <li>Information exchange</li> </ul>                                                                                                                         | 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 (macrobiotics)                                                                | 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     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>Legislation and regulations</b>                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| <ul style="list-style-type: none"> <li>changes in sector responsibilities</li> <li>legislation amendments</li> <li>in-country harmonization</li> </ul>                                                                                                                                         | <p>Set up committee for the Integrated Pesticide Management</p> <p>Detailed Rule for Enforcement Regulation based on Int. Code of Conduct, etc.</p> <ul style="list-style-type: none"> <li>registration, decision making set up,</li> <li>license Import/Export</li> <li>Labelling/Package/Advertise</li> </ul> <p>Training on revised Detailed Rule for Enforcement Regulation with requirement of Int. Treaties</p> | 2013-2014  |
| <b>Registration Application</b>                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| <p>a. Procedure</p> <ul style="list-style-type: none"> <li>written guidelines</li> <li>online application</li> </ul> <p>b. Minimum data requirements</p> <ul style="list-style-type: none"> <li>chemical</li> <li>biochemical</li> <li>microbial pest control agents</li> <li>other</li> </ul> | <p>Harmonization of data requirement for application based on intern. test protocols</p> <p>Renewal of local test protocol for main crops and pests</p> <p>National Network for Registration Application</p> <p>Particularly toxic and adverse effects to Environment</p>                                                                                                                                             | 2013– 2015 |
| <b>Technical evaluation</b>                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| <ul style="list-style-type: none"> <li>risk assessment,</li> <li>bio-efficacy,</li> <li>ecotoxicology</li> <li>quality</li> <li>residue</li> <li>hazard</li> <li>labelling</li> </ul>                                                                                                          | <p>Renewal guidelines for each assessment based on Int. Treaties</p>                                                                                                                                                                                                                                                                                                                                                  | 2013– 2015 |
| <b>Registration</b>                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| <ul style="list-style-type: none"> <li>registration options</li> <li>label</li> <li>validity period</li> <li>banned and restricted pesticides</li> </ul>                                                                                                                                       | <p>Review registration procedures on provisional, full, conditional, renewal and re-registration; labelling and validity period</p> <p>Update the list of Banned/Restricted pesticides in practice</p>                                                                                                                                                                                                                | 2013–2015  |
| <b>Post-registration activities</b>                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| <ul style="list-style-type: none"> <li>quality/residue monitoring</li> <li>information exchange</li> </ul>                                                                                                                                                                                     | <p>Monitoring quality control and adverse effects to human food and environment</p> <p>Establishment of Centre for Pesticide Information Integration and Sharing</p> <ul style="list-style-type: none"> <li>Capacity Building for monitoring Quality, Residue and Environment <ul style="list-style-type: none"> <li>Personnel</li> <li>Laboratory</li> </ul> </li> </ul>                                             | 2013–2018  |

| Category                                                                                                  | Activity                                                                                                                 | Period |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|--------|
| <b>Harmonization</b>                                                                                      |                                                                                                                          |        |
| <ul style="list-style-type: none"> <li>regional harmonization</li> <li>international, treaties</li> </ul> | Regional harmonization on quality, label, residue, risk and hazard<br>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

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Legislation and regulations, agencies, committees</b></p> <ul style="list-style-type: none"> <li>Disseminate pesticide regulation and overall of guideline for harmonization on data requirement of pesticide registration. <ul style="list-style-type: none"> <li>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.</li> </ul> </li> </ul> <p><b>Registration Application</b></p> <ul style="list-style-type: none"> <li>The Pesticide Registration Unit should revise the application form for plant protection product and submit to Director General for approval.</li> <li>Develop check list related data requirement on chemical, biochemical, microbial and botanical pest control agents.</li> </ul> <p><b>Technical evaluation</b></p> <ul style="list-style-type: none"> <li>The registrar should revise all documents of registered pesticide that provided by applicants based on harmonization guidelines.</li> <li>The DOA will organize training workshop on evaluation of pesticide inspection for 44 provincial staffs.</li> </ul> <p><b>Registration</b></p> <p>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.</p> <p>Registration pesticide should be also made attention on registration certificate from exported country and all related data.</p> <p><b>Post-registration activities</b></p> <p>DOA set up criteria for province in issuing license for importation pesticide.</p> <p>The registration unit will develop guideline for monitoring pesticide quality and provide to provinces.</p> <ul style="list-style-type: none"> <li>Build up infrastructure on pesticide formulation analysis</li> </ul> |
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|    | 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 |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------|------|------|------|------|------|
| <b>Legislation &amp; regulation</b>                                                                                              |                   |      |      |      |      |      |
| Amendments of Law to strengthen enforcement, to comply with government directives & to remove inconsistencies                    | 2013-2014<br>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         | /    | /    |      |      |      |
| <b>Registration Application</b>                                                                                                  |                   |      |      |      |      |      |
| 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              |      |      |      | /    |      |
| <b>Technical Evaluation – Training in assessment</b>                                                                             |                   |      |      |      |      |      |
| • Risk assessment BPCA                                                                                                           | 2016-2017         |      |      |      | /    | /    |
| • Bio-efficacy BPCA                                                                                                              | 2016-2017         |      |      |      | /    | /    |
| • Analysis of BPCA                                                                                                               | 2016-2017         |      |      |      | /    | /    |
| • Technical evaluation following Principle of Equivalence                                                                        | 2015-2016         |      |      | /    | /    |      |
| <b>Registration –</b>                                                                                                            |                   |      |      |      |      |      |
| Amend pesticide labelling requirements according to GHS if required                                                              | 2014              |      | /    |      |      |      |
| <b>Post-registration Activities</b>                                                                                              |                   |      |      |      |      |      |
| Improve Information exchange                                                                                                     | 2013              | /    |      |      |      |      |
| <b>Harmonization</b>                                                                                                             |                   |      |      |      |      |      |
| 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              |      |      |      |      | /    |
| <b>Other issues</b>                                                                                                              |                   |      |      |      |      |      |
| (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      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------|
| <b>Legislation and Regulation</b>                                                                                                                                                                                                                                   |                                                                                                                                                                                                     |                        |                  |
| <ul style="list-style-type: none"> <li>Legislation amendments</li> </ul>                                                                                                                                                                                            | Legislation amendments in line with pesticide harmonization requirements and parliament discussions                                                                                                 | 2013-                  | 2015             |
| <ul style="list-style-type: none"> <li>Changes in Pesticide Procedure relating to the current Law</li> </ul>                                                                                                                                                        | The related procedure in Law in line with new guidelines of harmonized on pesticide regulatory management                                                                                           | 2013-                  | 2015             |
| <ul style="list-style-type: none"> <li>Changes in pesticide definitions in details</li> </ul>                                                                                                                                                                       | According to the International Code of Conduct on the Distribution and Use of Pesticide latest version FAO (2010)                                                                                   | 2013-2014              |                  |
| <ul style="list-style-type: none"> <li>Changes decision making set up</li> </ul>                                                                                                                                                                                    | Reform the Pesticide Registration Board members                                                                                                                                                     | 2013-2014              |                  |
| <b>Registration Application</b>                                                                                                                                                                                                                                     |                                                                                                                                                                                                     |                        |                  |
| (a) Procedure                                                                                                                                                                                                                                                       |                                                                                                                                                                                                     |                        |                  |
| <ul style="list-style-type: none"> <li>Written guidelines <ul style="list-style-type: none"> <li>Labelling</li> <li>Bio-efficacy protocols</li> <li>Residue monitoring</li> <li>Registration requirements</li> <li>Biopesticide registration</li> </ul> </li> </ul> | Installation of new guidelines that based on harmonization of data requirements for application<br>Labelling requirements according to GHS.<br>Renewal of local test protocols                      | 2013-                  | 2015             |
| <ul style="list-style-type: none"> <li>Application form with instructions for applicants</li> </ul>                                                                                                                                                                 | Considering with Initial administrative actions/Issue of acknowledgement                                                                                                                            | 2013-2014              |                  |
| (b) Minimum data requirements                                                                                                                                                                                                                                       |                                                                                                                                                                                                     |                        |                  |
| <ul style="list-style-type: none"> <li>chemical pesticides</li> <li>botanical pesticides</li> <li>biochemical pesticides</li> <li>microbial pesticides</li> <li>others</li> </ul>                                                                                   | Fully regulate for chemical, botanical and biochemical pesticides with the harmonized data requirements in TCP<br>Need to identify and fully regulate for microbial pesticide and biocontrol agents | 2013-<br><br>2013-     | 2015<br><br>2017 |
| <b>Technical evaluation</b>                                                                                                                                                                                                                                         |                                                                                                                                                                                                     |                        |                  |
| <ul style="list-style-type: none"> <li>Labelling</li> <li>Bio-efficacy</li> <li>Ecotoxicology</li> <li>Residue</li> <li>Risk assessment</li> <li>Check list</li> </ul>                                                                                              | Make renewal & adopt the harmonized technical evaluation and analysis criteria<br>Adopt the check list for completeness of documents from this workshop                                             | 2013-<br><br>2013-2014 | 2015             |
| <b>Registration</b>                                                                                                                                                                                                                                                 |                                                                                                                                                                                                     |                        |                  |
| <ul style="list-style-type: none"> <li>Registration types</li> </ul>                                                                                                                                                                                                | According to new implementation on harmonized pesticide registration as supplementary registration                                                                                                  | 2013-                  | 2015             |
| <ul style="list-style-type: none"> <li>Validity period</li> </ul>                                                                                                                                                                                                   | Procedures to cancel or restrict a valid registration                                                                                                                                               | 2013-2014              |                  |
| <ul style="list-style-type: none"> <li>Label</li> </ul>                                                                                                                                                                                                             | Bilingual labels (English & national language)                                                                                                                                                      | 2013                   |                  |

| Proposed work plan                                                   | Activity                                                                                                                                                                             | 2-year plan | 5-year plan |
|----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|
| <b>Post-registration activities</b>                                  |                                                                                                                                                                                      |             |             |
| • 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<br>Publishing the list of Banned/Restricted pesticide in practice<br>Unscheduled reviews when new information becomes available | 2013-       | 2017        |
| <b>Harmonization</b>                                                 |                                                                                                                                                                                      |             |             |
| • Regional harmonization<br>• 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 |                     | <ul style="list-style-type: none"> <li>• The formation of New act will be completed which is in the process</li> <li>• Pesticide policy will also be completed which is in the process</li> </ul> | <ul style="list-style-type: none"> <li>• Stable government</li> <li>• Actors positive towards new act</li> </ul> | <ul style="list-style-type: none"> <li>• Regionally and internationally harmonized act &amp; policy instrument available</li> <li>• Efficient &amp; rational use of pesticide</li> <li>• Minimum risk to human health and environment</li> </ul> |

| 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 | <ul style="list-style-type: none"> <li>• Pesticide quality analysis</li> <li>• Residue monitoring on agri. product</li> <li>• Monitoring &amp; supervision (retailer, formulator, whole seller)</li> </ul> | <ul style="list-style-type: none"> <li>• Continuous</li> <li>• Pesticide Lab will be operationalized</li> </ul>                       | 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 seller)                                                                                 |      |      |      |      |      |
| 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 |
| <b>I. LEGISLATION AND REGULATIONS, AGENCIES, COMMITTEES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |             |             |
| • 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   |             |
| <b>II. PESTICIDES REGISTRATION APPLICATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |             |             |
| • 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 |
| <ul style="list-style-type: none"> <li>Amendment for acceptance of electronic files for registration and import permission of pesticides along with supporting documents and their online verification from concerned authorities.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                       |             | 2013–2016   |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                        |             | 2013–2016   |
| <ul style="list-style-type: none"> <li>Amendment for minimum data requirement for safe and highly used pesticides to incorporate them in Integrated Pest Management Plans.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 2013-2014   |             |
| <b>III. TECHNICAL EVALUATIONS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |             |             |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                    | 2013-2014   |             |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                                                                                                                                                                                                                                                     | 2013-2014   |             |
| <b>IV. PESTICIDES REGISTRATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |             |             |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                                                                                                                                                                                                                                                                        | 2012-2013   |             |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                                                                                                                                                | 2012-2013   |             |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                        | 2012-2013   |             |
| <ul style="list-style-type: none"> <li>Make Amendment for good labelling practice as per recent FAO and OECD countries guidelines.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 2013-2014   |             |
| <ul style="list-style-type: none"> <li>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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2013-2014   |             |
| <b>V. POST-REGISTRATION ACTIVITIES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |             |             |
| <ul style="list-style-type: none"> <li>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</li> </ul> |             | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |             |             |
| <ul style="list-style-type: none"> <li>• Make amendment for               <ul style="list-style-type: none"> <li>a) Specific guidelines for information sharing.</li> <li>b) Publication of data based list of registered pesticides regularly.</li> <li>c) Notifications of regular reports on observance of Code (Annex A).</li> <li>d) Final regulatory actions (Rotterdam), PIC procedure.</li> <li>e) MRL established in the country.</li> <li>f) Restricting Transport and marketing of pesticides along with consumer goods.</li> <li>g) Illegal trade of pesticides.</li> <li>h) Misleading advertisement.</li> <li>i) Monitoring and analysis of inert material, impurities of active ingredients, imported intermediates and precursors for pesticides manufacturing.</li> </ul> </li> </ul> |             | 2013–2015   |
| <b>VI. HARMONIZATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |             |             |
| <ul style="list-style-type: none"> <li>• 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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |             | 2013–2016   |
| <ul style="list-style-type: none"> <li>• Make amendment to ensure compliance of International Treaties like, Rotterdam Convention, Stockholm Convention, Basal Convention under guidelines of FAO, WHO, and OECD</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 2013-2014   |             |
| <ul style="list-style-type: none"> <li>• Make amendment for information exchange among regional countries, importing countries, OECD countries, etc.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 2013-2014   |             |
| <b>VII. OTHER ISSUES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |             |             |
| <ul style="list-style-type: none"> <li>• For transparency, guidelines/SOP for registration of pesticides, formulation plants, re-filling plants, all kinds of studies shall be made public online.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 2013-2014   |             |
| <ul style="list-style-type: none"> <li>• Public participation shall be enhanced by arranging seminars, workshops, walks, and trainings.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 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

| <b>Legislation and regulations, agencies, committees</b>                                                                                                         |                                                                                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>2-year plan</b>                                                                                                                                               | <b>5-year plan</b>                                                                                                                                                                                                                     |
| <ul style="list-style-type: none"> <li>• Draft guidelines on biopesticides for the review of technical advisory committee</li> </ul>                             | <ul style="list-style-type: none"> <li>• Issue a legislation and publish FAO harmonized guidelines on the registration of biopesticides &amp; biocontrol agents</li> </ul>                                                             |
| <ul style="list-style-type: none"> <li>• Adopt the latest definition of pesticides by FAO (2010) which include biocontrol agents</li> </ul>                      | <ul style="list-style-type: none"> <li>• Complete institutionalization and of harmonized pesticide guidelines that covers biopesticides</li> </ul>                                                                                     |
| <ul style="list-style-type: none"> <li>• Issue legislation on the harmonization of data requirements for different types of pesticides</li> </ul>                | <ul style="list-style-type: none"> <li>• Harmonize the pesticide regulation in the Philippines based on the latest 2010 FAO Code &amp; Conduct in the use and distribution of pesticides &amp; other related FAO guidelines</li> </ul> |
| <ul style="list-style-type: none"> <li>• Review and enhance qualifications and capability of the Pesticide Registration Committee</li> </ul>                     | <ul style="list-style-type: none"> <li>• Capability building for the members of Registration Committee and Pesticide Registration officers</li> </ul>                                                                                  |
| <ul style="list-style-type: none"> <li>• Capability Building for registration officer handling biocontrol agents/biopesticides</li> </ul>                        | Continue technical capability building                                                                                                                                                                                                 |
| <b>Registration Application</b>                                                                                                                                  |                                                                                                                                                                                                                                        |
| <b>a. Procedure</b>                                                                                                                                              |                                                                                                                                                                                                                                        |
| <b>2-year plan</b>                                                                                                                                               | <b>5-year plan</b>                                                                                                                                                                                                                     |
| 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>b. Minimum data requirements</b>                                                                                                                              |                                                                                                                                                                                                                                        |
| <b>2-year plan</b>                                                                                                                                               | <b>5-year plan</b>                                                                                                                                                                                                                     |
| 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**

| <b>2-year plan<br/>(2013-2014)</b>                                                                                 | <b>5-year plan<br/>(2013–2018)</b>                                          |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 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-efficacy evaluation criteria                |
| Identify what need to harmonize in the ecotoxicology evaluation criteria                                           | Adopt the harmonized ecotoxicology evaluation technical evaluation criteria |

