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PROGRESS IN PESTICIDE RISK ASSESSMENT AND PHASING-OUT OF HIGHLY HAZARDOUS PESTICIDES IN ASIA

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PESTICIDES IN ASIA**

**FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC
Bangkok, 2015**

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FOREWORD

FAO considers reduced reliance on pesticides as a principle element of its focus on Sustainable Production Intensification and Pesticide Risk Reduction through judicious selection of pesticides and proper pesticide management. Pillars of FAO's work in this area are its programme to promote the implementation of the new *International Code of Conduct on Pesticide Management* and providing the secretariat for the *Rotterdam Convention* for the part that concerns pesticides. Related work areas also include pesticide residues, pesticide specifications, and prevention and disposal of obsolete pesticides.

Over the past 30 years, the FAO Regional Office for Asia and the Pacific has assisted countries in the Asia and Pacific region in establishing pesticide legislation and regulations, and in managing these products in accordance with the *Code of Conduct* and other international conventions and treaties. Over the past years, the Office has organized a number of regional workshops aimed at enhancing harmonization among countries' regulatory framework for the control of pesticides. In 2012, the Regional Workshop on *Enhancement of regional collaboration in pesticides regulatory management* was held in Chiang Mai, Thailand, and reviewed national pesticide regulatory management systems in view of recommendations in the revised *International Code of Conduct on the distribution and use of pesticides* and five harmonization guidelines that were developed for Southeast Asia under a TCP project titled "*Assisting countries in Southeast Asia towards achieving pesticide regulatory harmonization*".

Recent events included a workshop on *Practical aspects of pesticide risk assessment and phasing out of highly hazardous pesticides*, which was held in Nanjing, China from 19 to 22 May 2014. This workshop aimed specifically on a number of practical aspects of pesticide management that were identified in the earlier workshops as areas for further attention. It also introduced the latest revision of the *Code of Conduct* which was adopted in 2013 under the new name of *Code of Conduct on pesticide management*.

This publication describes the updated status of pesticide risk reduction and progress in phasing out of highly hazardous pesticides in Asian countries. It further contains databases of registered and banned pesticides as well as important documents from the Nanjing workshop which could serve as a reference and encouragement to enhance closer collaboration among countries regarding the continuation of phasing out hazardous pesticides and other aspects of pesticide management. This will not only safeguard against adverse effects of pesticides to human health and the environment, but will also promote sustainable agricultural development for meeting the challenges of the future.



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LIST OF ACRONYMS

a.i.	active ingredient
ADI	Acceptable daily intake
AOEL	Acceptable Operator Exposure Level
APPPC	Asia-Pacific Plant Protection Commission
ARfD	Acute reference dose
ASEAN	Association of Southeast Asian Nations
CAS	Chemical Abstracts Service
CCPIA	China Crop Protection Industry Association
CMR	GHS category for carcinogenic, mutagenic and reproductive toxic substances
DG SANCO	Directorate General for Health and Consumer Affairs.
DOA	Department of Agriculture
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good agricultural practices
GHS	Globally harmonized system
HHP	Highly hazardous pesticides
ICAMA	Institute for the Control of Agrochemicals, Ministry of Agriculture
ILO	International Labour Organization
KemI	Swedish Chemicals Agency
MAFF	Ministry of Agriculture, Forestry and Fisheries
MOA	Ministry of Agriculture
MRL	Maximum residue Limits
MSDS	Material safety data sheet
NA	Not available
NGO	Non-governmental organization
NOEC	No observed effect level
OECD	Organisation for Economic Co-operation and Development
OPR	Office of Pesticide Registrar
PAN	Pesticide Action Network
PCD	Pesticide Control Division
PIC	Prior Informed Consent (Rotterdam Convention)
POP	Persistent organic pollutants (Stockholm Convention)
PPD	Plant Protection Department
PPDS	Plant Protection Sub-Department (Vietnam)
PRB	Pesticide Registration Board
PGR	Plant Growth Regulator
PRMD	Pesticide Registration and Management Division
QC	Quality control
RM	Reference material (for drinking water quality)
SAICM	Strategic Approach to International Chemicals Management
TCP	Technical Cooperation Programme
USD	United States dollar
US-EPA	United States Environmental Protection Agency
WHO	World Health Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

The publication “Progress in pesticide risk assessment and phasing out of highly hazardous pesticides in Asia” is based on the outputs from a regional workshop that was organized in Nanjing, China from 19 to 22 May 2014 for the purpose of informing Asian countries about new developments and encouraging them to join the international efforts to reduce pesticide risks and create a less toxic agricultural environment.

Aiming chiefly at countries with limited resources for implementing their regulatory framework for the control of pesticides, the objectives of the publication were to summarize to what extent use can be made of registration data from countries with advanced risk assessment procedures; present experiences related to the phasing out of highly hazardous pesticides (HHP); explore scope for collaboration in the review of new chemicals and current highly hazardous products; discuss mechanisms for collaboration among countries in addressing the problem of fake and substandard products; and provide updates on new developments, such as the revision of the *Code of Conduct* and the reforms of China’s labeling and Japan’s registration system.

The chapters of the publication cover how to check the registration status in other countries, obtain risk assessment information and justifications on regulatory actions, share lists of HHPs and alternatives, share reports on health and environmental incidences, as well as findings from monitoring for fake or substandard pesticides. Countries are encouraged to take appropriate actions based on the new *Code of Conduct on pesticide management* in reviewing the use of HHPs and in conducting basic risk assessment when considering registration of new compounds.

The publication shows that significant achievements have been made in the past five years. At the same time, a number of issues for the way forward and areas of collaboration are indicated. Increased efforts for risk assessment are needed in many countries to justify regulatory decisions, particularly with regard to highly hazardous chemicals. Even though almost all countries consider risk as part of the registration procedure, only a few have the resources and capacity to carry out a full risk assessment that includes the assessment of local exposure data. Most registration authorities primarily assess pesticide hazards based on a review of toxicological data. However, they also need mechanisms to review the risk of already registered substances as new information becomes available.

Increased efforts are also needed to supervise the pesticide market and the products that are sold, conduct research of their safety and risks, and regulate the international flow of these chemicals. For a successful economic and social development of the Asia region, countries need to work together and exchange information related to regulatory actions; technical information on risk assessment and phasing out of HHP; and cooperation on cracking down on substandard products and illegal trade.

The lists of registered, banned and restricted pesticides collected from 15 countries are included in the publication as a regional database of pesticides. Detail update information on the list relating to a country might be available by contacting authority of pesticide registration in the country.

1. INTRODUCTION AND NEW DEVELOPMENTS

1.1 BACKGROUND

Over the past 30 years, the FAO Regional Office for Asia and the Pacific has assisted countries in the Asia and Pacific region in establishing pesticide legislation and regulations, and in managing these products in accordance with the *Code of Conduct* and other international conventions and treaties. These efforts were closely coordinated with the Asia-Pacific Plant Protection Commission (APPPC) for which the FAO Regional Office also provides the secretariat.

Over the past 10 years, FAO has organized a number of measures to strengthen pesticide management in the region. In 2005, it organized a regional workshop on *Implementation, monitoring and observance of the International code of conduct on the distribution and use of pesticides* which included a questionnaire survey that produced country profiles on the status of pesticide management and the implementation of the Code.

Recognizing that access to information is an important instrument in the development of agriculture, these country profiles were expanded in 2007 to cover all aspects of pest and pesticide management and all member countries of the APPPC. They were published as *Plant protection profiles from Asia-Pacific countries* and have been updated in 2009 and 2011 to provide accurate and structured tables and lists for an efficient and transparent exchange of critical information on laws, infrastructure and activities as an important means to improve regional cooperation and development.