**Registration**

| <b>2-year plan<br/>(2013-2014)</b>                                                                                                                              | <b>5-year plan<br/>(2013–2018)</b>                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| 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**

| <b>2-year plan<br/>(2013-2014)</b>                                                                                                                                                                                 | <b>5-year plan<br/>(2013–2018)</b>                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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**

| <b>2-year plan<br/>(2013-2014)</b>                                                                                                                                                                                                                                                                                                                                      | <b>5-year plan<br/>(2013–2018)</b>                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 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<br>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                                                                                                                                                                                                                                |
| <b>Administrative set up and infrastructure</b> | <p>Status quo</p> <p>Improved communication between agencies involved i.e. from import to registration</p> <p>Import is regulated by another government agency</p>                                                                    | Status quo                                                                                                                                                                                                                            |
| <b>Application for registration</b>             | <ul style="list-style-type: none"> <li>• Fast track approval for specific products</li> <li>• Minimum data requirements for specific products</li> </ul>                                                                              | <ul style="list-style-type: none"> <li>• Consider adoption of ASEAN data requirements for biological control agents</li> </ul>                                                                                                        |
| <b>Data review and registration decision</b>    | <ul style="list-style-type: none"> <li>• Strengthening technical evaluation by adopting guidelines applicable to SG's context.</li> <li>• Adoption of GHS for pesticide hazards evaluation &amp; labelling when available.</li> </ul> | <ul style="list-style-type: none"> <li>• Strengthening technical evaluation by adopting guidelines applicable to SG's context.</li> <li>• Adoption of GHS for pesticide hazards evaluation &amp; labelling when available.</li> </ul> |
| <b>Post-registration activities</b>             | <p>Phased in strengthening of post-registration activities:</p> <ul style="list-style-type: none"> <li>• Monitoring of farm usage</li> <li>• Collection of data – farm usage</li> </ul>                                               | 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<br>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                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>Legislation and regulations, agencies, committees</b> <ul style="list-style-type: none"> <li>legislation amendments</li> <li>in-country harmonization</li> </ul>             | <p>Amend data requirement for biocontrol agent to be minimum to facilitate more registration.</p> <p>Harmonized standard deviation of technical material and finished product labelling (adopt GHS).</p>                                                                                                                                                                 | <p>2013</p> <p>Currently</p>                              |
| <b>Registration Application</b> <p>a. Procedure</p> <ul style="list-style-type: none"> <li>written guidelines</li> <li>online monitoring</li> <li>online application</li> </ul> | <p>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).</p> <p>Results of quality control monitoring will be uploaded on DOA website</p> <p>Import and having in possession license shall be applied online</p> | <p>Currently</p> <p>2014</p> <p>2015</p>                  |
| <p>b. Minimum data requirements</p> <ul style="list-style-type: none"> <li>chemical,</li> <li>biochemical and</li> <li>microbial pest control agents</li> </ul>                 | <p>The minimum data requirement shall be finalized</p> <p>The minimum data requirement shall be finalized</p> <p>The minimum data requirement shall be finalized</p>                                                                                                                                                                                                     | <p>2015</p> <p>2015</p> <p>2015</p>                       |
| <b>Technical evaluation</b> <ul style="list-style-type: none"> <li>bio-efficacy</li> </ul>                                                                                      | <p>Develop bio-efficacy protocols for microbial and botanical control agent as well as pheromone</p>                                                                                                                                                                                                                                                                     | <p>2015</p>                                               |
| <b>Registration</b> <ul style="list-style-type: none"> <li>registration options</li> <li>label</li> <li>banned and restricted pesticides</li> </ul>                             | <p>Full registration experimental use permit</p> <p>Draft notification relating to label</p> <p>Adopt GHS</p> <p>Currently 96 pesticides banned</p> <p>Reviews registration of carbofuran, dicofos, EPN, methomyl. If the result of the review leads to ban, DOA will take action.</p>                                                                                   | <p>Currently</p> <p>2013</p> <p>2015</p> <p>2012-2013</p> |
| <b>Post-registration activities</b> <ul style="list-style-type: none"> <li>residue monitoring,</li> <li>information exchange</li> </ul>                                         | <p>TCP guideline adopted</p> <p>Information relating to pesticide will be uploaded</p>                                                                                                                                                                                                                                                                                   | <p>Currently</p> <p>2014</p>                              |
| <b>Harmonization</b> <ul style="list-style-type: none"> <li>regional harmonization</li> <li>International, treaties</li> <li>Information exchange</li> </ul>                    | <p>Harmonized TCP guideline shall be adopted</p> <p>Already complied with Rotterdam, Stockholm and Basel Conventions; Montreal protocol and FAO Code of Conduct.</p> <p>Recommendation for information exchange shall be adopted</p>                                                                                                                                     | <p>2015</p> <p>2015</p>                                   |
| <b>Other issues</b> <ul style="list-style-type: none"> <li>Public participation</li> </ul>                                                                                      | <p>Public hearing has to be done before issuing every rules and regulations</p>                                                                                                                                                                                                                                                                                          | <p>Currently</p>                                          |

## 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<br>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<br>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 increase 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.



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**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**

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# 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<br>No/NR = 0 | Y          | Y        | Y     | Y         | Y     | Y          | Y       | Y        | Y       | Y     | Y        | Y           | Y         | Y         | Y        | Y        |
| Pesticide Board                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Yes = 8<br>No/NR = 8  | Y          | N        |       | Y         | N     | Y          |         | Y        | Y       | Y     |          | Y           |           | N         | N        | Y        |
| Registration Committee                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Yes = 13<br>No/NR = 3 | Y          | Y        | Y     | Y         | N     | Y          | Y       | Y        | Y       | N     | Y        | Y           |           | Y         | Y        | Y        |
| Technical committee                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Yes = 15<br>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<br>Malaysia: Pesticide Advertisement Committee, Committee on Determination of National Pesticide MRLs, Pesticide Licensing Committee, Anti-Smuggling Committee (Illegal Pesticides), Pesticides Consultative Body<br>Nepal: Legal sub-committee and Obsolete Pesticide Disposal and Implementation Committee<br>Pakistan: Pesticides Advertisement Material Committee<br>Philippines: FPA Biotech Core Team (for Biotech based pesticides)<br>Sri Lanka: Agricultural Pesticides Sub-Committee; Public Health Pesticide Sub-Committee; Industrial Pesticides Sub-Committee<br>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<br>No/NR = 8  |            | Y        | N     | Y         | N*    | Y          |         | Y        |         | Y     |          | Y           |           | Y         | Y        |          |
| Forestry pesticides                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Yes = 12<br>No/NR = 4 |            | Y        | Y     | Y         | Y     | Y          |         | Y        | Y       | Y     |          | Y           |           | Y         | Y        | Y        |
| Fisheries pesticides                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Yes = 6<br>No/NR = 10 |            | Y        | N     | Y         | N*    | N          |         | Y        |         | Y     |          | Y           |           | N         | Y        |          |
| Public health pesticides                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Yes = 11<br>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<br>Japan: Livestock and fish drugs by Veterinary Ministry; Public Health by Ministry of Health, Labour and Welfare<br>Malaysia: Household, Pest Control Operator<br>Nepal: Household pesticides<br>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<br>Singapore: Regulated by the National Environment Agency (NEA)<br>Sri Lanka: Industrial Pesticides<br>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 |
|----------------------------------------------------------------------------------------|--------|------------|----------|-------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Signed/Ratified</b>                                                                 |        |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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        |
| <b>Fully/Partially Implemented</b>                                                     |        |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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<br>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<br>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        |
| <b>All 3 = 13</b>                                                                                | <b>Y =</b>            | <b>3</b>   | <b>2</b> | <b>3</b> | <b>1</b>  | <b>3</b> | <b>3</b>   | <b>3</b> | <b>3</b> | <b>1</b> | <b>3</b> | <b>3</b> | <b>3</b>    | <b>3</b>  | <b>3</b>  | <b>3</b> | <b>3</b> |
| * 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 <sup>1</sup> | 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 <sup>2</sup> | 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       | 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        | 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        | Y        |
| • residues                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Yes = 14 | Y          | Y        | 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       | Y        | N       | Y     | Y        | Y           | Y         | Y         | Y        | Y        |
| • public participation in regulatory process                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Yes = 13 | Y          | Y        | Y     | Y         | Y <sup>3</sup> | Y          | 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        | Y           | N         | Y         | Y        | Y        |
| • information sharing on pesticide regulatory matters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Yes = 13 | Y          | Y        | Y     | Y         | Y              | N          | Y       | 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:<br>*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.<br>*2 For pesticides designated as poisonous or deleterious substances.<br>*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.<br>Malaysia: only those pesticides considered as strategically hazardous<br>Singapore: by NEA<br>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                                                                                                                                                                                                                                                                                                                                                                               | <b>F = 16</b>                                   | F          | F        | F        | F         | F              | F          | F        | F        | F        | F        | F        | F           | F         | F         | F        | F        |
| • Botanical pesticides (Neem, Rotenone, Pyrethrin, Nicotine, etc.)                                                                                                                                                                                                                                                                                                                                  | <b>F = 12</b><br><b>P = 3</b><br><b>N = 1</b>   | P          | N        | F        | P         | F              | P          | F        | F        | F        | F        | F        | F           | F         | F         | F        | F        |
| • Biochemical pesticides (Semiochemicals, hormones, plant regulators, insect growth regulators, enzymes)                                                                                                                                                                                                                                                                                            | <b>F = 11</b><br><b>P = 4</b><br><b>N = 1</b>   | 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)                                                                                                                                                                                                                                      | <b>F = 10</b><br><b>P = 5</b><br><b>N = 1</b>   | 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)                                                                                                                                                                                                                                                                                                                    | <b>F = 5</b><br><b>P = 2</b><br><b>N/NR = 9</b> | P          | N        | F        | N         | N              | N          | N        | F        | P        | N        | N        | F           | F         | N         | N        | F        |
| • Biocontrol agents                                                                                                                                                                                                                                                                                                                                                                                 | <b>F = 5</b><br><b>P = 7</b><br><b>N = 4</b>    | P          | P        | F        | N         | P <sup>1</sup> | P          | N        | P        | P        | F        | N        | F           | F         | P         | N        | F        |
| • Non-pesticide active ingredients in formulations                                                                                                                                                                                                                                                                                                                                                  | <b>F = 4</b><br><b>P = 5</b><br><b>N/NR = 7</b> | F          | N        |          | N         | P <sup>2</sup> | P          | N        | P        | N        | N        | P        | F           | N         | P         | F        | F        |
| • Other substances such as defoliant, desiccants, agents for setting or thinning of fruits, or substances to protect commodities from deterioration during storage and transport                                                                                                                                                                                                                    | <b>F = 4</b><br><b>P = 5</b><br><b>N/NR = 7</b> | P          | N        | P        | N         | F              | P          | N        | P        | N        | N        | N        | F           | P*        | N         | F        | F        |
|                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Fully =</b>                                  | <b>2</b>   | <b>3</b> | <b>6</b> | <b>1</b>  | <b>5</b>       | <b>2</b>   | <b>3</b> | <b>4</b> | <b>3</b> | <b>4</b> | <b>4</b> | <b>8</b>    | <b>6</b>  | <b>2</b>  | <b>6</b> | <b>8</b> |
| Japan:<br>*1 Indigenous natural enemies can be sold and used for pest management without registration.<br>*2 Acute effects of adjuvants and other non-active ingredients are assessed through acute toxicity tests of pesticide formulations.<br>Singapore: * only for defoliant & desiccants defined as pesticide under the Act.<br>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 (macro-bials) are regulated in more than 2/3 of the countries (fully or partially).

### Conclusions

- Even though all countries regulate agricultural pesticides, they 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. <i>Guidelines on the registration of biological pest control agents</i>                                               | Fully = 4<br>Part. = 5<br>?/NR = 7  | F          | F        | P     | F         |       | P          | P       |          | -       | P     |          | F           | -         | ?         | -        | P        |
| FAO 1989. <i>Guidelines for legislation on the control of pesticides</i>                                                        | Fully = 8<br>Part. = 6<br>?/NR = 2  | F          | F        | P     | F         |       | P          | F       | P        | P       | P     | F        | F           | -         | F         | F        | P        |
| FAO 1991. <i>Initial introduction and subsequent development of a simple national pesticide registration and control scheme</i> | Fully = 5<br>Part. = 4<br>?/NR = 7  | F          | F        | P     | F         |       | ?          | ?       |          | P       | F     | P        |             | -         | F         | -        | P        |
| FAO 1995. <i>Guidelines on good labelling practice for pesticides</i>                                                           | Fully = 10<br>Part. = 5<br>NR = 1   | F          | F        | P     | F         |       | P          | F       | P        | F       | P     | P        | F           | F         | F         | F        | F        |
| FAO 2002. <i>International Code of Conduct on the Distribution and Use of Pesticides (revised edition)</i>                      | Fully = 9<br>Part. = 2<br>?/NR = 5  | F          | F        | P     | F         |       | F          | F       |          | F       | P     | F        | ?           |           | F         | F        |          |
| UN 2005. <i>The Globally harmonized system of classification and labelling of chemicals (GHS)</i>                               | Fully = 5<br>Part. = 5<br>?/NR = 6  | F          | F        | P     | F         | P     | P          | P       |          | F       | ?     | ?        | ?           |           | F         | -        | P        |
| OECD 2005. <i>Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances</i>               | Fully = 3<br>Part. = 3<br>?/NR = 10 | F          | F        | P     | P         | P     | ?          | ?       |          | -       | ?     | ?        | ?           |           | F         | -        | ?        |
| FAO 2006. <i>Guidelines on efficacy evaluation of plant protection products</i>                                                 | Fully = 6<br>Part. = 7<br>?/NR = 3  | F          | F        | P     | P         |       | F          | P       | P        | P       | P     | F        | ?           |           | F         | F        | P        |
| FAO 2006. <i>Guidelines on monitoring and observance of the Code of Conduct</i>                                                 | Fully = 6<br>Part. = 5<br>?/NR = 5  | F          | F        | P     | P         |       | F          | F       | P        | P       | ?     | F        | ?           |           | F         | -        | P        |
| OECD 2008. <i>Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances</i>             | Fully = 2<br>Part. = 5<br>?/NR = 9  | F          | F        | P     | P         | P     | P          | ?       |          | -       | ?     | ?        | ?           |           | P         | -        | ?        |
| WHO 2009. <i>The WHO recommended classification of pesticides by hazard and guidelines to classification</i>                    | Fully = 10<br>Part. = 4<br>?/NR = 2 | F          | F        | P     | F         |       | P          | P       | P        | F       | F     | F        | ?           | F         | F         | F        | F        |
| FAO 2006. <i>Guidelines on compliance and enforcement of a pesticide regulatory programme</i>                                   | Fully = 5<br>Part. = 6<br>?/NR = 5  | F          | F        | P     | P         |       | P          | F       | P        | P       | F     |          | ?           |           | F         | -        | P        |
| FAO/WHO 2010. <i>Guidelines for the Registration of Pesticides</i>                                                              | Fully = 5<br>Part. = 5<br>?/NR = 6  | F          | F        | P     | P         |       | P          | ?       | P        | P       | F     | F        | ?           |           | F         | -        | ?        |
| FAO 2010. <i>Guidance on Pest and Pesticide Management Policy Development</i>                                                   | Fully = 3<br>Part. = 5<br>?/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 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|------------|-----------|-----------|-----------|-----------|------------|----------|----------|----------|----------|----------|-------------|-----------|-----------|----------|----------|
|                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Fully =</b>      | <b>14</b>  | <b>14</b> |           | <b>7</b>  |           | <b>3</b>   | <b>5</b> |          | <b>4</b> | <b>4</b> | <b>6</b> | <b>3</b>    | <b>2</b>  | <b>12</b> | <b>5</b> | <b>2</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Partially =</b>  |            |           | <b>14</b> | <b>6</b>  | <b>3</b>  | <b>8</b>   | <b>5</b> | <b>8</b> | <b>7</b> | <b>6</b> | <b>2</b> |             |           | <b>1</b>  |          | <b>7</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Don't know =</b> |            |           |           | <b>1</b>  | <b>11</b> | <b>3</b>   | <b>4</b> | <b>6</b> | <b>3</b> | <b>4</b> | <b>6</b> | <b>11</b>   | <b>12</b> | <b>1</b>  | <b>9</b> | <b>5</b> |
| Japan: The establishment of our national legislation predated the publication of the documents unchecked above.<br>Philippines: The latest Philippine Guidelines on Pesticide Regulation was updated in year 2001 and all guidelines issued by<br>FAO, WHO and EPA were used as reference in crafting the aforesaid guidelines. The said guideline served as the<br>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<br>P = 1<br>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<br>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<br>P = 1<br>M = 2 | F          | F        | F     | F         | F     | P          | M       | F        | F       | M     | F        | F           | F         | F         | F        | F        |
| • Technical and scientific evaluation                                                                            | F = 14<br>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<br>P = 5<br>M = 3  | F          | F        | F     | P         | F     | P          | M       | F        | M       | M     | P        | F           | F         | F         | F        | P        |
| • Preparation of summaries and conclusions                                                                       | F = 12<br>P = 1<br>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<br>P = 3<br>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 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|------------|----------|-------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Active Substance</b>                                                                                                                                                                                                                                                                                  |           |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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        |          |
| <b>Finished Product</b>                                                                                                                                                                                                                                                                                  |           |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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<br>Sri Lanka: Export only<br>Thailand: – Exception from registration is applied to pesticide used as analytical standard in laboratory.<br>No exception for permit.<br>– 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:                                                                                                                                                                                                                                                                                                                                                              |          |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| <ul style="list-style-type: none"> <li>Botanical, Biochemical, microbial and biocontrol agents are classified under Biorational pesticides with the same registration procedures and data requirements.</li> <li>Biotech based pesticide e.g. Plant-Incorporated-Protectant (PIP) is separately regulated under DA Administrative Order No. 8, series of 2002.</li> </ul> |          |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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<br>High = ∞ |            | 8        | 6     | 5         | 15    | 5          | 2       | 8        | *       |       |          | 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<br>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<br>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                           |         |  | Bangladesh | Cambodia | China | Indonesia | Japan | Korea, DPR | Lao PDR | Malaysia | Myanmar | Nepal | Pakistan | Philippines | Singapore | Sri Lanka | Thailand | Viet Nam |
|----------------------------------------------------|---------|--|------------|----------|-------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| Folder                                             |         |  |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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<br><br>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<br>Folder               |               | Bangladesh | Cambodia | China | Indonesia | Japan | Korea, DPR | Lao PDR  | Malaysia | Myanmar  | Nepal | Pakistan | Philippines | Singapore | Sri Lanka | Thailand | Viet Nam |
|----------------------------------------------------|---------------|------------|----------|-------|-----------|-------|------------|----------|----------|----------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Chemical Pest Control Products</b>              |               |            |          |       |           |       |            |          |          |          |       |          |             |           |           |          |          |
| 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           |           |           |          |          |
|                                                    | <b>Total:</b> |            |          |       | <b>7</b>  |       | <b>6</b>   | <b>7</b> |          | <b>4</b> |       | <b>1</b> | <b>7</b>    |           |           |          | <b>6</b> |
| <b>Botanical Pest Control Products</b>             |               |            |          |       |           |       |            |          |          |          |       |          |             |           |           |          |          |
| 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           |           |           |          |          |
|                                                    | <b>Total:</b> |            |          |       | <b>6</b>  |       | <b>4</b>   | <b>7</b> |          | <b>3</b> |       | <b>1</b> | <b>7</b>    |           |           |          | <b>6</b> |
| <b>Biochemical Pest Control Products</b>           |               |            |          |       |           |       |            |          |          |          |       |          |             |           |           |          |          |
| 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           |           |           |          |          |
|                                                    | <b>Total:</b> |            |          |       | <b>6</b>  |       | <b>6</b>   | <b>7</b> |          | <b>3</b> |       |          | <b>7</b>    |           |           |          | <b>6</b> |
| <b>Microbial Pest Control Products</b>             |               |            |          |       |           |       |            |          |          |          |       |          |             |           |           |          |          |
| 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           |           |           |          |          |
|                                                    | <b>Total:</b> |            |          |       | <b>6</b>  |       | <b>5</b>   | <b>7</b> |          | <b>3</b> |       |          | <b>7</b>    |           |           |          | <b>6</b> |