To promote greater pesticide regulatory harmonization, FAO implemented from 2009 to 2011 a project under its Technical Cooperation Programme (TCP) titled *Assisting countries in Southeast Asia towards achieving pesticide regulatory harmonization*. The project provided the necessary technical inputs to achieve regulatory harmonization as well as training to increase the capacities of the regulatory agencies. In particular, it produced a set of guidelines to support the countries in their efforts to harmonize their registration systems. These guidelines were published by FAO under the title *Guidance for harmonizing pesticide regulatory management in Southeast Asia*.

As a follow-up to the harmonization project, a regional workshop on *Enhancement of regional collaboration in pesticides regulatory management* was held in 2012 in Chiang Mai, Thailand. The workshop reviewed the national pesticide regulatory management systems considering the recommendations in the revised *International Code of Conduct* and the five harmonization guidelines that were developed for Southeast Asia under the TCP project.

Although countries are aware of internationally recommended procedures for the registration of pesticides, there are often impediments that prevent the application of full-fledged registration procedures. This is particularly the case for countries with limited human and financial resources. Assessing the human and environmental risks of pesticides in a comprehensive, science-based manner is a complex and expensive task for which many countries lack the expertise and resources. However, phasing out internationally recognized highly hazardous pesticides (HHP) is a first step toward reducing pesticide risks which every country can take.

To address these issues, a regional workshop on *Practical aspects of pesticide risk assessment and phasing out of highly hazardous pesticides* was organized in Nanjing, China from 19 to 22 May 2014. It was attended by 27 delegates from 15 Asian countries as well as by resource persons from FAO

and the Swedish Chemicals Agency (KemI). (See Annex 4 for workshop programme and list of participants)

This workshop aimed chiefly at countries with limited human and financial resources for implementing their regulatory framework for the control of pesticides. The comprehensive risk assessment procedures that are followed in the EU, US and other more advanced countries were presented to explain the methodologies followed. Several Asian countries also have well developed procedures. The workshop included practical demonstrations on how countries with limited resources can make use of risk assessment information available from more advanced countries. Furthermore, the workshop explored the scope and mechanisms for collaboration among the Asian countries for the phasing out of HHPs and other aspects of pesticide management.

More specifically, the purpose of the workshop was to...

- review to what extent use can be made of registration data from countries with advanced risk assessment procedures;
- exchange experiences related to the phasing out of highly hazardous pesticides, with emphasis on practical aspects of such phasing out;
- explore scope for collaboration in the review of new chemicals and current highly hazardous products;
- discuss mechanisms for collaboration among countries in addressing the problem of fake and substandard products;
- provide updates on new developments, such as the revision of the International Code of Conduct and the reforms of China's labeling and Japan's registration system.

In preparation to the workshop a questionnaire survey was conducted to collect information on the status of pesticide registration, risk assessment, HHP and quality management. Furthermore, lists of banned, restricted and registered pesticides were collected. The results from this survey are presented in the Annexes.

The workshop was divided into four parts:

- (1) Pesticide registration and risk assessment;
- (2) Phasing out of highly hazardous pesticides (HHP);
- (3) Cracking down on fake and substandard pesticides; and
- (4) New developments.

The sessions demonstrated and discussed how to check the registration status in other countries, obtain risk assessment information and justifications on regulatory actions, share lists of HHPs and alternatives, share reports on health and environmental incidences, as well as findings from monitoring for fake or substandard pesticides. Countries were encouraged to take appropriate actions in reviewing the use of HHPs and in conducting basic risk assessment when considering registration of new compounds.

The suggested strategy for phasing out HHPs was based on the new *Code of Conduct on pesticide management* and its recommendation.

1.2 NEW INTERNATIONAL DEVELOPMENTS

1.2.1 Revised Code of Conduct on pesticide management

Since its first adoption in 1985 by the FAO Conference of Parties, the *International Code of Conduct on the distribution and use of pesticides* has been revised several times. The latest revision was approved in June 2013 by the 38th FAO Conference under the new name *Code of Conduct on pesticide management*. In January 2014, it was also formally adopted by WHO. Thus for the first time, a unified code was created for all pesticides used in agriculture and public health.

The Code of conduct is a voluntary standard that covers all aspects of pesticide management and serves as a point of reference for governments and the pesticide industry. It is accepted by all main stakeholders, i.e. governments, industry, public interest groups and farmer organizations. It considers pesticide management as an integral part of chemicals management as well as of sustainable agricultural development.

The main changes in the new version are:

- Inclusion of public health pesticides and Integrated Vector Management
- Updated definitions
- More emphasis on health and environment
- Introduction of GHS for classification and labelling
- Several minor text changes to better align with new developments
- Change of title to reflect life-cycle approach

The most important updated definitions in the new *Code of Conduct* are:

Pesticide means any substance, or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any **pest**, or regulating plant growth.

Pest means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products, materials or environments and includes vectors of parasites or pathogens of human and animal disease and animals causing public health nuisance.

Risk is the probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to a pesticide.

Highly Hazardous Pesticides means pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in relevant binding international agreements or conventions. **In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous**

Other new definitions include: Integrated Vector Management; Pest Control Operator; public health uses of pesticides; vulnerable groups; pesticide management; life cycle; container; co-formulant; and specification.

With regard to highly hazardous pesticides, the new *Code of Conduct* recommends:

7.5 Prohibition of the importation, distribution, sale and purchase of **highly hazardous pesticides** may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment.

The *Code of conduct* advises governments to ...

6.1.1 introduce the necessary policy and legislation for the regulation of pesticides, their marketing and use throughout their life cycle, and make provisions for its effective coordination and enforcement, including the establishment of appropriate educational, advisory, extension and health-care services, using as a basis FAO and WHO guidelines and, where applicable, the provisions of relevant legally binding instruments. In so doing, **governments should take full account of factors such as local needs, social and economic conditions, levels of literacy, climatic conditions, availability and affordability of appropriate pesticide application and personal protective equipment;**

For the first time, reference is made to children in line with the ILO Convention.

6.1.2 as recommended by the International Partnership for Cooperation on Child Labour in Agriculture, introduce legislation to **prevent the use of pesticides by and sale of pesticides to children**. The use of pesticides by children in a work situation should be included in National Hazardous Work Lists for children under ILO Convention No. 182 on the Worst Forms of Child Labour in countries which have ratified it;

The pesticide industry is advised to...

8.2.9 not knowingly supply pesticides that are restricted for use by particular groups of users, for sale to unauthorized users.

Governments are also advised to facilitate the exchange of information for

9.1.2.4 cases of counterfeit and illegal pesticides being traded;

9.1.2.5 poisoning and environmental contamination incidents data;

and to...

9.4.1 support the process of information exchange and facilitate access to information on matters including pesticide hazards and risks, residues in food, drinking water and the environment, the use of pesticides in or on non-food products, IPM/IVM, pesticide efficacy, alternatives to highly hazardous pesticides and related regulatory and policy actions;

In support of the Code of Conduct, an extensive set of technical guidelines has been developed by the FAO/WHO Joint Meeting on Pesticide Management, which guides the preparation and ensures their independence and quality. A pesticide registration toolkit is under development.

These technical guidelines provide more detailed guidance on the following specific areas of the Code of Conduct, such as legislation; policy; registration; compliance and enforcement; distribution and sales; use; application equipment; prevention and disposal of obsolete stocks; post registration surveillance; and monitoring observance of the Code.