### 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<br>Folder                                                                                                                                                                                     |         | Bangladesh | Cambodia | China | Indonesia | Japan | Korea, DPR | Lao PDR | Malaysia | Myanmar | Nepal | Pakistan | Philippines | Singapore | Sri Lanka | Thailand | Viet Nam |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|----------|-------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Chemical Pest Control Products</b>                                                                                                                                                                         |         |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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           |           |           |          |          |
| <b>Total:</b>                                                                                                                                                                                                 |         |            |          |       | 7         |       | 6          | 7       | 2        | 3       |       |          | 7           |           | 6         | 6        | 1        |
| <b>Botanical Pest Control Products</b>                                                                                                                                                                        |         |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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           |           |           |          |          |
| <b>Total:</b>                                                                                                                                                                                                 |         |            |          |       | 6         |       | 4          | 7       | 2        | 3       |       |          | 7           |           | 6         | 6        | 1        |
| <b>Biochemical Pest Control Products</b>                                                                                                                                                                      |         |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| A. Identity and properties                                                                                                                                                                                    | Yes = 7 |            |          |       | Y         |       |            | Y       | Y        | Y       |       |          | Y           |           | Y         | Y        |          |
| B. Toxicology data                                                                                                                                                                                            | Yes = 6 |            |          |       | Y         | /     | Y          | Y       | *        | Y       |       |          | Y           |           | Y         | Y        |          |
| C. Bio-efficacy data                                                                                                                                                                                          | Yes = 5 |            |          |       | Y         | /     | Y          | Y       | *        |         |       |          | Y           |           | Y         | Y        |          |
| D. Residue data                                                                                                                                                                                               | Yes = 5 |            |          |       | Y         | /     | Y          | Y       | *        |         |       |          | Y           |           | Y         | Y        |          |
| E. Human health/Environmental fate and effect data                                                                                                                                                            | Yes = 4 |            |          |       |           | /     | 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           |           |           |          |          |
| <b>Total:</b>                                                                                                                                                                                                 |         |            |          |       | 6         |       | 6          | 7       | 2        | 3       |       |          | 7           |           | 6         | 2        | 1        |
| <b>Microbial Pest Control Products</b>                                                                                                                                                                        |         |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| 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       |          |         |       |          |             |           |           |          |          |
| <b>Total:</b>                                                                                                                                                                                                 |         |            |          |       | 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 |
|------------------------------------------------------|----------------------------|------------|----------|-------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Provisional Registration</b>                      |                            |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Same as regular registration                         | Yes = 6<br>N = 3<br>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<br>N = 5<br>NA = 7 | NA         | N        | N     | N         | NA    | N          | Y       | NA       | N       | Y     | NA       | Y           | NA        | Y         | NA       | NA       |
| <b>Regular Registration</b>                          |                            |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Same requirements for different pest control agents? | Yes = 8<br>N = 8           | Y          | N        | N     | N         | N     | N          | Y       | Y        | N       | Y     | N        | Y           | Y         | Y         | N        | Y        |
| <b>Supplementary Registration</b>                    |                            |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Same as regular registration                         | Yes = 4<br>N = 2<br>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<br>N = 3<br>NA = 9 | Y          | NA       | NA    | N         | NA    | N          | Y       | NA       | N       | NA    | NA       | Y           | NA        | NA        | NA       | Y        |
| <b>Re-registration Registration</b>                  |                            |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Same as regular registration                         | Yes = 6<br>N = 4<br>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<br>N = 3<br>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<br>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<br>No = 5<br>NR = 2 | Y          | N        | N     | Y         | N <sup>1</sup> |            | Y       | Y        | Y       | N     | Y        | Y           | Y         | Y         | N        |          |
| Do you accept evaluation reports (monographs) in the OECD format?                                                                                                                                                                                                           | Yes = 9<br>No = 6<br>NR = 1 | Y          | N        | N     | Y         | N <sup>1</sup> |            | Y       | Y        | Y       | N     | Y        | Y           | Y         | Y         | N        | N        |
| Do you verify analytical methods/test protocols?                                                                                                                                                                                                                            | Yes = 14<br>No = 2          | Y          | Y        | Y     | Y         | Y              | 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<br>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<br>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<br>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.<br>Japan: *1 We will start accepting submissions in OECD format next year.<br>*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<br>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<br>No = 4<br>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<br>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<br>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<br>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<br>hi = >100         | ✓          | 1        |       | 1         | 1     |            | 3       |          | 26      | NA    | *        |             | -         | >2        | 100      |          |
| Number of field trials required for major pests on major crops                                                         | low = 1<br>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<br>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<br>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<br>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<br>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<br>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<br>No = 4 | Y          | Y        | Y     | Y         | Y              | Y          | N       | Y        | N       | N     | N        | Y           | Y <sup>1</sup> | Y         | Y        | Y        |
| Do you require residue data to be generated in accordance with <i>Codex Alimentarius</i> ?                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Yes = 15<br>No = 1 | Y          | Y        | Y     | Y         | N <sup>1</sup> | Y          | Y       | Y        | Y       | Y     | Y        | Y           | Y <sup>2</sup> | 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<br>No = 2 | Y          | Y        | Y     | N         | Y <sup>2</sup> | Y          | Y       | Y        | Y       | Y     | Y        | Y           | Y              | Y         | Y        | N        |
| Do you require residue trials to be conducted in your country?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Yes = 8<br>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<br>No = 3 | Y          | Y        | N     | Y         | N <sup>3</sup> | Y          | Y       | Y        | Y       | Y     | N        | Y           | Y              | Y         | Y        | Y        |
| Do you use maximum residue limits defined by the <i>Codex Alimentarius</i> 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.<br>*2 Minimum number of residue trials for major crops will be increased from 2 to 6 from 2014.<br>*3 We accept data on indoor trials conducted in other countries.<br>Singapore: /1 Mostly following OECD<br>/2 Yes for setting national MRL; no for setting import tolerance<br>Thailand: Residue data generated in other countries is accepted provided that application dose rate different not exceed 25%<br>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<br>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<br>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<br>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<br>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<br>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<br>N/NR = 8 | Y          | Y        | Y     | N         | Y     | Y          | N       | N        |         | N     | N        | Y           | N         | N         | Y        | Y        |
| consumer risks?                                                                                                                | Yes = 10<br>No = 6  | Y          | Y        | Y     | Y*        | Y     | Y          | N       | Y        | Y       | N     | N        | N           | N         | N         | Y        | Y        |
| environmental risks?                                                                                                           | Yes = 8<br>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<br>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<br>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 <i>Revised guidelines on environmental criteria for the registration of pesticides</i> (1989) | Yes = 12<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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        |
| <b>Remarks:</b><br>Malaysia: Technical evaluations/analysis are carried out based on expert opinion.<br>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<br>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<br>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<br>No = 9<br>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<br>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<br>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<br>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 statutory 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     | AB<br>O    | A       | AB       | B       | A     | A        | A           | A*        | A         | HS       | A        |
| Sale and retail licenses                                                                                                                                                                                                                                                                                                                                                                         |  | A          | O        |       |           | O*    | AB<br>O    | A       | B        | O       | A     | O        | A           | A*        | A         | HS       | A        |
| Licensing of commercial pesticide applicators                                                                                                                                                                                                                                                                                                                                                    |  | A          | O        |       |           | /     | AB<br>O    | A       | B        | B       | A     |          | A           | A         | A         | HS       | A        |
| Cambodia: MAFF<br>Japan: *Distributors of pesticides shall notify their place of business to respective prefectural governments.<br>Pakistan: Provincial Govt.<br>Philippines: *Region<br>Singapore: For chemicals by NEA<br>Thailand: R = Registration Sub-committee; HS = Hazardous Substances Regulatory group<br>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<br>hi = 5  | -          | 1        | 1     | 1         | /     | 1          | -       |          | 5       |       | 1+       | 1           | NA        | 1         | -        |          |
| Full registration                                                                             | low = 2<br>hi = 10 | 2          | 3        | 5     | 5         | 3     | 4-5        | 2       | 5        | 10      | 5     | 3        | 3           | ∞*        | 3         | 6        | 5        |
| Conditional registration with restrictions                                                    | low = 1<br>hi = 5  | -          | 1        |       | -         | /     | 1          | -       |          | 2       | 1     | *        | 1           | NA        | 1         | -        | 5        |
| Renewal or re-registration                                                                    | low = 2<br>hi = 6  | 3          | 3        | 1/5   | 5         | 3     | 4-5        | 2       | 5        | 5       | 5     | 3        | 3           | NA        | 3         | 6        | 5        |
| * Pakistan: No period defined<br>* 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 |
|----------------------------------------------------------|-------------------------|------------|----------|--------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Active Substances</b>                                 |                         |            |          |        |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Number or registered chemical pesticides                 | low = 73<br>hi = 2 950  | 2 950      |          | 580    |           | 470   |            |         | 449      | 201     | 92    | 236      |             | -         | 141       | 93       |          |
| Number or registered botanical pesticides                | low = 0<br>hi = 15      | -          |          | 15     |           |       |            |         | 3        |         | 1     | -        |             | -         | 1         | -        |          |
| Number or registered biochemical pesticides              | low = 0<br>hi = 20      | -          |          | 20     |           | 33    |            |         |          |         |       | 1        |             | -         |           | -        |          |
| Number or registered microbial pesticides                | low = 2<br>hi = 13      | -          |          | 13     |           | 40    |            |         | 1        |         | 5     | -        | 5           | -         | 1         | -        |          |
| <b>Formulated Products</b>                               |                         |            |          |        |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Number or registered chemical pesticides                 | low = 73<br>hi = 20 000 | 9          | 1 532    | 20 000 | 2 628     |       |            | 73      | 2 477    | 1 517   | 833   | 6 218    | 1 176       | 301       | ~800      | 1 943    |          |
| Number or registered botanical pesticides                | low = 0<br>hi = 150     | -          | 0        | 150    | 66        | 4 358 |            | 0       | 6        | 4       | 10    | 1        | 2           | 3         | 1         | 2        |          |
| Number or registered biochemical pesticides              | low = 0<br>hi = 300     | -          | 0        | 300    |           |       |            | 0       |          | 60      | x     | 1        |             | 0         |           | -        |          |
| Number or registered microbial pesticides                | low = 0<br>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<br>hi = 54   | 12         | 42       | 26    |           | 7     |            | 46      | 3        | 10      | 5     | 26       | 28          | -         | 4         | 6        | 29       |
| Number of banned/restricted Persistent Organic Pollutants (POPs)          | low = 0<br>hi = 15   | 9          | 12       | 8     | 42        | 15    | 8          | 9       | 9        | 9       | 9     | 9        | 9           | -         | all       | 12       | 0        |
| Number of other banned/restricted pesticides                              | low = 0<br>hi = 116  | CC<br>A    | 116      | 26    |           | 6     | 32         | 0       | 19       | 7       |       |          | 19          | -         | 1         | 84       | 0        |
| Total                                                                     | low = 14<br>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<br>hi = 2 639   | 150        | 52       |       |           | 16    |            | 8       | 2 639    | 583     | ~60    | 136      | 318         |           |           | 848      |          |
| • manufacture of pesticides                                                  | low = 0<br>hi = 4 342   | -          | 0        |       |           | 4 342 |            | 0       |          | 0       | 5      | 1        | 120         |           |           | 893      |          |
| • sale and retail shops                                                      | low = 14<br>hi = 50 000 | ~50 000    | 14       |       |           | NA    |            | 15      | 5 000    | 2 684   | ~4 000 |          | 118         |           | 3 000     | 311      |          |
| • commercial pesticide applicators                                           | low = 1<br>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<br>P = 1<br>M = 3 | F          | P        | F     | F         | F     | F          | M       | F        | F       | M     |          | M           | F         | F         | F        | F        |
| Post-registration monitoring of quality of pesticides                                  | F = 8<br>P = 4<br>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<br>P = 5<br>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<br>P = 8<br>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<br>P = 6<br>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<br>P = 2<br>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<br>P = 2<br>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<br>P = 3<br>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<br>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<br>No = 5<br>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<br>No = 3<br>NR = 2 | Y          | Y        | Y     | Y         | Y     |            | N       | N        | Y       | Y     | N        | Y           | Y         | Y         | Y        |          |
| • regional level                                                                                 | Yes = 9<br>No = 4<br>NR = 3  | Y          | Y        | Y     | Y         | Y     |            | N       | N        | Y       | Y     | N        | Y           |           | Y         | N        |          |
| • community level                                                                                | Yes = 9<br>No = 4<br>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<br>No = 6<br>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<br>No = 6<br>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<br>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<br>No = 1<br>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<br>No = 3<br>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<br>No = 5<br>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<br>No = 4<br>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<br>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<br>No = 5<br>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 of 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<br>*1 |            |         |          |         | X     |          | -           | -         |           | 3<br>*1  |          |
| Number of ad-hoc reports on observance of Code (Annex B)                                                                                                                                                                                                          | Yes = 1 | -          |          |       |           | >1<br>*1 |            |         |          |         | X     |          | -           | -         |           | -        |          |
| Notifications of final regulatory actions (Rotterdam)                                                                                                                                                                                                             | Yes = 4 | -          |          |       |           | 67<br>*2 | 30         |         |          |         | 1     |          | -           | -         |           | 96       |          |
| Notifications of PIC procedures (Rotterdam)                                                                                                                                                                                                                       | Yes = 5 | -          |          |       |           | 43       |            |         | 3        | 1       | 1     |          | -           | -         |           | 47<br>*2 |          |
| Notifications of MRLs established by the country                                                                                                                                                                                                                  | Yes = 2 | -          |          |       |           | NA<br>*3 | 0          |         |          |         | X     |          | -           | 0         |           | 50       |          |
| Count =                                                                                                                                                                                                                                                           |         |            |          |       |           | 4        | 1          |         | 1        | 1       | 2     |          |             |           |           | 4        |          |
| * Japan:   *1 In 2009<br>*2 Including 35 final regulatory actions on pesticide regulation<br>*3 Notifications are regularly made, but no statistics available<br>Thailand: *1 In 2008, 2010 and 2011<br>*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<br>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<br>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<br>No = 1<br>NR = 1 | Y          |          | Y     | N         | Y     | Y          | Y       | Y        | Y       | Y     | Y        | Y           | Y*        | Y         | Y        | Y        |
| • illegal trade in pesticides                                                                                        | Yes = 14<br>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<br>No = 4           | Y          | Y        | Y     | N         | N     | Y          | Y       | Y        | N       | Y     | N        | Y           | Y         | Y         | Y        | Y        |
| • misleading advertisement                                                                                           | Yes = 12<br>No = 3<br>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<br>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<br>No = 5   | Y          | N        | Y     | N         | Y <sup>1</sup> | Y          | N       | N        | Y       | Y     | Y        | Y           | N         | Y         | Y        | Y        |
| Do you monitor imported intermediates and precursors for pesticide manufacture?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Yes = 6<br>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<br>No = 4   | Y          | N        | Y     | N         | Y <sup>2</sup> | 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:<br>*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.).<br>*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<br>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<br>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<br>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 countries 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<br>Plant Protection Wing, DAE |
| Address                                               |                                        |
| Contact person                                        | Name:<br>Title:<br>E-mail:             |

#### Cambodia

|                                                       |                                                                                                                                                       |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of national authority for pesticide registration | Department of Agricultural Legislation (DAL).                                                                                                         |
| Address                                               | Ministry of Agricultural, Forestry and Fisheries (MAFF)<br>No. 200, Preah Norodom Bld., Sangkat Tonle Basak, Khan<br>Chamkarmon, Phnom Penh, Cambodia |
| Contact person                                        | Name: Mr Ouk Syphan<br>Title: Director General of DAL.<br>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<br>Title:<br>E-mail: pmd@agri.gov.cn |

**Indonesia**

|                                                       |                                                                                                                                     |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Name of national authority for pesticide registration | Pesticide Commission                                                                                                                |
| Address                                               | Ministry of Agriculture<br>Jl. Harsono. RM., No. 3. Building D, 8 <sup>th</sup> Floor<br>Ragunan Pasar-Minggu, South Jakarta        |
| Contact person                                        | Name: Dr Sumarjo Gatot Irianto<br>Title: Chairman of Pesticide Committee/General Director of Facility and Infrastructure<br>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<br>Title: Director, Agricultural Chemicals Office, MAFF<br>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<br>Title: Director, Research Institute of Agro-chemicalization<br>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<br>Department of Agriculture<br>B.O. Box 811, Vientiane, Lao PDR    |
| Contact person                                        | Name: Khamphoui<br>Title: Director of Regulatory Division<br>E-mail: phoui2@hotmail.com, doag@laotel.com |

**Malaysia**

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

## Myanmar

|                                                       |                                                                                                                   |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Name of national authority for pesticide registration | Pesticide registration Board<br>Plant Protection Division                                                         |
| Address                                               | Plant Protection Division, Department of Agriculture<br>Bayintnaung Road, West Gyogone, Insein P.O. 11011, Yangon |
| Contact person                                        | Name: U Aye Tun<br>Title: Secretariat<br>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<br>Title: Pesticide Registrar<br>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<br>Title: Deputy Director Registration<br>E-mail: registration@plantprotection.gov.pk |

## Philippines

|                                                       |                                                                                                         |
|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Name of national authority for pesticide registration | Fertilizer & Pesticide Authority                                                                        |
| Address                                               | FPA Building, BAI Compound, Visayas Avenue<br>Diliman, Quezon City Philippines                          |
| Contact person                                        | Name: Dr Norlito R. Gigana<br>Title: Executive Director<br>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<br>Singapore                                |
| Contact person                                        | Name: Ms Yap Mei Lai<br>Title: Programme Chief (Plant Health)<br>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<br>Title: Registrar of Pesticides<br>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<br>Title: Senior Agricultural Scientist<br>E-mail: ssupanon@yahoo.com |

**Viet Nam**

|                                                       |                                                                                |
|-------------------------------------------------------|--------------------------------------------------------------------------------|
| Name of national authority for pesticide registration | Plant Protection Department (PPD) – MARD                                       |
| Address                                               | 149 Ho Duc Di street, Dong Da, Hanoi, Viet Nam                                 |
| Contact person                                        | Name: Nguyen Xuan Hong<br>Title: Director General<br>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<br>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<br>hi = 6  |            | 1        | 6     |           | 0     |            | 0       |          | -       | 1     | 2        | 3           | *         | 0         | 1        | 5        |
| Number of residue analysis laboratories                                                                                                                                                                                                         | low = 0<br>hi = 73 | -          | 1        | 73    | 3         | *     | 6          | 1       | 4        | 3       | 1     | 2        | 4           | */2       | 1         | 9        |          |
| Number of internationally accredited residue analysis laboratories                                                                                                                                                                              | low = 0<br>hi = 5  |            | 0        |       |           | 0     | 0          |         |          |         | 1     | 1        | 3           | 1         | 0         | 3        | 5        |
| Number of toxicology laboratories                                                                                                                                                                                                               | low = 0<br>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<br>/2 For food safety control = 1; for environmental testing = 5                                                                                                           |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| <b>Instrumentation of quality control laboratories</b>                                                                                                                                                                                          |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Number of GC                                                                                                                                                                                                                                    | low = 0<br>hi = 8  | 2          | 1        |       |           | 2     | 8          | 0       | 3        | 2       | 1     | -        | 8           | *         | 2         | 4        |          |
| Number of GC-MS                                                                                                                                                                                                                                 | low = 0<br>hi = 3  | -          | 1        |       |           | 1     | 2          | 0       | 1        | -       | x     |          | 3           | *         | 1         | 1        |          |
| Number of LC-MS                                                                                                                                                                                                                                 | low = 0<br>hi = 2  | -          |          |       |           | 1     | 2          | 0       |          | -       | x     |          | 2           | *         | -         | -        |          |
| Number of HPLC                                                                                                                                                                                                                                  | low = 0<br>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                                                                                                                                                                                                                     |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| <b>Instrumentation of residue analysis laboratories</b>                                                                                                                                                                                         |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Number of GC                                                                                                                                                                                                                                    | low = -<br>hi = 30 | -          | 1        |       |           | *     | 7          |         | 30       | 1       | 1     | 12       | 8           | 11        | -         | 7        |          |
| Number of GC-MS                                                                                                                                                                                                                                 | low = -<br>hi = 5  | -          | 1        |       |           | *     | 2          |         | 3        | -       | x     | 2        | 3           | 5         | -         | 4        |          |
| Number of LC-MS                                                                                                                                                                                                                                 | low = -<br>hi = 3  | -          |          |       |           | *     | 2          |         | 3        | -       | x     | 2        | 2           | 2         | -         | 1        |          |
| Number of HPLC                                                                                                                                                                                                                                  | low = -<br>hi = 8  | -          | 1        |       |           | *     | 6          |         |          | 1       | x     | 8        | 8           | 2         | -         | 4        |          |
|                                                                                                                                                                                                                                                 |                    |            | 3        |       |           |       | 17         |         | 36       | 2       | 1     | 24       | 21          | 20        |           | 16       |          |
| Japan:<br>* 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<br>hi = 70  | 1          | 1        |       | 13        | ~70   | 5          | 5       | 35       | 29      | 2     | 4        | 7           | 3         | 4         | 9        | 7        |
| Number of enforcement officers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | low = 1<br>hi = 660 | 1          | 1        |       | 13        | *1    | 12         | 2       | 13       | 72      | 1     | 660      | 25          | 14        | 60        | 245<br>* | 558      |
| Number of quality control laboratory personnel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | low = 1<br>hi = 35  | 3          | 1        |       |           | 8     | 32         | 0       | 11       | 5       | x     |          | 7*          | -         | 3         | 23       | 35       |
| Number of residue laboratory personnel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | low = 0<br>hi = 42  | -          | 0        |       |           | *2    | 42         | 4       | 25       | 5       | x     | 30       | 3*          | 9         | -         | 19       | 35       |
| Number of toxicology laboratory personnel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | low = 0<br>hi = 40  | -          | 1        |       |           | -     | 40         | 0       | 8        | -       | x     | 40       | 3*          | -         | 0         | -        |          |
| Total                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | low = 3<br>hi = 734 | 5          | 4        |       | 26        | 81    | 131        | 11      | 92       | 111     | 3     | 734      | 45          | 26        | 67        | 296      | 635      |
| Japan:<br>*/1 Officers of the national and prefectural government working in the areas of agriculture, health and the environment are involved.<br>*/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.<br>Philippines: min/lab<br>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 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|------------|----------|-------|-----------|-------|------------|---------|----------|---------|-------|----------|-------------|-----------|-----------|----------|----------|
| <b>Within agency</b>                                                                                                                                                        |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Agriculturalists                                                                                                                                                            | low = 3<br>hi = 78 | 7          | Y        | √     | 9         | Y*    | 5          | 5       | Y        | 34      | 78    |          | 3           | Y         |           | 14       |          |
| Biologists                                                                                                                                                                  | low = 2<br>hi = 9  | -          | Y        | √     | 9         | Y*    | 3          |         | Y        | 2       | x     |          | 0           | Y         |           |          |          |
| Bio-efficacy specialist                                                                                                                                                     | low = 1<br>hi = 6  | -          | Y        | √     | 3         | Y*    | 6          |         | Y        | 5       | x     |          | 2           | Y         | 1         | 64       |          |
| Pesticide chemists                                                                                                                                                          | low = 1<br>hi = 4  | 3          | Y        | √     | 2         | Y*    | 4          |         | Y        | 3       | x     | 2        | 3           | Y         | 1         | 9        |          |
| Toxicologists/medical doctor                                                                                                                                                | low = 1<br>hi = 3  | 1          | Y        | √     | 2         |       | 3          |         | Y        | 3       | x     | 2        | 1           |           | 1         |          |          |
| Other (please specify)                                                                                                                                                      |                    |            | Y        | √     | 1*        |       |            |         |          |         |       |          | 0           |           | 2*        |          |          |
| Total                                                                                                                                                                       | low = 4<br>hi = 87 | 11         | Y        | √     | 26        | Y*    | 21         | 5       | Y        | 47      | 78    | 4        | 9           | Y         | 5         | 87       |          |
| China: Environmentalist<br>Indonesia: Pesticide database<br>Japan: Numbers unknown<br>Sri Lanka: Research Officers                                                          |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| <b>Outside agency</b>                                                                                                                                                       |                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |
| Agriculturalists                                                                                                                                                            | low = 4<br>hi = 20 |            |          |       |           |       | 4          |         | Y        |         |       |          | 20          |           |           |          |          |
| Biologists                                                                                                                                                                  | low = 1<br>hi = 10 |            |          |       |           |       | 3          |         | Y        |         | 1     |          | 10          |           |           |          |          |
| Bio-efficacy specialist                                                                                                                                                     | low = 6<br>hi = 10 |            |          |       |           |       | 6          |         | Y        |         |       |          | 10          |           |           |          |          |
| Pesticide chemists                                                                                                                                                          | low = 4<br>hi = 32 |            |          |       |           |       | 4          |         | Y        |         |       | 32       | 8           |           |           |          |          |
| Toxicologists/medical doctor                                                                                                                                                | low = 2<br>hi = 8  |            |          |       |           | Y*    | 2          |         | Y        |         |       | 8        | 4           |           |           | 3        |          |
| Other (please specify)                                                                                                                                                      |                    |            |          |       |           |       |            |         |          |         |       |          | 5*          |           |           | -        |          |
| Total                                                                                                                                                                       | low = 1<br>hi = 57 |            |          |       |           | Y*    | 19         |         | Y        |         | 1     | 40       | 57          |           |           | 3        |          |
| Japan: Numbers unknown<br>Philippines: Entomologist<br>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<br>hi = 90<br>sum =    | -          |          |       |           | 3 <sup>1</sup>   | 90         | 1       | 3        | 12      | x     | 2        | 2           | 3         | 0         | 64       |          |
| Number of persons trained in pesticide label evaluation                                                   | low = 1<br>hi = 54             | 1          |          |       |           | 3 <sup>1</sup>   |            | 1       | 2        | 54      | x     | 4        | 2           | 1         | 1         | 4        |          |
| Number of persons trained in pesticide residue analysis                                                   | low = -<br>hi = 17             | -          |          |       |           | 5 <sup>1</sup>   | 5          | 1       | 17       | 3       | 2     | -        | 2           | 7         | 1         | 19       |          |
| Number of persons trained in pesticide formulation analysis                                               | low = 1<br>hi = 23             | 3          |          |       |           | 3 <sup>1</sup>   | 12         | 1       | 10       | 5       | x     | 2        | 2           | 0         | 1         | 23       |          |
| Number of persons trained in toxicology and risk assessment                                               | low = -<br>hi = 7<br>Sum = 26  | -          |          |       |           | 7 <sup>1,2</sup> | 6          | 2       | 4        | -       | x     | -        | 4           | 0         | 0         | 3        |          |
| Number of persons trained in ecotoxicology assessment                                                     | low = 0<br>hi = 5<br>Sum = 16  | -          |          |       |           | 3 <sup>1</sup>   | 5          | 0       | 4        | -       | x     | -        | 2           | 0         | 0         | 2        |          |
| Number of persons trained in information management on pesticide regulatory matters                       | low = 0<br>hi = 14<br>Sum = 21 | 3          |          |       |           | -                |            | 0       | 2        | -       | x     | 2        | 14          | 0         | 0         | 0        |          |
|                                                                                                           | low = 2<br>hi = 118            | 7          |          |       |           | 24               | 118        | 6       | 42       | 74      | 2     | 10       | 28          | 11        | 3         | 115      |          |
| Japan:<br>*1 Number of capacity building <i>activities</i><br>*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 |
|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>1a</b>                                                                                                     | <b>Guideline translated</b>                                              |          |          |         |          |         |             |          |          |
|                                                                                                               | 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>b</b>                                                                                                      | <b>Guideline adopted</b>                                                 |          |          |         |          |         |             |          |          |
|                                                                                                               | 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        |
| <b>c</b>                                                                                                      | <b>Guideline officially published</b>                                    |          |          |         |          |         |             |          |          |
|                                                                                                               | 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<br>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 PDR 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<br>Partially = 0 | F        | N       | N        | F       | N           | N        | N        |
| Annex 1B: Check Sheet (for official use only)                                            | Fully = 2<br>Partially = 0 | F        | N       | N        | F       | N           | N        | N        |
| Annex 2A: Chemical pesticide, proprietary registration, technical grade AI               | Fully = 1<br>Partially = 1 | P        | N       | N        | F       | N           | N        | N        |
| Annex 2B: Chemical pesticide, proprietary registration, formulated product               | Fully = 2<br>Partially = 0 | F        | N       | N        | F       | N           | N        | N        |
| Annex 2C: Chemical pesticide, supplementary registration, formulated product             | Fully = 1<br>Partially = 1 | P        | N       | N        | F       | N           | N        | N        |
| Annex 3A: Biochemical pesticide, proprietary registration, technical concentrate         | Fully = 1<br>Partially = 0 | N        | N       | N        | F       | N           | N        | N        |
| Annex 3B: Biochemical pesticide, proprietary registration, formulated product            | Fully = 1<br>Partially = 0 | N        | N       | N        | F       | N           | N        | N        |
| Annex 3C: Biochemical pesticide, supplementary registration, formulated product          | Fully = 1<br>Partially = 0 | N        | N       | N        | F       | N           | N        | N        |
| Annex 4A: Microbial pesticide, proprietary registration, active agent                    | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
| Annex 4B: Microbial pesticide, proprietary registration, formulated product              | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
| Annex 4C: Microbial pesticide, supplementary registration, formulated product            | Fully = 0<br>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<br>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<br>Partially = 1 | P        | N       | N        | F       | N           | N        | N        |
| Annex A3. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF PHEROMONE (semiochemicals)                                                                       | Fully = 1<br>Partially = 1 | P        | N       | N        | F       | N           | N        | N        |
| Annex A4. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF MICROBIAL PEST CONTROL AGENTS                                                                    | Fully = 1<br>Partially = 0 | N        | N       | N        | F       | N           | N        | N        |
| Annex BI. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF BOTANICAL PESTICIDES – provisional registration, technical concentrate                                | Fully = 1<br>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<br>Partially = 0 | N        | N       | N        | F       | N           | N        | N        |
| Annex BII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PESTICIDE – Provisional Registration                                                       | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
| Annex BII. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PESTICIDE – Regular Registration                                                           | Fully = 0<br>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<br>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<br>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<br>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<br>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<br>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<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |

| 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 BV. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOPATHOGENIC FUNGI – Provisional Registration  | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
|                                               | Annex BV. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOPATHOGENIC FUNGI – Regular Registration      | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
|                                               | Annex BVI. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC FUNGI – Provisional Registration     | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
|                                               | Annex BVI. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC FUNGI – Regular Registration         | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
|                                               | Annex BVII. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC BACTERIA – Provisional Registration | Fully = 0<br>Partially = 1 | N        | N       | N        | P       | N           | N        | N        |
|                                               | Annex BVII. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC BACTERIA – Regular Registration     | Fully = 0<br>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 |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------|-----------|-----------|----------|-------------|-----------|----------|
| <b>A1</b> | <b>Chemical identity of active ingredient/agent</b>                                                                                         |                 |          |           |           |          |             |           |          |
| 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        |
|           |                                                                                                                                             | <b>Sum = 36</b> | <b>6</b> | <b>4</b>  | <b>6</b>  | <b>3</b> | <b>6</b>    | <b>5</b>  | <b>6</b> |
| <b>A2</b> | <b>Physical properties of pure active ingredient/agent</b>                                                                                  |                 |          |           |           |          |             |           |          |
| 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 °C, 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 °C)                                 | 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         |          |
|           |                                                                                                                                             | <b>Sum = 65</b> | <b>9</b> | <b>10</b> | <b>10</b> | <b>8</b> | <b>10</b>   | <b>10</b> | <b>8</b> |
| <b>A3</b> | <b>Technical grade product identity</b>                                                                                                     |                 |          |           |           |          |             |           |          |
| 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        |
| <b>A4</b> | <b>Material Safety Data Sheet (MSDS)</b>                                                                                                                                                                                                                         |          |          |         |          |         |             |          |          |
| 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       |
| <b>A5</b> | <b>Product identity of finished product</b>                                                                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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        |
| <b>A6</b> | <b>Composition of finished product</b>                                                                                                                                                                                                                           |          |          |         |          |         |             |          |          |
| 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        |
| <b>A7</b> | <b>Physical-chemical properties of finished product</b>                                                                                                                                                                                                          |          |          |         |          |         |             |          |          |
| 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        |
| <b>A8</b> | <b>Physical properties of the finished product related to use</b>              |          |          |         |          |         |             |          |          |
| 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 |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>A1</b> | <b>Chemical identity of active ingredient/agent</b>                                                                                                     |          |          |         |          |         |             |          |          |
| 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        |
| <b>A2</b> | <b>Physical properties of pure active ingredient/agent</b>                                                                                              |          |          |         |          |         |             |          |          |
|           | 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 <sup>-3</sup> 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        |
| <b>A3</b> | <b>Technical grade product identity</b>                                                                                                                                                                                                                          |          |          |         |          |         |             |          |          |
| 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        |
| <b>A4</b> | <b>Material Safety Data Sheet (MSDS)</b>                                                                                                                                                                                                                         |          |          |         |          |         |             |          |          |
|           | 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       |
| <b>A5</b> | <b>Product identity of finished product</b>                                                                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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        |
| <b>A6</b> | <b>Composition of finished product</b>                                                                                                                                                                                                                           |          |          |         |          |         |             |          |          |
| 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        |          |