The new version of the Code of Conduct, the guidelines and other tools can be found on the FAO website <http://www.fao.org/agriculture/crops/core-themes/theme/pests/en/>.

1.2.2 FAO Policy on HHP

In 2006, the FAO Council mandated FAO to step-up its work on risk reduction and HHPs. Specifically, it suggested:

“In view of the broad range of activities envisaged within SAICM, the Council suggested that the activities of FAO could include risk reduction, including the progressive ban on highly hazardous pesticides,”

In follow-up to the Council's guidance, the FAO/WHO Joint Meeting on Pesticide Management formulated criteria for HHPs. It followed the definition of HHPs in the revised Code of Conduct which refers to WHO and GHS hazard criteria, but also includes a flexible criterion to include pesticides that cause severe or irreversible harm to health or the environment under conditions of use in a country.

While still under discussion, the FAO/WHO Joint Meeting on Pesticide Management formulated the following identification criteria:

- Pesticide formulations that meet the criteria of classes IA or IB of the **WHO Recommended Classification of Pesticides by Hazard**; or
- Pesticide active ingredients and their formulations that meet the criteria of **carcinogenicity Categories 1A and 1B of the Globally Harmonized System** on Classification and Labelling of Chemicals (GHS); or
- Pesticide active ingredients and their formulations that meet the criteria of **mutagenicity Categories 1A and 1B of the GHS**; or
- Pesticide active ingredients and their formulations that meet the criteria of **reproductive toxicity Categories 1A and 1B of the GHS**; or
- Pesticide active ingredients listed by the **Stockholm Convention** in its Annexes A and B, and those meeting all the criteria in paragraph 1 of annex D of the Convention;
- Pesticide active ingredients and formulations listed by the **Rotterdam Convention** in its Annex III; or
- Pesticides listed under the **Montreal Protocol**; or
- Pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

For the management of HHPs, the following specific recommendations in the *Code of Conduct* apply:

- **3.6** Pesticides whose handling and application require the use of personal protective equipment that is uncomfortable, expensive or not readily available should be avoided, especially in the case of small-scale users and farm workers in hot climates.
- **7.5** Prohibition of the importation, distribution, sale and purchase of **highly hazardous pesticides** may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment.
- **9.4** All entities addressed by this Code should:
- **9.4.1 support the process of information exchange and facilitate access to information on matters including** pesticide hazards and risks, residues in food, drinking water and the environment, the use of pesticides in or on non-food products, IPM/IVM, pesticide efficacy, **alternatives to highly hazardous pesticides and related regulatory and policy actions;**

To phase out HHPs in their territories, countries can do the following:

1. Identify HHPs registered and in use (paying special attention to local conditions of use);
2. Evaluate the risk to human health and hazard to the environment (pay special attention to current use practices);
3. If needed, conduct a survey to map the extent of use and related risks;
4. Assess whether their availability is really necessary and what alternatives are available:
 - a. Where possible, take regulatory action to phase out the products concerned. Provide guidance about alternatives where needed;
 - b. Where not possible, consider what risk mitigation action can be applied (e.g. restricted use, different formulation, stricter PPE requirements);

5. Establish, strengthen and maintain monitoring and reporting systems for health and environmental impacts of pesticides.

Experience has shown that some countries are afraid of phasing out certain chemicals for fear of damage to agricultural production, while in countries that have actually phased out these products there had been no problems. Sharing of information could thus be important in mitigating such fears.

To support each other in the efforts to phase out HHPs, countries can collaborate in the following specific areas:

1. Share data from monitoring and reporting systems for health and environmental impacts of pesticides;
2. Share information on examples of successful phasing out of HHPs and viable alternatives;
3. Share information on related regulatory and policy actions.

To support national governments and pesticide registration authorities in their efforts, the FAO/WHO Joint Meeting on Pesticide Management is in the process of preparing guidelines on phasing out HHPs.

1.3 SUMMARY AND CONCLUSIONS

Pesticide management is a dynamic field as evident from the latest revision of the *Code of Conduct* and other international developments. Over the years, the focus of regulatory management has shifted from controlling the quality of products to assessing their human and environmental risks in order to safeguard human health and the environment from the potential harmful effects of these chemicals. Developments in Asia have followed international trends, and FAO and APPPC have had a leading role in strengthening pesticide regulatory management in the region. The latest workshop on *Practical aspects of risk assessment and phasing out of HHPs* was highly relevant to the present situation and challenges of the future. It followed the recommendations of the new *Code of Conduct* and FAO's policy on HHPs. Countries were made aware of new developments and international efforts to reduce pesticide risks and create a less toxic agricultural environment.

The *Code of Conduct* encourages countries to regulate all pesticides used in their territory under a single national authority and to optimize the use of limited resources. The complexity of risk assessment and new classes of pesticides make pesticide registration an increasingly complicated task, especially for countries with limited human resources and infrastructure. Therefore international cooperation on a regional basis is increasingly required to evaluate risks and to exchange experiences on poisoning and environmental contamination incidents, as well as regulatory actions. The adoption of international standards and work sharing will ensure higher quality, save resources and better protect human health and the environment.

The phasing out of HHP is an international and Asian goal. However, more effort is needed to agree on a common approach, harmonize regulatory management and exchange information in order to create a non-toxic agricultural environment as a healthy foundation for a sustainable economic and social development.

2. PESTICIDE REGISTRATION

2.1 STATUS OF PESTICIDE REGISTRATION IN ASIA

Status of registered products

The questionnaire survey that was conducted in 2014 in preparation for the *Regional workshop on risk assessment and phasing out of HHPs* showed a great diversity in approaches to pesticide registration (for the complete results, see Annex 3). The number of registered formulated products per country ranged from 119 to more than 30 000 (Figure 1), while the number of registered active ingredients ranged from 79 to 645. A high ratio between the numbers of formulated products versus active ingredients indicates numerous registrations for the same pesticide chemical. For example, five countries had more than 100 registered products containing Cypermethrin, while two countries had more than 100 products containing Abamectrin. There were clear differences between the countries: while some countries had on average more than 20 registrations per pesticide chemical, others had fewer than three (Figure 2). Numerous products with the same active ingredient are likely to confuse customers when selecting a pest control product. In such situations, farmers' main sources of pesticide information may be advertisements

and salesperson recommendations rather than knowledge of its chemical properties. They may be unaware of applying the same chemical repeatedly in different commercial products. This could increase the number of unnecessary applications and raise the risk of pest resistance.

Most Asian countries have a registration validity period of 3-5 years. However, there were notable exceptions with one country having only a 2-year period, while another had a 10-year period. Some countries (India, Mongolia and Singapore) grant indefinite registration periods. While a short registration period may overburden the registration authority, unlimited registration periods make it difficult to know the number pesticides used in the country. Furthermore, these countries lack a routine regulatory procedure to review pesticide registrations in view of new risk information or pest control needs.