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

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

|           | 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 °C, 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 °C)                                                                                                                                                      | 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        |
| <b>A3</b> | <b>Technical grade product identity</b>                                                                                                                                                                                                                          |          |          |         |          |         |             |          |          |
| 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        |
| <b>A4</b> | <b>Material Safety Data Sheet (MSDS)</b>                                                                                                                                                                                                                         |          |          |         |          |         |             |          |          |
|           | 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       |
| <b>A5</b> | <b>Product identity of finished product</b>                                                                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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 |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>A6</b>                                                              | <b>Composition of finished product</b>                                                                                                                  |          |          |         |          |         |             |          |          |
| 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        |
| <b>A7</b>                                                              | <b>Physical-chemical properties of finished product</b>                                                                                                 |          |          |         |          |         |             |          |          |
| 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        |
| <b>A8</b>                                                              | <b>Physical properties of the finished product related to use</b>                                                                                       |          |          |         |          |         |             |          |          |
| 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. Suspensibility (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 |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>A1</b> | <b>Chemical identity of active ingredient/agent</b>                                                                                                                                                                                                                     |          |          |         |          |         |             |          |          |
| 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        |
|           | <b>For microbial pest control agents: Identification characteristics</b>                                                                                                                                                                                                | 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        |
| <b>A3</b> | <b>Technical grade product identity</b>                                                                                                                                                                                                                                 |          |          |         |          |         |             |          |          |
|           | 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        |
| <b>A3</b> | <b>Biological properties of microbial pest control agent</b>                                                                                                                                                                                                            |          |          |         |          |         |             |          |          |
| 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 |
|-------------------------------|------------------------------------------------------------|------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                                                            |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                                                            |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                                                            |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                                                            |      |          |         |          |         |             |          |          |     |              |
| 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 |
|-------------------------------|------------------------------------------------------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                                                            |          |         |          |         |             |          |          |     |              |
| A1                            | Chemical identity of active ingredient/agent               | 6        | 4       | 6        | 3       | 6           | 5        | 6        | 36  | 86%          |
| A2                            | Physical properties of pure active ingredient/agent        | 10       | 10      | 10       | 8       | 10          | 10       | 8        | 65  | 93%          |
| A3                            | Technical grade product identity                           | 11       | 8       | 11       | 6       | 11          | 9        | 7        | 63  | 79%          |
| A4                            | Material Safety Data Sheet (MSDS)                          | 10       | 10      | 10       | 7       | 10          | 10       | 10       | 67  | 89%          |
| A5                            | Product identity of finished product                       | 4        | 4       | 4        | 4       | 4           | 4        | 4        | 28  | 100%         |
| A6                            | Composition of finished product                            | 3        | 3       | 3        | 3       | 3           | 3        | 3        | 21  | 100%         |
| A7                            | Physical-chemical properties of finished product           | 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       | 77  | 100%         |
|                               | Sum                                                        | 62       | 61      | 57       | 62      | 48          | 62       | 58       | 55  | 403          |
|                               | % harmonized                                               | 98%      | 92%     | 100%     | 77%     | 100%        | 94%      | 89%      |     | 91%          |
| <b>Botanical Pesticides</b>   |                                                            |          |         |          |         |             |          |          |     |              |
| A1                            | Chemical identity of active ingredient/agent               | 5        | 4       | 3        | 3       | 5           | 4        | 5        | 24  | 69%          |
| A3                            | Technical grade product identity                           | 8        | 7       | 8        | 3       | 8           | 0        | 5        | 31  | 55%          |
| A5                            | Product identity of finished product                       | 4        | 4       | 4        | 4       | 2           | 2        | 4        | 20  | 71%          |
| A6                            | Composition of finished product                            | 2        | 2       | 2        | 2       | 2           | 2        | 2        | 12  | 86%          |
| A7                            | Physical-chemical properties of finished product           | 6        | 6       | 6        | 3       | 6           | 5        | 4        | 30  | 71%          |
| A8                            | Physical properties of the finished product related to use | 5        | 5       | 5        | 5       | 5           | 5        | 5        | 30  | 86%          |
|                               | Sum                                                        | 30       | 28      | 28       | 20      | 28          | 18       | 25       | 147 |              |
|                               | % harmonized                                               | 0%       | 93%     | 93%      | 67%     | 93%         | 60%      | 83%      |     | 70%          |
| <b>Biochemical Pesticides</b> |                                                            |          |         |          |         |             |          |          |     |              |
| A1                            | Chemical identity of active ingredient/agent               | 7        | 4       | 3        | 4       | 7           | 6        | 7        | 31  | 63%          |
| A2                            | Physical properties of pure active ingredient/agent        | 10       | 8       | 10       | 10      | 10          | 10       | 8        | 56  | 80%          |
| A3                            | Technical grade product identity                           | 8        | 8       | 8        | 4       | 8           | 0        | 4        | 32  | 57%          |
| A5                            | Product identity of finished product                       | 4        | 4       | 4        | 4       | 4           | 4        | 4        | 24  | 86%          |
| A6                            | Composition of finished product                            | 6        | 6       | 6        | 5       | 6           | 6        | 5        | 34  | 81%          |
| A7                            | Physical-chemical properties of finished product           | 7        | 7       | 7        | 6       | 7           | 6        | 5        | 38  | 78%          |
| A8                            | Physical properties of the finished product related to use | 8        | 8       | 8        | 8       | 8           | 8        | 8        | 48  | 86%          |
|                               | Sum                                                        | 50       | 45      | 46       | 41      | 50          | 40       | 41       | 263 |              |
|                               | % harmonized                                               | 0%       | 90%     | 92%      | 82%     | 100%        | 80%      | 82%      |     | 75%          |
| <b>Microbial Pesticides</b>   |                                                            |          |         |          |         |             |          |          |     |              |
| A1                            | Chemical identity of active ingredient/agent               | 6        | 3       | 6        | 5       | 5           | 3        | 6        | 28  | 67%          |
|                               | Identification characteristics for microbial PCA           | 9        | 6       | 9        | 8       | 9           | 0        | 0        | 32  | 51%          |
| A3                            | Biological properties of microbial PCA                     | 5        | 5       | 5        | 5       | 5           | 3        | 0        | 23  | 66%          |
| A4                            | Source of microbial pest control agent                     | 2        | 2       | 0        | 2       | 2           | 1        | 1        | 8   | 57%          |
| A5                            | Product identity of finished product                       | 3        | 3       | 3        | 3       | 1           | 1        | 3        | 14  | 67%          |
| A6                            | Composition of finished product                            | 7        | 7       | 7        | 7       | 7           | 6        | 5        | 39  | 80%          |
|                               | Sum                                                        | 32       | 26      | 30       | 30      | 29          | 14       | 15       | 144 |              |
|                               | % harmonized                                               | 0%       | 94%     | 94%      | 94%     | 91%         | 44%      | 47%      |     | 64%          |
| <b>Overall % harmonized</b>   |                                                            |          |         |          |         |             |          |          |     |              |
|                               |                                                            | 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  |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------|----------|-----------|-----------|----------|-------------|-----------|-----------|
| <b>B1</b>                                                              | <b>Acute Toxicity tests</b>                                                                       |                 |          |           |           |          |             |           |           |
| R                                                                      | 1.1. Acute oral toxicity/infectivity (i.e., LD <sub>50</sub> 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 <sub>50</sub> expressed as mg/kg of body weight) | Y = 7           | Y        | Y         | Y         | Y        | Y           | Y         | Y         |
| R                                                                      | 1.3. Acute inhalation toxicity (LC <sub>50</sub> in mg/l)                                         | Y = 6           | Y        | Y         | Y         | Y        |             | Y         | Y         |
|                                                                        |                                                                                                   | <b>Sum = 20</b> | <b>3</b> | <b>3</b>  | <b>3</b>  | <b>3</b> | <b>2</b>    | <b>3</b>  | <b>3</b>  |
| <b>B2</b>                                                              | <b>Irritation tests</b>                                                                           |                 |          |           |           |          |             |           |           |
| 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         |
|                                                                        |                                                                                                   | <b>Sum = 64</b> | <b>9</b> | <b>10</b> | <b>10</b> | <b>5</b> | <b>10</b>   | <b>10</b> | <b>10</b> |
| Y = Yes; R = As required in the harmonization guidelines (shaded rows) |                                                                                                   |                 |          |           |           |          |             |           |           |

|                                                                        | Botanical Pesticides                                                                              |                 | Cambodia | Lao PDR   | Malaysia  | Myanmar   | Philippines | Thailand  | Viet Nam  |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------|----------|-----------|-----------|-----------|-------------|-----------|-----------|
| <b>B1</b>                                                              | <b>Acute Toxicity tests</b>                                                                       |                 |          |           |           |           |             |           |           |
| R                                                                      | 1.1. Acute oral toxicity/infectivity (i.e., LD <sub>50</sub> 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 <sub>50</sub> expressed as mg/kg of body weight) | Y = 6           |          | Y         | Y         | Y         | Y           | Y         | Y         |
| R                                                                      | 1.3. Acute inhalation toxicity (LC <sub>50</sub> in mg/l)                                         | Y = 5           |          | Y         | Y         | Y         |             | Y         | Y         |
|                                                                        |                                                                                                   | <b>Sum = 17</b> | <b>0</b> | <b>3</b>  | <b>3</b>  | <b>3</b>  | <b>2</b>    | <b>3</b>  | <b>3</b>  |
| <b>B2</b>                                                              | <b>Irritation tests</b>                                                                           |                 |          |           |           |           |             |           |           |
| 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         |
|                                                                        |                                                                                                   | <b>Sum = 60</b> | <b>0</b> | <b>10</b> | <b>10</b> | <b>10</b> | <b>10</b>   | <b>10</b> | <b>10</b> |
| Y = Yes; R = As required in the harmonization guidelines (shaded rows) |                                                                                                   |                 |          |           |           |           |             |           |           |

|                                                                        | Biochemical Pesticides                                                                            |          | Cambodia | Lao PDR | Malaysia | Myanmar | Philippines | Thailand | Viet Nam |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>B1</b>                                                              | <b>Acute Toxicity tests</b>                                                                       |          |          |         |          |         |             |          |          |
| R                                                                      | 1.1. Acute oral toxicity/infectivity (i.e., LD <sub>50</sub> 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 <sub>50</sub> expressed as mg/kg of body weight) | Y = 6    |          | Y       | Y        | Y       | Y           | Y        | Y        |
| R                                                                      | 1.3. Acute inhalation toxicity (LC <sub>50</sub> in mg/l)                                         | Y = 5    |          | Y       | Y        | Y       |             | Y        | Y        |
|                                                                        |                                                                                                   | Sum = 17 | 0        | 3       | 3        | 3       | 2           | 3        | 3        |
| <b>B2</b>                                                              | <b>Irritation tests</b>                                                                           |          |          |         |          |         |             |          |          |
| 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 |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>B1</b>                                                              | <b>Acute Toxicity tests</b>                                                                       |          |          |         |          |         |             |          |          |
| R                                                                      | 1.1. Acute oral toxicity/infectivity (i.e., LD <sub>50</sub> 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 <sub>50</sub> expressed as mg/kg of body weight) | Y = 6    |          | Y       | Y        | Y       | Y           | Y        | Y        |
| R                                                                      | 1.3. Acute inhalation toxicity (LC <sub>50</sub> in mg/l)                                         | Y = 6    |          | Y       | Y        | Y       | Y           | Y        | Y        |
|                                                                        |                                                                                                   | Sum = 18 | 0        | 3       | 3        | 3       | 3           | 3        | 3        |
| <b>B2</b>                                                              | <b>Irritation tests</b>                                                                           |          |          |         |          |         |             |          |          |
| 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 |
|-------------------------------|----------------------|------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                      |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                      |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                      |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                      |      |          |         |          |         |             |          |          |     |              |
| 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 |
|-------------------------------|----------------------|------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                      |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                      |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                      |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                      |      |          |         |          |         |             |          |          |     |              |
| 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 | <b>Bio-efficacy and Pest information</b>                                                                                                                                                               |          |          |         |          |         |             |          |          |
| 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 | <b>Crop/Commodity information</b>                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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 | <b>Bio-efficacy and Pest information</b>                                                                                                                                                               |          |          |         |          |         |             |          |          |
| 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 | <b>Crop/Commodity information</b>                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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 |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>C1</b>                                                              | <b>Bio-efficacy and Pest information</b>                                                                                                                                                               |          |          |         |          |         |             |          |          |
| 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        |
| <b>C2</b>                                                              | <b>Crop/Commodity information</b>                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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 |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>C1</b>                                                              | <b>Bio-efficacy and Pest information</b>                                                                                                                                                               |          |          |         |          |         |             |          |          |
| 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        |
| <b>C2</b>                                                              | <b>Crop/Commodity information</b>                                                                                                                                                                      |          |          |         |          |         |             |          |          |
| 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 |
|-------------------------------|-----------------------------------|------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                                   |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                                   |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                                   |      |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                                   |      |          |         |          |         |             |          |          |     |              |
| 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**

|           | <b>Chemical Pesticides</b>                                                                                                                                                                                                                                                                                                             |                 | <b>Cambodia</b> | <b>Lao PDR</b> | <b>Malaysia</b> | <b>Myanmar</b> | <b>Philippines</b> | <b>Thailand</b> | <b>Viet Nam</b> |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|----------------|-----------------|----------------|--------------------|-----------------|-----------------|
| <b>D1</b> | <b>Plant metabolism:</b>                                                                                                                                                                                                                                                                                                               |                 |                 |                |                 |                |                    |                 |                 |
| R         | 1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)                                                                                                                                                                                                               | <b>Y = 6</b>    | <b>Y</b>        | <b>Y</b>       | <b>Y</b>        | <b>-</b>       | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
| R         | 1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)                                                                                                                                                                                                                               | <b>Y = 5</b>    | <b>Y</b>        | <b>Y</b>       |                 | <b>-</b>       | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
| R         | 1.3. Crop groupings                                                                                                                                                                                                                                                                                                                    | <b>Y = 5</b>    | <b>Y</b>        | <b>Y</b>       |                 | <b>-</b>       | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
| R         | 1.1. Use of radio labelling material (C-14, P-32, S-35)                                                                                                                                                                                                                                                                                | <b>Y = 5</b>    | <b>Y</b>        | <b>Y</b>       | <b>Y</b>        | <b>-</b>       | <b>Y</b>           |                 | <b>Y</b>        |
| R         | 1.1. Dosage rate (at least equal to intended use)                                                                                                                                                                                                                                                                                      | <b>Y = 6</b>    | <b>Y</b>        | <b>Y</b>       | <b>Y</b>        | <b>-</b>       | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
| R         | 1.2. Identification & characterization of residues                                                                                                                                                                                                                                                                                     | <b>Y = 6</b>    | <b>Y</b>        | <b>Y</b>       | <b>Y</b>        | <b>-</b>       | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
| R         | 1.3. Residue definition (The “marker compound concept” should be used for enforcement and “toxicological relevant compounds” should be used for risk assessment)                                                                                                                                                                       | <b>Y = 4</b>    | <b>Y</b>        | <b>Y</b>       | <b>Y</b>        | <b>-</b>       |                    |                 | <b>Y</b>        |
|           |                                                                                                                                                                                                                                                                                                                                        | <b>Sum = 37</b> | <b>7</b>        | <b>7</b>       | <b>5</b>        | <b>0</b>       | <b>6</b>           | <b>5</b>        | <b>7</b>        |
| <b>D2</b> | <b>Farm Animal Metabolism:</b>                                                                                                                                                                                                                                                                                                         |                 |                 |                |                 |                |                    |                 |                 |
| R         | 2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken                                                                                                                                                                                                                                                    | <b>Y = 3</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 | <b>Y</b>        |
| R         | 2.2. Duration of dosing (dosed daily for 3 consecutive days)                                                                                                                                                                                                                                                                           | <b>Y = 3</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 | <b>Y</b>        |
| R         | 2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)                                                                                                                                                                                                                                  | <b>Y = 3</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 | <b>Y</b>        |
| R         | 2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg                                                                                                                                                                                                                                      | <b>Y = 3</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 | <b>Y</b>        |
| R         | 2.5. Parental compounds should be used                                                                                                                                                                                                                                                                                                 | <b>Y = 2</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    |                 | <b>Y</b>        |
|           |                                                                                                                                                                                                                                                                                                                                        | <b>Sum = 14</b> | <b>5</b>        | <b>0</b>       | <b>4</b>        | <b>0</b>       | <b>0</b>           | <b>0</b>        | <b>5</b>        |
| <b>D3</b> | <b>Farm Animal Feeding Studies:</b>                                                                                                                                                                                                                                                                                                    |                 |                 |                |                 |                |                    |                 |                 |
| R         | 3.1. Species: ruminants (normally lactating cows) and poultry (chickens)                                                                                                                                                                                                                                                               | <b>Y = 2</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 |                 |
| 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)                                                                                                                                                          | <b>Y = 1</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    |                 |                 |
| R         | 3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)                                                                                                                                                                                                         | <b>Y = 2</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 |                 |
| 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)                                                                                                                                         | <b>Y = 1</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    |                 |                 |
| R         | 3.5. Material used: usually parent compound                                                                                                                                                                                                                                                                                            | <b>Y = 2</b>    | <b>Y</b>        |                | <b>Y</b>        | <b>-</b>       |                    |                 |                 |
|           |                                                                                                                                                                                                                                                                                                                                        | <b>Sum = 8</b>  | <b>5</b>        | <b>0</b>       | <b>3</b>        | <b>0</b>       | <b>0</b>           | <b>0</b>        | <b>0</b>        |
| <b>D4</b> | <b>Processing Studies</b>                                                                                                                                                                                                                                                                                                              |                 |                 |                |                 |                |                    |                 |                 |
| R         | 4.1. Data on transfer of residues into processed commodities                                                                                                                                                                                                                                                                           | <b>Y = 1</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    |                 |                 |
| R         | 4.2. Minimum of 2 studies/commodity<br>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) | <b>Y = 2</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    |                 | <b>Y</b>        |
| R         | 4.3. Residue trials carried out over different years (at least minimum of 3 trials)                                                                                                                                                                                                                                                    | <b>Y = 2</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    | <b>Y</b>        |                 |
| R         | 4.4. Glasshouse trials (protected crops)                                                                                                                                                                                                                                                                                               | <b>Y = 1</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    |                 |                 |
| R         | 4.5. Post-harvest treatment studies (wheat, potato)                                                                                                                                                                                                                                                                                    | <b>Y = 2</b>    | <b>Y</b>        |                |                 | <b>-</b>       |                    | <b>Y</b>        |                 |
| R         | 4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)                                                                                                                                                                                                                            | <b>Y = 2</b>    | <b>Y</b>        |                |                 | <b>-</b>       | <b>Y</b>           |                 |                 |

|                                                                   | <b>Chemical Pesticides</b>                                                                                                                                                                                                                                                                                       |                 | <b>Cambodia</b> | <b>Lao PDR</b> | <b>Malaysia</b> | <b>Myanmar</b> | <b>Philippines</b> | <b>Thailand</b> | <b>Viet Nam</b> |
|-------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|----------------|-----------------|----------------|--------------------|-----------------|-----------------|
| R                                                                 | 4.7. Decline Studies (4 sampling intervals, i.e., five samples)<br>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 | <b>Y = 4</b>    | <b>Y</b>        |                | <b>Y</b>        | -              |                    | <b>Y</b>        | <b>Y</b>        |
| R                                                                 | 4.8. Extrapolation studies $\pm 25\%$ rule could be used when comparing GAPs                                                                                                                                                                                                                                     | <b>Y = 5</b>    | <b>Y</b>        |                | <b>Y</b>        | -              | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
|                                                                   |                                                                                                                                                                                                                                                                                                                  | <b>Sum = 19</b> | <b>8</b>        | <b>0</b>       | <b>2</b>        | <b>0</b>       | <b>2</b>           | <b>4</b>        | <b>3</b>        |
| <b>D5 Analytical Methods/standards for residue determination:</b> |                                                                                                                                                                                                                                                                                                                  |                 |                 |                |                 |                |                    |                 |                 |
| R                                                                 | 5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues                                                                                                                                                                    | <b>Y = 5</b>    |                 | <b>Y</b>       | <b>Y</b>        | -              | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
| R                                                                 | 5.2. Analytical standards/reference chemicals                                                                                                                                                                                                                                                                    | <b>Y = 5</b>    |                 | <b>Y</b>       | <b>Y</b>        | -              | <b>Y</b>           | <b>Y</b>        | <b>Y</b>        |
|                                                                   |                                                                                                                                                                                                                                                                                                                  | <b>Sum = 10</b> | <b>0</b>        | <b>2</b>       | <b>2</b>        | <b>0</b>       | <b>2</b>           | <b>2</b>        | <b>2</b>        |

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

|                                        | <b>Botanical Pesticides</b>                                                                                                                                                   |                 | <b>Cambodia</b> | <b>Lao PDR</b> | <b>Malaysia</b> | <b>Myanmar</b> | <b>Philippines</b> | <b>Thailand</b> | <b>Viet Nam</b> |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|----------------|-----------------|----------------|--------------------|-----------------|-----------------|
| <b>D1 Plant metabolism:</b>            |                                                                                                                                                                               |                 |                 |                |                 |                |                    |                 |                 |
|                                        | 1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)                                                      | <b>Y = 3</b>    |                 | <b>Y</b>       |                 | -              | <b>Y</b>           | <b>Y</b>        |                 |
|                                        | 1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)                                                                      | <b>Y = 3</b>    |                 | <b>Y</b>       |                 | -              | <b>Y</b>           | <b>Y</b>        |                 |
|                                        | 1.3. Crop groupings                                                                                                                                                           | <b>Y = 2</b>    |                 |                |                 | -              | <b>Y</b>           | <b>Y</b>        |                 |
|                                        | 1.1. Use of radio labelling material (C-14, P-32, S-35)                                                                                                                       | <b>Y = 1</b>    |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                        | 1.1. Dosage rate (at least equal to intended use)                                                                                                                             | <b>Y = 4</b>    |                 | <b>Y</b>       | <b>Y</b>        | -              | <b>Y</b>           | <b>Y</b>        |                 |
|                                        | 1.2. Identification & characterization of residues                                                                                                                            | <b>Y = 3</b>    |                 | <b>Y</b>       |                 | -              | <b>Y</b>           | <b>Y</b>        |                 |
|                                        | 1.3. Residue definition (The “marker compound concept” should be used for enforcement and “toxicological relevant compounds” should be used for risk assessment)              | <b>Y = 1</b>    |                 | <b>Y</b>       |                 | -              |                    |                 |                 |
|                                        |                                                                                                                                                                               | <b>Sum = 17</b> | <b>0</b>        | <b>5</b>       | <b>1</b>        | <b>0</b>       | <b>6</b>           | <b>5</b>        | <b>0</b>        |
| <b>D2 Farm Animal Metabolism:</b>      |                                                                                                                                                                               |                 |                 |                |                 | -              |                    |                 |                 |
|                                        | 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                                                                                                                                        |                 |                 |                |                 | -              |                    |                 |                 |
|                                        |                                                                                                                                                                               | <b>Sum = 0</b>  | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>0</b>           | <b>0</b>        | <b>0</b>        |
| <b>D3 Farm Animal Feeding Studies:</b> |                                                                                                                                                                               |                 |                 |                |                 |                |                    |                 |                 |
|                                        | 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) |                 |                 |                |                 | -              |                    |                 |                 |

|                                                                        | <b>Botanical Pesticides</b>                                                                                                                                                                                                                                                                                                            |              | <b>Cambodia</b> | <b>Lao PDR</b> | <b>Malaysia</b> | <b>Myanmar</b> | <b>Philippines</b> | <b>Thailand</b> | <b>Viet Nam</b> |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|----------------|-----------------|----------------|--------------------|-----------------|-----------------|
|                                                                        | 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                                                                                                                                                                                                                                                                                            |              |                 |                |                 | -              |                    |                 |                 |
|                                                                        | <b>Sum = 0</b>                                                                                                                                                                                                                                                                                                                         | <b>0</b>     | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>0</b>           | <b>0</b>        | <b>0</b>        |
| <b>D4</b>                                                              | <b>Processing Studies</b>                                                                                                                                                                                                                                                                                                              |              |                 |                |                 |                |                    |                 |                 |
|                                                                        | 4.1. Data on transfer of residues into processed commodities                                                                                                                                                                                                                                                                           |              |                 |                |                 | -              |                    |                 |                 |
|                                                                        | 4.2. Minimum of 2 studies/commodity<br>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)                                                                                                                                                                                                                            | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | 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 $\pm 25\%$ rule could be used when comparing GAPs                                                                                                                                                                                                                                                           | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | <b>Sum = 2</b>                                                                                                                                                                                                                                                                                                                         | <b>0</b>     | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>2</b>           | <b>0</b>        | <b>0</b>        |
| <b>D5</b>                                                              | <b>Analytical Methods/standards for residue determination:</b>                                                                                                                                                                                                                                                                         |              |                 |                |                 |                |                    |                 |                 |
|                                                                        | 5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues                                                                                                                                                                                          | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | 5.2. Analytical standards/reference chemicals                                                                                                                                                                                                                                                                                          | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | <b>Sum = 2</b>                                                                                                                                                                                                                                                                                                                         | <b>0</b>     | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>2</b>           | <b>0</b>        | <b>0</b>        |
| Y = Yes; R = As required in the harmonization guidelines (shaded rows) |                                                                                                                                                                                                                                                                                                                                        |              |                 |                |                 |                |                    |                 |                 |

|           | Biochemical Pesticides                                                                                                                                                                                                                                                                                                                 |                 | Cambodia | Lao PDR  | Malaysia | Myanmar  | Philippines | Thailand | Viet Nam |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------|----------|----------|----------|-------------|----------|----------|
| <b>D1</b> | <b>Plant metabolism:</b>                                                                                                                                                                                                                                                                                                               |                 |          |          |          |          |             |          |          |
|           | 1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)                                                                                                                                                                                                               | <b>Y = 4</b>    |          | <b>Y</b> | <b>Y</b> | -        | <b>Y</b>    | <b>Y</b> |          |
|           | 1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)                                                                                                                                                                                                                               | <b>Y = 3</b>    |          | <b>Y</b> |          | -        | <b>Y</b>    | <b>Y</b> |          |
|           | 1.3. Crop groupings                                                                                                                                                                                                                                                                                                                    | <b>Y = 2</b>    |          |          |          | -        | <b>Y</b>    | <b>Y</b> |          |
|           | 1.1. Use of radio labelling material (C-14, P-32, S-35)                                                                                                                                                                                                                                                                                | <b>Y = 2</b>    |          |          | <b>Y</b> | -        | <b>Y</b>    |          |          |
|           | 1.1. Dosage rate (at least equal to intended use)                                                                                                                                                                                                                                                                                      | <b>Y = 4</b>    |          | <b>Y</b> | <b>Y</b> | -        | <b>Y</b>    | <b>Y</b> |          |
|           | 1.2. Identification & characterization of residues                                                                                                                                                                                                                                                                                     | <b>Y = 4</b>    |          | <b>Y</b> | <b>Y</b> | -        | <b>Y</b>    | <b>Y</b> |          |
|           | 1.3. Residue definition (The “marker compound concept” should be used for enforcement and “toxicological relevant compounds” should be used for risk assessment)                                                                                                                                                                       | <b>Y = 2</b>    |          | <b>Y</b> | <b>Y</b> | -        |             |          |          |
|           |                                                                                                                                                                                                                                                                                                                                        | <b>Sum = 21</b> | <b>0</b> | <b>5</b> | <b>5</b> |          | <b>6</b>    | <b>5</b> | <b>0</b> |
| <b>D2</b> | <b>Farm Animal Metabolism:</b>                                                                                                                                                                                                                                                                                                         |                 |          |          |          |          |             |          |          |
|           | 2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken                                                                                                                                                                                                                                                    | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           | 2.2. Duration of dosing (dosed daily for 3 consecutive days)                                                                                                                                                                                                                                                                           | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           | 2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)                                                                                                                                                                                                                                  | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           | 2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg                                                                                                                                                                                                                                      | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           | 2.5. Parental compounds should be used                                                                                                                                                                                                                                                                                                 |                 |          |          |          | -        |             |          |          |
|           |                                                                                                                                                                                                                                                                                                                                        | <b>Sum = 4</b>  | <b>0</b> | <b>0</b> | <b>4</b> | <b>0</b> | <b>0</b>    | <b>0</b> | <b>0</b> |
| <b>D3</b> | <b>Farm Animal Feeding Studies:</b>                                                                                                                                                                                                                                                                                                    |                 |          |          |          |          |             |          |          |
|           | 3.1. Species: ruminants (normally lactating cows) and poultry (chickens)                                                                                                                                                                                                                                                               | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           | 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)                                                                                                                                                                                                         | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           | 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                                                                                                                                                                                                                                                                                            | <b>Y = 1</b>    |          |          | <b>Y</b> | -        |             |          |          |
|           |                                                                                                                                                                                                                                                                                                                                        | <b>Sum = 3</b>  | <b>0</b> | <b>0</b> | <b>3</b> | <b>0</b> | <b>0</b>    | <b>0</b> | <b>0</b> |
| <b>D4</b> | <b>Processing Studies</b>                                                                                                                                                                                                                                                                                                              |                 |          |          |          |          |             |          |          |
|           | 4.1. Data on transfer of residues into processed commodities.                                                                                                                                                                                                                                                                          |                 |          |          |          | -        |             |          |          |
|           | 4.2. Minimum of 2 studies/commodity<br>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)                                                                                                                                                                                                                            | <b>Y = 1</b>    |          |          |          | -        | <b>Y</b>    |          |          |

|                                                                        | 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 $\pm 25\%$ rule could be used when comparing GAPs                                                                                                                                                                                                                                  | Y = 1   |          |         |          | -       | Y           |          |          |
|                                                                        |                                                                                                                                                                                                                                                                                                               | Sum = 3 | 0        | 0       | 1        | 0       | 2           | 0        | 0        |
| <b>D5</b>                                                              | <b>Analytical Methods/standards for residue determination:</b>                                                                                                                                                                                                                                                |         |          |         |          |         |             |          |          |
|                                                                        | 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 |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>D1</b> | <b>Plant metabolism:</b>                                                                                                                                                      |          |          |         |          |         |             |          |          |
|           | 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        |
| <b>D2</b> | <b>Farm Animal Metabolism:</b>                                                                                                                                                |          |          |         |          |         |             |          |          |
|           | 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        |
| <b>D3</b> | <b>Farm Animal Feeding Studies:</b>                                                                                                                                           |          |          |         |          |         |             |          |          |
|           | 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) |          |          |         |          | -       |             |          |          |

|                                                                        | <b>Microbial Pesticides</b>                                                                                                                                                                                                                                                                                                            |              | <b>Cambodia</b> | <b>Lao PDR</b> | <b>Malaysia</b> | <b>Myanmar</b> | <b>Philippines</b> | <b>Thailand</b> | <b>Viet Nam</b> |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|----------------|-----------------|----------------|--------------------|-----------------|-----------------|
|                                                                        | 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                                                                                                                                                                                                                                                                                            |              |                 |                |                 | -              |                    |                 |                 |
|                                                                        | <b>Sum = 0</b>                                                                                                                                                                                                                                                                                                                         | <b>0</b>     | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>0</b>           | <b>0</b>        | <b>0</b>        |
| <b>D4</b>                                                              | <b>Processing Studies</b>                                                                                                                                                                                                                                                                                                              |              |                 |                |                 |                |                    |                 |                 |
|                                                                        | 4.1. Data on transfer of residues into processed commodities                                                                                                                                                                                                                                                                           |              |                 |                |                 | -              |                    |                 |                 |
|                                                                        | 4.2. Minimum of 2 studies/commodity<br>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)                                                                                                                                                                                                                            | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | 4.7. Decline Studies (4 sampling intervals, i.e., five samples)<br>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 $\pm 25\%$ rule could be used when comparing GAPs                                                                                                                                                                                                                                                           | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | <b>Sum = 2</b>                                                                                                                                                                                                                                                                                                                         | <b>0</b>     | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>2</b>           | <b>0</b>        | <b>0</b>        |
| <b>D5</b>                                                              | <b>Analytical Methods/standards for residue determination:</b>                                                                                                                                                                                                                                                                         |              |                 |                |                 |                |                    |                 |                 |
|                                                                        | 5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues                                                                                                                                                                                          | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | 5.2. Analytical standards/reference chemicals                                                                                                                                                                                                                                                                                          | <b>Y = 1</b> |                 |                |                 | -              | <b>Y</b>           |                 |                 |
|                                                                        | <b>Sum = 2</b>                                                                                                                                                                                                                                                                                                                         | <b>0</b>     | <b>0</b>        | <b>0</b>       | <b>0</b>        | <b>0</b>       | <b>2</b>           | <b>0</b>        | <b>0</b>        |
| 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 |
|-------------------------------|---------------------------------------------|-------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                                             |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                                             |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                                             |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                                             |             |          |         |          |         |             |          |          |     |              |
| 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 |
|-----------------------------------------------------------|-------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>                                |             |          |         |          |         |             |          |          |     |              |
| 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%      |     |              |
| <b>Botanical Pesticides</b>                               |             |          |         |          |         |             |          |          |     |              |
| 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%       |     |              |
| <b>Biochemical Pesticides</b>                             |             |          |         |          |         |             |          |          |     |              |
| 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%       |     |              |
| <b>Microbial Pesticides</b>                               |             |          |         |          |         |             |          |          |     |              |
| 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**