Figure 1: Number of registered formulated products

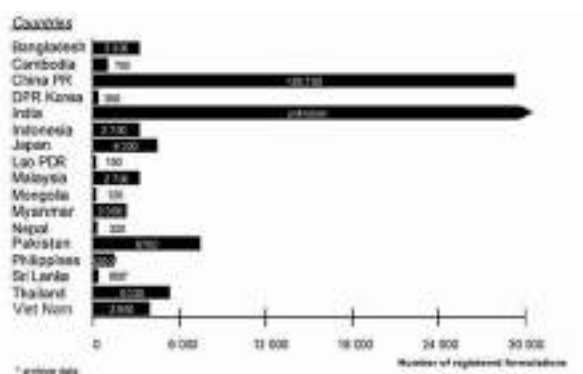
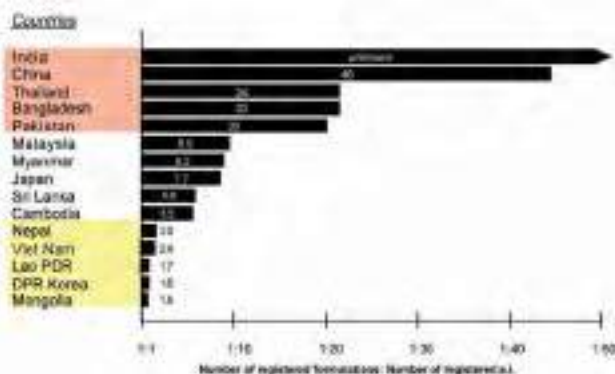


Figure 2: Ratio formulations vs. active ingredients



In total, there were about 1 170 active ingredients registered in Asian countries (see also Annex 1). Surprisingly, half of these pesticides were only registered in a single country. Only 88 active ingredients were widely used and registered in 10 or more countries. While many of these single-country registrations were modern, recently developed pesticides, biopesticides or plant growth regulators, others were outdated or rare products that were refused registration in other countries. When a pesticide is only used in a single country, it may be difficult to obtain risk information or learn from experiences in other countries. It was noticed that the majority of these products (88%) have not been rated by the *WHO Recommended classification of pesticides by hazard* or evaluated in the EU.

Status of banned pesticides

All countries in Asia use banning as a regulatory action to withdraw a pesticide from use in their country. However, the number of banned products ranged widely from 4 to 164, showing different approaches to the use of this regulatory instrument. Half the pesticides banned in Asia were only banned in a single country; 77 pesticides have been banned in 3 or more countries. Only Dieldrin was banned in all surveyed countries (see also Annex 2).

Status of restricted use pesticides

Most countries have restricted the use of one or more pesticides because of health or environmental concern. In total, there were 112 active ingredients that have been restricted in Asia. The number of restricted products per country varied widely between 1 and 109. Also, the reasons for restricting a registration varied greatly. While most countries restricted the use of highly hazardous pesticides to persons with special safety training or equipment (e.g. fumigation applicators), other countries counted general household pesticides or those registered for specific crops as restricted use pesticides.

Status of Convention pesticides

Due to the different approaches to banning or restricting the use of a pesticide, there is no uniform regulatory response to the pesticides listed by the Stockholm or Rotterdam Conventions or the Montreal Protocol. Only one pesticide (Dieldrin) has been banned in all 15 surveyed countries. Of the total of 35 convention pesticides, only 15 have been banned in ten or more countries.

Figure 3: Frequency of regional registrations

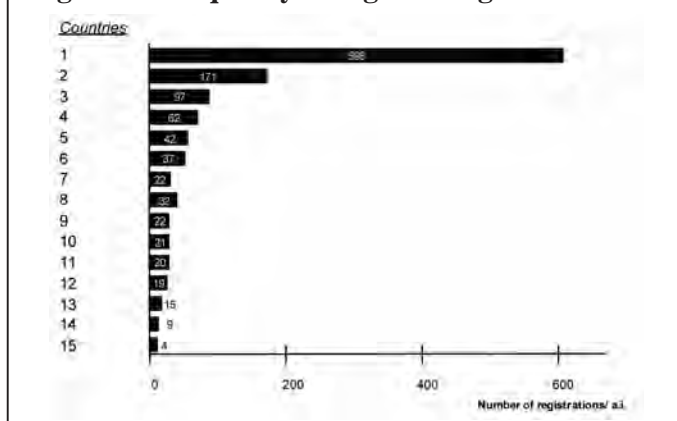


Figure 4: Number of banned active ingredients

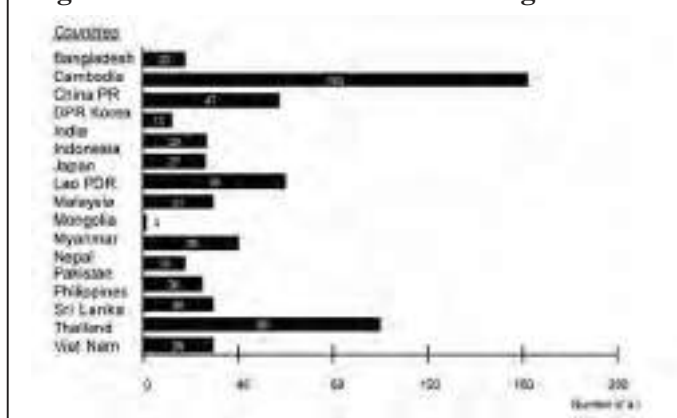
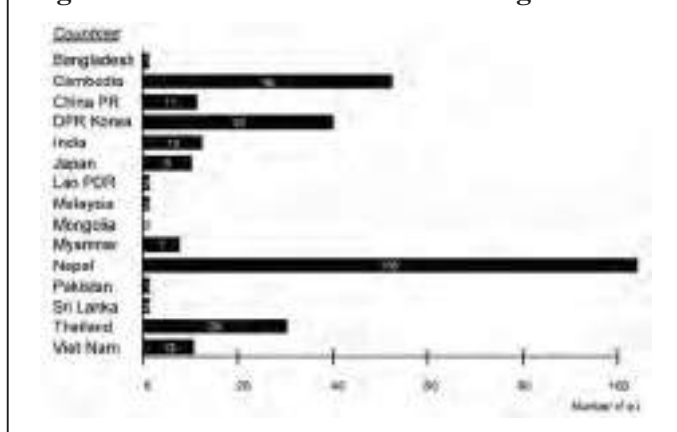