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

| Botanical Pesticides                                                   |                                                                                                                                               |          | Cambodia | Lao PDR | Malaysia | Myanmar | Philippines | Thailand | Viet Nam |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>E1</b>                                                              | <b>Human Health Exposure Effects:</b>                                                                                                         |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E2</b>                                                              | <b>Evaluation of Environmental Fate &amp; Effects:</b>                                                                                        |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E4</b>                                                              | <b>Monitoring of environmental effects:</b>                                                                                                   |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E5</b>                                                              | <b>Post-registration data generation</b>                                                                                                      |          |          |         |          |         |             |          |          |
|                                                                        | 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 |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>E1</b>                                                              | <b>Human Health Exposure Effects:</b>                                                                                                         |          |          |         |          |         |             |          |          |
| 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        |
| <b>E2</b>                                                              | <b>Evaluation of Environmental Fate &amp; Effects:</b>                                                                                        |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E4</b>                                                              | <b>Monitoring of environmental effects:</b>                                                                                                   |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E5</b>                                                              | <b>Post-registration data generation</b>                                                                                                      |          |          |         |          |         |             |          |          |
|                                                                        | 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 |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>E1</b>                                                              | <b>Human Health Exposure Effects:</b>                                                                                                         |          |          |         |          |         |             |          |          |
| 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        |
| <b>E2</b>                                                              | <b>Evaluation of Environmental Fate &amp; Effects:</b>                                                                                        |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E4</b>                                                              | <b>Monitoring of environmental effects:</b>                                                                                                   |          |          |         |          |         |             |          |          |
|                                                                        | 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        |
| <b>E5</b>                                                              | <b>Post-registration data generation</b>                                                                                                      |          |          |         |          |         |             |          |          |
|                                                                        | 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 |
|-------------------------------|--------------------------------------------|-------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                                            |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                                            |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                                            |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                                            |             |          |         |          |         |             |          |          |     |              |
| 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 |
|-----------------------------------------------|-------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>                    |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>                   |             |          |         |          |         |             |          |          |     |              |
| 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%           |
| <b>Biochemical Pesticides</b>                 |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>                   |             |          |         |          |         |             |          |          |     |              |
| 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  |
|-----------|--------------------------------------------------------------------------------------------------------------------------|------------------|-----------|-----------|-----------|-----------|-------------|-----------|-----------|
| <b>F1</b> | <b>Labelling</b>                                                                                                         |                  |           |           |           |           |             |           |           |
| 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         |
|           |                                                                                                                          | <b>Sum = 104</b> | <b>10</b> | <b>16</b> | <b>16</b> | <b>16</b> | <b>16</b>   | <b>14</b> | <b>16</b> |
| <b>F2</b> | <b>Packaging</b>                                                                                                         |                  |           |           |           |           |             |           |           |
| 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           |           |           |
|           |                                                                                                                          | <b>Sum = 12</b>  | <b>1</b>  | <b>3</b>  | <b>2</b>  | <b>1</b>  | <b>4</b>    | <b>1</b>  | <b>0</b>  |
| <b>F3</b> | <b>Storage tests (Shelf life)</b>                                                                                        |                  |           |           |           |           |             |           |           |
| R         | Storage tests (Shelf life)                                                                                               |                  | Y         | Y         |           | Y         | Y           | Y         | Y         |
|           |                                                                                                                          | <b>Sum = 6</b>   | <b>1</b>  | <b>1</b>  |           | <b>1</b>  | <b>1</b>    | <b>1</b>  | <b>1</b>  |

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

|           | Biochemical Pesticides                                                                                                   |          | Cambodia | Lao PDR | Malaysia | Myanmar | Philippines | Thailand | Viet Nam |
|-----------|--------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>F1</b> | <b>Labelling</b>                                                                                                         |          |          |         |          |         |             |          |          |
| 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       |
| <b>F2</b> | <b>Packaging</b>                                                                                                         |          |          |         |          |         |             |          |          |
| 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        |
| <b>F3</b> | <b>Storage tests (Shelf life)</b>                                                                                        |          |          |         |          |         |             |          |          |
| 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 |
|-----------|--------------------------------------------------------------------------------------------------------------------------|----------|----------|---------|----------|---------|-------------|----------|----------|
| <b>F1</b> | <b>Labelling</b>                                                                                                         |          |          |         |          |         |             |          |          |
| 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       |
| <b>F2</b> | <b>Packaging</b>                                                                                                         |          |          |         |          |         |             |          |          |
| 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        |
| <b>F3</b> | <b>Storage tests (Shelf life)</b>                                                                                        |          |          |         |          |         |             |          |          |
| 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 |
|-------------------------------|----------------------------|-------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |                            |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |                            |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |                            |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |                            |             |          |         |          |         |             |          |          |     |              |
| 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 |
|-------------------------------|-------------|----------|---------|----------|---------|-------------|----------|----------|-----|--------------|
| <b>Chemical Pesticides</b>    |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Botanical Pesticides</b>   |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Biochemical Pesticides</b> |             |          |         |          |         |             |          |          |     |              |
| 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%          |
| <b>Microbial Pesticides</b>   |             |          |         |          |         |             |          |          |     |              |
| 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<br>If yes, please indicate the number of modified test protocols: _____ | Y = 2    | Y        | N       | N        | N       | N           | Y<br>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 too complicated and extensive to be seen as helpful

## **Lists of banned and restricted pesticides**

|                                                     | <i>Page</i> |
|-----------------------------------------------------|-------------|
| List of all pesticides .....                        | 297         |
| List of Rotterdam Convention pesticides (PIC) ..... | 303         |
| List of Stockholm Convention pesticides (POP) ..... | 304         |



## 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-dichlorophenol                |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|            | 2, 4-dichlorophenol                |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|            | 2, 5-dichlorophenol                |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 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-dichlorophenol        |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 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             |
|            | Bromoxynil/Ioxynil                 |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|            | Butocarboxim                       |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|            | Cadmium compound (Cb)              |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 3             |

| PIC<br>or<br>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             |
|                  | Dinitroresol                     |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
| PIC              | Dinoseb and its salts and esters |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 7             |

| PIC<br>or<br>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             |
|                  | Gliflor                                   |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 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<br>or<br>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 quintozone                                |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 2             |
| POP              | Pentachlorobenzene (PeCB)                      |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 3             |
|                  | Pentachlorophenate sodium                      |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 3             |
| PIC              | Pentachlorophenol/PCP and its salts and esters |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 9             |
|                  | Phenamiphos                                    |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |

| PIC<br>or<br>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             |
|                  | Pyrimuron (piriminil)                 |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Safrole                               |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | <i>Salmonella</i> 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 (tepen 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<br>or<br>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             |
|                  | Vamidithion                                                                  |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Vinyl chloride monomer                                                       |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Zineb                                                                        |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Zinc phosphide                                                               |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 5             |
| Mixtures         |                                                                              |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          |               |
|                  | Na <sub>2</sub> SiF <sub>6</sub> 80% + ZnCl <sub>2</sub> 20%                 |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Methylene bis thiocyanate 10% +<br>2-(thiocyanomethylthio) benzothiazole 10% |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Methylene bis Thiocyanate 5% +<br>Quaternary ammonium compounds 25%          |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | Sodium Tetraborate decahydrate 54% +<br>Boric acid 36%                       |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 1             |
|                  | CuSO <sub>4</sub> 50% + K <sub>2</sub> Cr <sub>2</sub> O <sub>7</sub> 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            |   |
| Heptachlor                                     |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 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            |
| $\alpha$ -HCH             |            |          |       |           |       |            |         |          |         |       |          |             |           |           |          |          | 14            |
| $\beta$ -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

**giz** German Institute for  
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and Development

**ASEAN Biocontrol for Sustainable Agrifood Systems (ABC)**

**Highlights of GIZ-ASEAN harmonization proposal for BCA and common aspects with the regional FAO/TCP guidelines**

Dr Thomas Jäckel  
CIM Expert on Biological Control and Regulatory Affairs to the  
Department of Agriculture, Thailand

On the Occasion of the  
**APPPC Regional Workshop for enhancement of regional collaboration in  
pesticide regulatory management**  
26–30 November 2012, Chiang Mai, Thailand

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**Contents**

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- ❖ Why regulate biocontrol agents?
- ❖ Important BCA in ASEAN and regulatory problems
- ❖ Sources for regulatory guideline development:  
Remarks on the new FAO guidelines for Southeast Asia  
and on others
- ❖ What does regulatory harmonization mean?

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**What are BCA?**

Molecules (e.g. Cry-  
Toxin, pheromones,  
botanical extracts,  
etc.)

*Beauveria*

*Nematode*

*Baculovirus*

*Mycorrhiza*

*Bacillus*

Predator

Parasitic wasp

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**Definition of biocontrol agents (BCA)**

- The classical definition of BCA is based on population processes of biological control and does not provide for satisfactory categorization anymore
  - Application of plant extracts or the use of insect pheromones, if targeted directly at a pest, would not qualify as biological control.
- The term 'biopesticides' implies a killing effect, which is not the working principle of all the products in question.

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**Definition of biocontrol agents (BCA)**

|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>FAO</b></p> <ul style="list-style-type: none"> <li>• (Bio)pesticides           <ul style="list-style-type: none"> <li>• Microbial</li> <li>• Botanical (phyto-chemicals)</li> <li>• Biochemical (semiochemicals, hormones, plant regulators, etc.)</li> </ul> </li> <li>• Biocontrol Agents           <ul style="list-style-type: none"> <li>• Macro-organisms</li> </ul> </li> </ul> | <p><b>IBMA (BCA)</b><br/>(International Biocontrol Manufacturers' Association)</p> <ul style="list-style-type: none"> <li>• Microbials</li> <li>• Macro-bials</li> <li>• Botanicals</li> <li>• Semiochemicals</li> </ul> | <p><b>BCPC (BCA)</b><br/>(British Crop Protection Council):</p> <ul style="list-style-type: none"> <li>• Micro-organisms</li> <li>• Macro-organisms</li> <li>• Natural products</li> <li>• Semiochemicals</li> </ul> <p>Natural products:<br/>• Compounds/molecules with a claim for acrop effect, derived from living organisms ('nature')</p> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**Definition of biocontrol agents (BCA)**

- ❖ ASEAN Regional Expert Group on Regulation has agreed to work with the BCPC definition
- ❖ Advantage: 'Natural Products' allows for inclusion of various products with a crop effect that are difficult to categorize otherwise
- ❖ Categorization reflects market structure rather than scientific definitions
- ❖ Abamectin (and related compounds) excluded

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## 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

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## 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'
    - ▶ Microbials, Semiochemicals: Would they need regulation at all?
    - ▶ Microbials: environmental aspects relevant (exotic vs. native; how within-ASEAN trade?)

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## 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)<br>Well documented safe use                                                |
| Nematodes (EPN) | Background population in nature<br>Long time experience with no problems<br>Low risk for spreading (aggregation)                          |
| SCLP Pheromones | Short-chained lepidopteran pheromones, substantially reduced data requirements (OECD):<br>Non-toxic, target specific, naturally occurring |
| Macrobiais      | No toxins produced<br>No allergic reaction                                                                                                |

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## 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

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### 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.)

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## 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                                                                                                                                                                                                                                              |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Microbials     | <ul style="list-style-type: none"> <li>▶ Leading users of BCA in ASEAN: Indonesia, Thailand, Viet Nam</li> <li>▶ Most important group (Bt. market leader)</li> <li>▶ Significant taxonomic and analytical problems</li> <li>▶ Post-registration quality check needed</li> </ul> |
| 2. Botanicals     | <ul style="list-style-type: none"> <li>▶ Market size second to microbials in ASEAN (Neem most abundant product)</li> <li>▶ Significant analytical problems due to complex mixture of ingredients</li> </ul>                                                                     |
| 3. Semiochemicals | <ul style="list-style-type: none"> <li>▶ Use patchy (e.g. plantations), many not registered</li> <li>▶ No field testing protocols</li> <li>▶ Large future potential, pheromones could become useful and economic tools if requirements were relaxed</li> </ul>                  |
| 4. Macrobiais     | <ul style="list-style-type: none"> <li>▶ Rarely produced and traded (by local companies); mainly used by government programmes</li> <li>▶ Most ASEAN countries do not regulate macrobiais: import and release covered by international guidelines (e.g. FAO)</li> </ul>         |

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## 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

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- ▶ 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.

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## Sources for regulatory guideline development

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- 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-targeted safety (infectious organisms that do not infect would not necessarily need a tox-study)
    - Common skin-, inhalation-, injection-tox inappropriate for many microbials

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## Sources for regulatory guideline development

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- 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!

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## Sources for regulatory guideline development

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- 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)

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## 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                          | <ul style="list-style-type: none"> <li>More emphasis on existing scientific information than on prescribed tests; non-target safety well documented</li> <li>Environmental fate and behaviour minor concern in risk assessment of regulatory authorities worldwide</li> <li>Genetic 'stability' problematic, erase</li> </ul> |
| Macrobials                          | <ul style="list-style-type: none"> <li>Harmonize import and release of non-native species</li> <li>Harmonize environmental risk assessment (ERA)</li> </ul>                                                                                                                                                                   |
| Natural Products (here: Botanicals) | <ul style="list-style-type: none"> <li>Plant extracts complex mixtures, analytical methods should be focusing on active substances or substances of concern</li> <li>Waiving of data based on history of safe use</li> </ul>                                                                                                  |
| Semiochemicals                      | <ul style="list-style-type: none"> <li>Rationales for relaxation of data requirements available; exemption from registration could be considered</li> <li>Protocols for efficacy testing need to be adapted for semiochemicals (and for other BCA as well)</li> </ul>                                                         |

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## 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

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## 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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**FAO Regional Office for Asia and the Pacific**

39 Phra Atit Road, Bangkok 10200, Thailand

Tel: (66 2) 697 4000 Fax: (66 2) 697 4445

E-mail: [FAO-RAP@fao.org](mailto:FAO-RAP@fao.org)

Website: <http://www.fao.org/asiapacific>

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