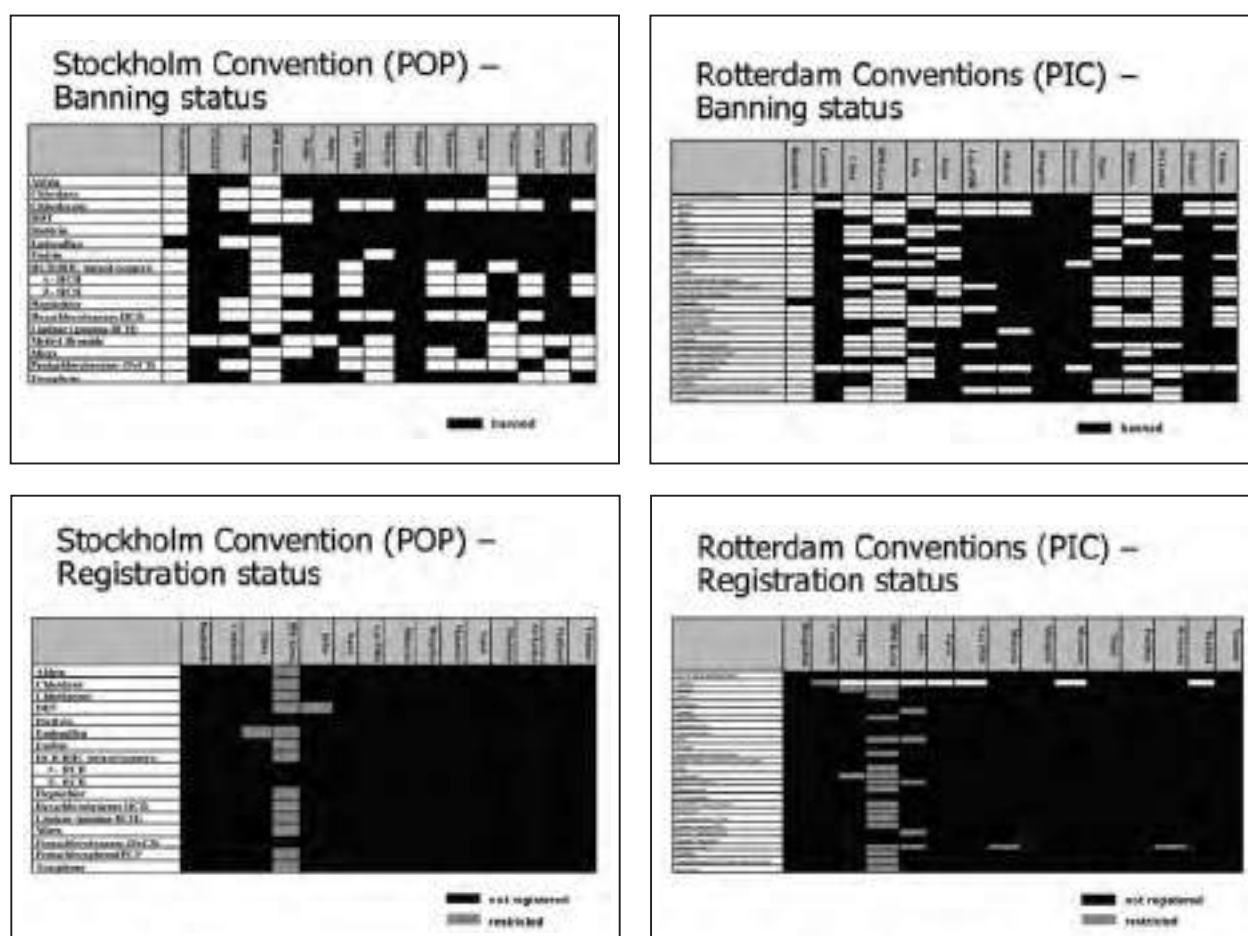
Figure 5: Number of restricted use registrations



Even without banning, pesticides are legally forbidden when they have never been registered or their registration has expired. Under this aspect, all Stockholm Convention pesticides in Asia are either not registered or their registration is restricted (Figure 6). While in most countries the Stockholm Convention pesticides have been totally withdrawn, 13 of these persistent organic pollutants are still registered for restricted use in DPR Korea.

With regard to the Rotterdam Convention, a similar situation emerged insofar most of the pesticides were not registered in Asia. Only Alachlor carried regular registrations in six countries, while five pesticides were registered for restricted use in two or more countries. Again, most Rotterdam Convention pesticides were registered for restricted use in DPR Korea.

Figure 6: Banning and registration status of Convention pesticides



With regard to the Montreal Protocol, Methyl Bromide was still registered for restricted use in eight countries, and for unrestricted use in one country.

Information exchange on pesticide registration

In preparation to the regional workshop on risk assessment and phasing out of HHPs, the country lists of registered active ingredients were collected and combined in a single document that allowed comparisons and analyses (Annex 1). It is now available to all countries and registration authorities can find out where a certain pesticide is registered and obtain further information.

For more detailed information on registered formulated products, a number of countries have published their pesticide registration information on internet sites. However, some of these websites are only

available in the national language. Persons from other countries may be able to access this information with the use of automatic website translation engines that may give them a general understanding of the content of foreign language web pages. In Asia, the following internet sites with registration information are available:

China

The website <http://www.chinapesticide.gov.cn/index.html> has both a Chinese and English part. The English part of the website does not yet cover all Chinese pages, but it includes a search engine that allows looking up the registration status of individual products in China.

Japan

The website <http://www.acis.famic.go.jp/searchF/vtllm000.html> is only available in Japanese. It was developed by the Food and Agricultural Materials Inspection Center (FAMIC) and makes it possible to search for registrations, active substances, etc., and it is possible to see GAP tables for approved pesticides. The development of an English version is under discussion. Since 2012, Ministry of Agriculture, Forestry and Fisheries (MAFF) has published assessment reports for registered pesticides at their website in order to improve the general public's access to information and to improve transparency of the decision making process for pesticides. The list of registered active ingredients in English is included in Annex 1.

Malaysia

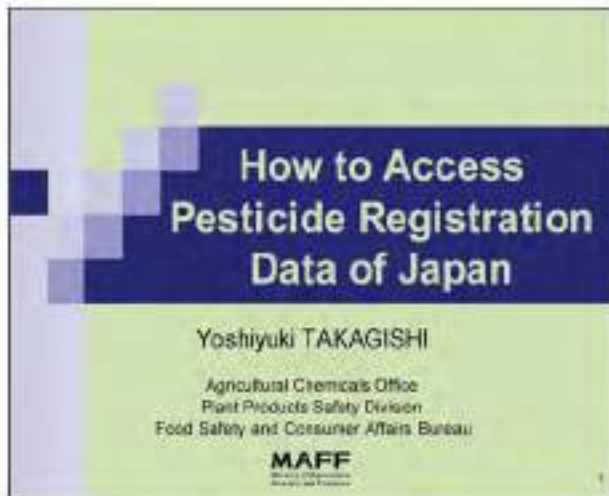
Information about the various rules and regulations under the Pesticide Act are available on the website of Department of Agriculture. The *Highly Toxic Pesticides Regulations* of 1996 regulate the management of HHPs. The <http://www.doa.gov.my/web/guest/senarai-racun-makhluk-perosak-berdaftar> website has an English version and it is possible to find information on registered pesticides, such as active substance, concentration, trade name, usage, etc. There is also a pesticide information system (SISMARP) website in Bahasa Malaysia language that provides pesticide recommendations for different crops and pests for farmers and extension agents.

Thailand

Thailand has some information related to pesticide registration available on-line, but only in Thai language. The website contains information on the types of registrations and the registration procedure. About 71% of the registered pesticides are imported from China. Some of the documents available online (in Thai language) are the *Hazardous Substance Act* and registration application forms. The Royal Thai Government Gazette website www.ratchakitcha.soc.go.th publishes the government notifications.

2.2 PRESENTATIONS

2.2.1 How to assess pesticide registration data of Japan by Yoshiyuki Takagishi



Data of registered pesticide

Registration No.	Registration date	Expiration date
Common name (Active ingredients and formulation type)		
Commercial name		
Contents of active ingredient(s)		
Contents of other ingredients		
Name and address of the manufacturer		
GAP table		

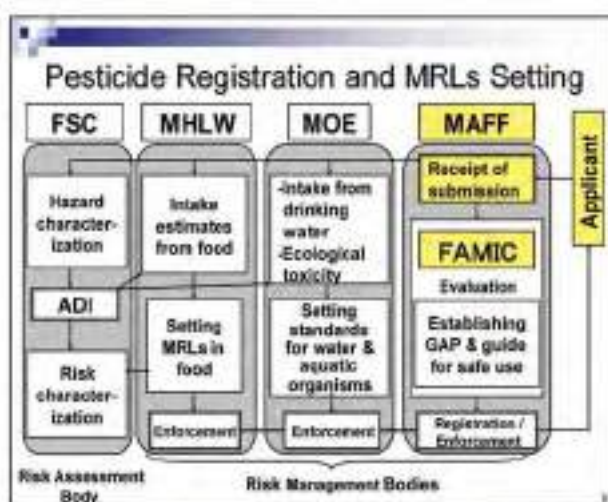
Click

-Click the GAP table to see the approved use pattern

Contents of GAP table

Crops	Pest or group of pests controlled	Application rate (g, kg/10a)	Pre or growth stage	Type of application (e.g. foliar spray, soil treatment)	Maximum number of applications (excluding the seed)
Apple	Apple scab, etc.	100g/10a	From bud break to fruiting	Foliar spray	3
Wheat	Wheat rust, etc.	50g/10a	From jointing to grain filling	Foliar spray	2
Orange	Orange rust, etc.	100g/10a	From bud break to fruiting	Foliar spray	3

GAP table:
Crops, pests controlled, method of application, etc.
(as approved under the Agricultural Chemicals Regulation Law)



Assessment Report for Registration

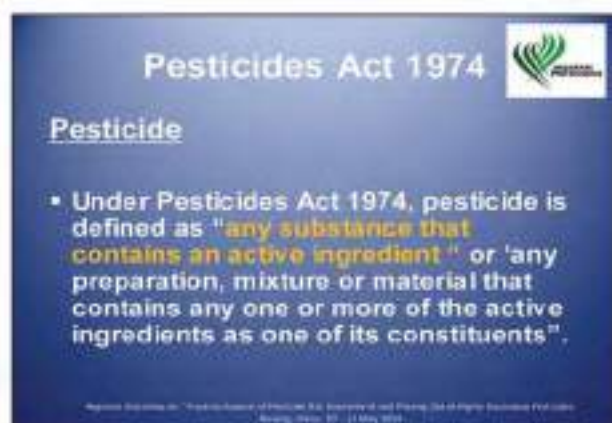
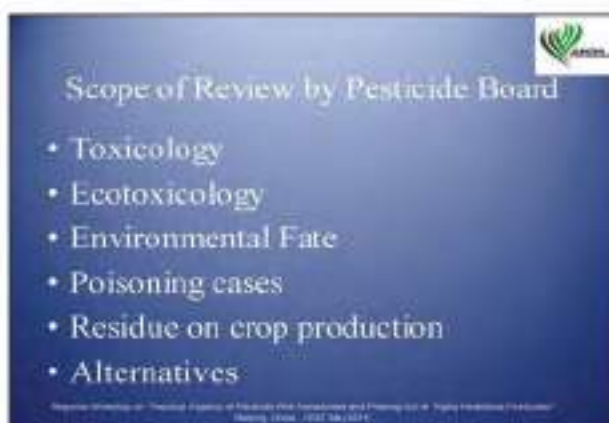
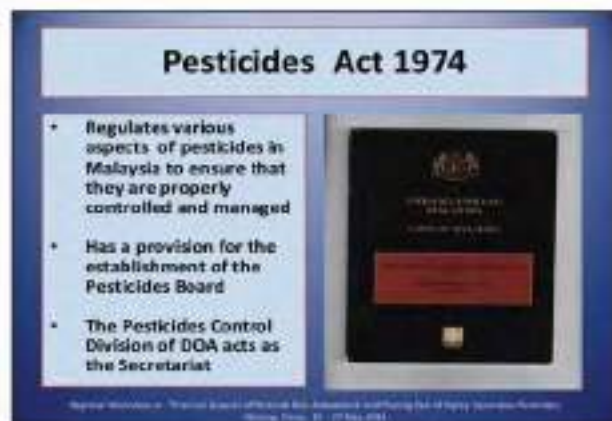
- MAFF publishes assessment reports for registered pesticides (available only in Japanese)
http://www.maff.go.jp/nouyakuin_sinsai/index.html
- Covers summaries of assessment by 4 relevant ministries including the following areas:
 - Information on a.i. / formulation; method of analysis; effects on human and animal health; residues; environmental fate; effects on non-target organisms; efficacy / phytotoxicity
- Published for 8 pesticides since September 2012

Improve the Transparency of Decision Making Process for Pesticide Registration

Assessment Report for Registration

- For other remaining pesticides, assessment reports are published **independently** by each ministry
 - Toxicological evaluation (establishment of ADI) by FSC
<http://www.fsc.go.jp/fscis/evaluationDocument/list?itemCategory=001>
 - Dietary Exposure assessment and MRL setting by MHLW
<http://www.mhlw.go.jp/stf/shingi/2r985200000008fcs.html>
 - Establishment of standards for water and aquatic organisms by MOE
 - (For Water) http://www.env.go.jp/water/dojo/nouyaku/odaku_kijun/kijun.html
 - (For Aquatic organisms) <http://www.env.go.jp/water/sui-kaitai/kijun.html>

2.2.2 How to assess pesticide registration data of Malaysia by Atikah Abdul Kadir Jailani



Pesticides Act 1974 - Provisions



1. Pesticides Registration
2. Control of Pesticides Labeling
3. Control of Importation of Unregistered Pesticides for Educational and Research Purposes

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

Pesticides Act 1974 - Provisions



4. Control of Sale and Storage for Sale Through Licensing
5. Control of Pesticide Advertisements
6. Highly Toxic Pesticides Regulations
7. Control on Pest Control Operators
8. Administrative Control of Aerial Spraying

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

Pesticides Act 1974



Rules and Regulations

- Pesticides (Registration) Rules 1976, Amended 2005
- Pesticides (Importation for Educational and Research Purposes) Rules 1981
- Pesticides (Labeling) Regulations 1984

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

Pesticides Act 1974



- Pesticides (Licensing for Sale and Store for Sale) Rules 1988
- Pesticides (Highly Toxic Pesticides) Regulation 1996
- Pesticides (Advertisement) Rules 1996
- Pesticides (Pesticides Control Operators) Regulation 2004
- **Pesticides (Manufacturing) Regulations 20...**

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

DATA ACCESSIBILITY



- Registration data is available on line
- www.doa.gov.my
- Language: English

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

DATA ACCESSIBILITY



Information available (1)

- ❖ Active Ingredient
- ❖ Concentration
- ❖ Class
- ❖ Registration Number (LRMP No.)
- ❖ Registrant

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

DATA ACCESSIBILITY



Information available(2)

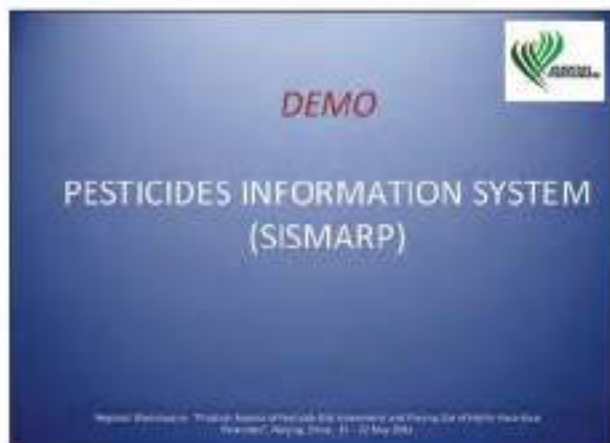
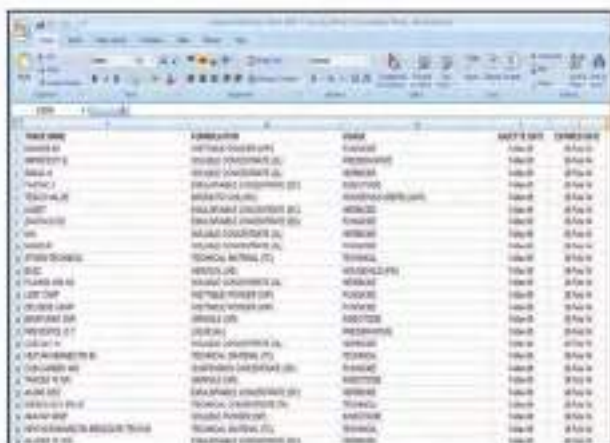
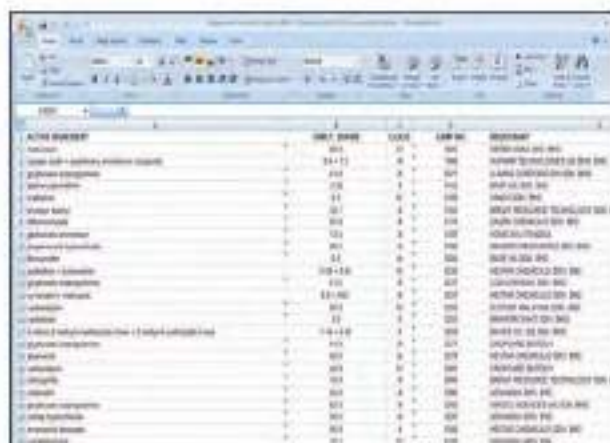
- ❖ Trade Name
- ❖ Formulation
- ❖ Usage
- ❖ Gazette Date
- ❖ Expired Date (of the Gazette)

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014

DEMO

LIST OF REGISTERED PESTICIDES

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Planning (Use of Highly Toxic Pesticides)"
Buenos Aires, 19 - 21 May 2014



.....SISMARP

- recommendation according to category:
- # Crops
- # Pest
- # Pesticides

Registered Activities on "Thematic aspects of Technical Risk Assessment and Planning for strongly Hazardous Pesticides" Meeting, 2006, 25-27 May 2006

2.2.3 How to assess pesticide registration data of Thailand by Panida Chaiyanboon

Pesticide Registration in Thailand

Ms. Panida Chaiyanboon
Department of Agriculture
Bangkok, Thailand

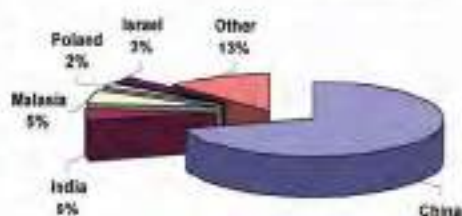
FAO RAP: Regional Workshop on:
"Practical aspects of pesticide risk assessment and phasing out of Highly Hazardous
Pesticides (HHPs)" 19 - 22 May 2014, Nanjing, China

Pesticide Import Data in Thailand

Year	Active Ingredient : ton				Total
	Herbicide	Insecticide	Fungicide	Others	
2007	50,176	8,609	6,609	2,501	67,895
2008	47,646	9,469	7,206	2,242	66,563
2009	53,615	8,112	4,890	2,152	68,769
2010	51,900	9,995	5,956	1,999	69,850
2011	57,607	10,571	6,980	2,361	87,619

Office of Agricultural Regulation, Department of Agriculture

Pesticide Import Data in Thailand



Year 2011

Office of Agricultural Regulation, Department of Agriculture

1. Regulation and Responsibilities

1.1 Regulation

- 1) The government of Thailand enacted the Poisonous Article Act B.E. 2510 in 1967 for control of pesticide
- 2) Replaced by the Hazardous Substance Act B.E. 2535 (1992), effective since April 7, 1992
- 3) Replaced by the Hazardous Substance Act (No. 3) B.E. 2551 (2008), effective since 26 Feb 2008

Ten Groups of Substances

1. Explosives	Explosives.
2. Flammable Substance	Flammable Gases / Aerosols / Liquids / Solids
3. Oxidizing Agent and Peroxide	Oxidizing Gases / Liquids / Solids Organic Peroxides
4. Toxic Substance	Acute Toxicity
5. Substance Causing Diseases	All Health Hazards
6. Radioactive Substances	
7. Mutant Causing Substance	Germ Cell Mutagenicity

Ten Groups of Substances

8. Corrosive Substance	Corrosive to Metals Skin Corrosion Serious Eye Damage
9. Irritating Substance	Skin Irritation Eye Irritation
10. Other Substance either chemical or otherwise which may cause injury (damage) to the persons, animals, plants, property, or the environments	All Health and Environmental Hazards All Other Physical Hazards - Gases Under Pressure - Self-Reactive Substances - Pyrophoric Liquids / Solids - Self-Heating Substances - Substances which, in contact with water, emit flammable gases

1. Regulation and Responsibilities

1.2 Responsibilities

The Hazardous Substance Act (No. 3) B.E. 2551 (2008)

Ministry	Department
1. Ministry of Industry	Dept. of Industrial Works
2. Ministry of Agriculture and Cooperatives	Dept. of Agriculture (DOA) Dept. of Fishery Dept. of Livestock Development
3. Ministry of Public Health	Office of Food and Drug Administration
4. Ministry of Science and Technology	Office of Atoms for Peace
5. Ministry of Natural Resources and Environments	Dept. of Pollution Control
6. Ministry of Energy	Dept. of Energy Business

1. Regulation and Responsibilities

1.2 Responsibilities

Department of Agriculture

Responsible for Pesticide Used for Plant Protection

Registration	- import - production - export
Control After Registration	- license - quality in market - HHPs

2. Pesticide Registration

Hazardous Substance Act B.E. 2551 (2008)

The substances be divided into 4 types according to severity of toxicity



Three Phases of Registration

Phase	Remark
1. Trials clearance	<ul style="list-style-type: none"> to conduct efficacy test and assess acute toxicity Sample be allowed to be imported for efficacy test and quality analysis
2. Provisional or Demonstration clearance	<ul style="list-style-type: none"> to demonstrate efficacy test in farmers field and assess subchronic toxicity and effects to the ecosystem
3. Full Registration	<ul style="list-style-type: none"> to make decision whether the pesticide is accepted for use or not. requires result of assessment of chronic toxicity including data from 2-year feeding study in test animals, efficacy test result and quality analysis result

2. Pesticide Registration

2.1 Registration Process



2.1 Registration Process

Process	Remark
1. DOA sets up list of pesticides	One formulation for one concentration (published in Government Gazette)
2. Registrants apply to Office of Agricultural Regulation, DOA	One product – three trade names (for one registrant)
3. Submit data for evaluation	1. Toxicological data 2. Efficacy test data 3. Certificate of Pesticide Quality analysis 4. Residue Trial data 5. Registration Certificate in the country of production 6. Letter of Authorization from Manufacture / Sponsor
4. Approved by the Registration Sub Committee under DOA	
5. Issue Registration Certificate	Certificate Import, Production, Export Certificate is valid for 6 years

2. Pesticide Registration

2.2 Data Requirement

Data	Generic Pesticide	New Pesticide
1. Toxicological data Be generated by GLP Lab.		
1.1 Acute	/	/
1.2 Chronic / Long term	X	/
1.3 Environment	X	/
2. Efficacy test data	/	/
3. Certificate of Quality analysis	/	/
4. Residue Trial data	/	/
5. Registration Certificate in the country of production	/	/
6. Letter of Authorizations from Manufacture / Sponsor	/	/

Pesticide Registration in Thailand

Content	Number
Active Ingredient	207
Formulated Product	5,053
Type of Formulated Product	30

Update: January 2014

3. Conclusion

Pesticide Registration in Thailand

Regulation of Hazardous Substance

- The Hazardous Substance Act (No. 3) B.E. 2551 (2008)
- Dept. of Agriculture, Ministry of Agriculture and Cooperatives
- Responsibly for Pesticide Used for Plant Protection

Pesticide Registration

- One formulation for one concentration
- Toxicology data be generated by GLP laboratories
- Registration certificate is valid for 6 years

4. Conclusion

Pesticide Registration in Thailand

Documents concern with pesticide registration (in Thai Language)

- The Hazardous Substance Act
- Notifications
 - Registration form
 - Request form for import, produce etc.
 - Residue Trial
 - Efficacy etc.

www.doa.go.th

Department of Agriculture
50 Phaholyothin rd. Chatuchak, Bangkok 10900, Thailand

www.ratchakitcha.soc.go.th

Royal Thai Government Gazette

2.3 SUMMARY AND CONCLUSIONS

Summary observations

Pesticide registration

- All countries have a pesticide registration system;
- There are about 1 170 different active ingredients registered in Asia;
- The number of registered formulations and active ingredients varies greatly from country to country;
- In five countries, the number of registered products is more than 20 times the number of registered active ingredients, indicating multiple registrations for the same pesticide chemical;
- The average registration validity period is from 3-5 years; some countries have unlimited registration periods.

Banning and restrictions

- Unlike the EU or USA, all Asian countries use banning to forbid the use of certain pesticides;
- There is no common approach to banning or restricting a pesticide; while some countries have banned up to 163 pesticides, others have banned as few as four;
- There are a total of 230 pesticides that have been banned and 112 that have been restricted;
- While the banning status of Convention pesticides is quite uneven among the countries, the registration status is largely uniform insofar the majority of these pesticides are not registered in almost all countries.

Conclusions

- Multiple registrations for the same pesticide – often 100 or more – may confuse consumers and encourages repeated applications;
- Unlimited registration validity periods make it difficult to determine the pesticides currently in use and to review their risk regularly;
- Very large numbers of registrations may exceed the capacity of the responsible authority to properly evaluate the risks of each product at the time of registration or renewal;
- Without common criteria for banning or restricting a pesticide, country comparisons yield confusing results;
- To determine compliance with international conventions and treaties it is more informative to determine the registration status of these pesticides rather than their banning status.

3. PESTICIDE RISK ASSESSMENT

3.1 STATUS OF RISK ASSESSMENT IN ASIA

Risk assessment is an important tool to predict pesticide effects on human health or the environment. It is therefore widely used to justify registration decisions for reducing pesticide risks.

Almost all Asian countries assess risk as part of the registration procedure; only two countries do not (Figure 7). Most countries conduct a hazard assessment based on a review of toxicology data. Fewer countries conduct a full risk assessment that includes the assessment of exposure data

Information on pesticide risks from international organizations is widely considered. Authorities generally consult FAO/WHO pesticide information as well as the lists attached to the Rotterdam and Stockholm Conventions (Figure 8). The registration status in the EU or USA is checked to a lesser extent.

Re-registration of a pesticide after expiration of the validity period is an opportunity to re-assess the risk of registered products. Most countries consider new data – such as updated lists of the international Conventions – and conduct a partial review if needed. A full review of the application dossier at the time of re-registration is conducted in five countries. Sometimes, however, re-registration is a simple administrative procedure after payment of a registration fee.

While most countries consider national incidence reports, only three countries have specific surveillance programs to monitor the field impact of pesticides.

During the past five years, most surveyed countries have either banned or restricted some pesticides because of health or environmental risk concerns (Figure 9). Two-third of the pesticides withdrawn in five countries were highly toxic (WHO Class I) ones or Convention pesticides.

Figure 7: Risk assessment in Asia

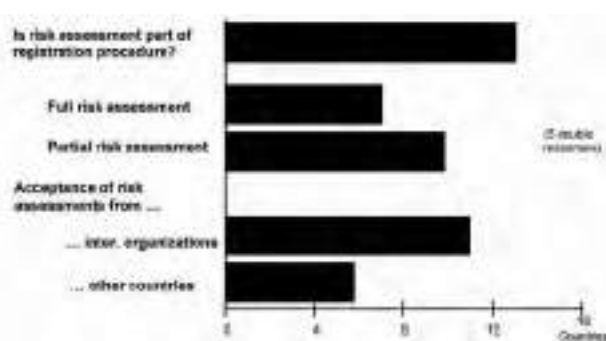


Figure 8: Checking of international resources

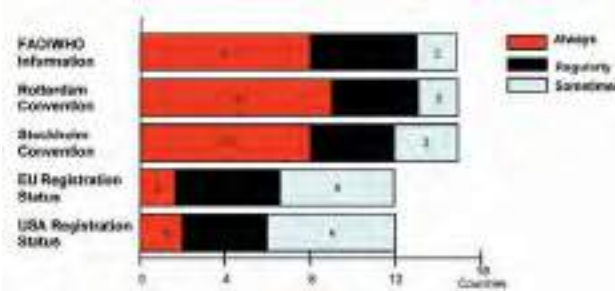
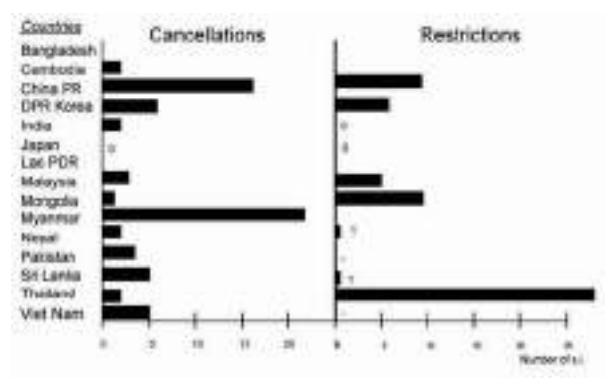


Figure 9: Registration actions in last 5 years



International resources for pesticide risk information

Health and environmental risk assessment in the EU

Risk assessment procedures in the EU includes hazard assessment using standardized test methods and exposure assessment, including exposure to vulnerable groups such as children, consumers and pesticide application operators.

Since 2011, pesticides that belong to the CMR¹ category 1A and 1B, endocrine disrupters and very persistent and bio-accumulating substances are not to be approved. Presently, the EU has evaluated 1312 substances, of which 458 were approved and 781 were not approved; 53 decision are pending. The established reference values e.g. ADI, AOEL, ARfD and NOEC values can be found in different reports on active substances, such as EFSA conclusion reports. This information can be used globally by pesticide registration authorities for assessing country-specific risks.

The exposure models used in EU are based on measured data from different countries/regions in Europe and the US that were used to build up common databases. The estimations of exposure in other regions should be adapted to local circumstances of use.

Environmental risk assessments consider predicted exposure concentrations (PEC) in birds and mammals, bees, soil, surface and ground water. Very stringent exposure limits have been set for ground and drinking water.

Current issues under discussion are neonicotinoids, endocrine disrupting substances and the “cocktail effect” from exposure to a combination of pesticides. (See presentation under 3.2.1 on page 24)

Risk assessment in China

In China, the focus of pesticide management has changed from quality control to risk management. The assessment of health risks covers dietary, occupational and residential risks, while the assessment of environmental risks covers groundwater, aquatic ecosystems, silkworm, birds, honeybees and beneficial arthropods. The hazard assessments, exposure studies, computer models and risk characterizations follow international standard methodologies which have been adjusted to the Chinese situation.

There are two fate models for groundwater contamination, one called China-PEARL for the dry lands in Northern China, and another one called Paddy-PEARL for the rice areas in Southern China. The models are subdivided into different scenario zones.

Accomplishments to date include: Establishment of MRLs; registration reviews of new compounds; pesticide safety monitoring and evaluation project for residue, groundwater and surface water monitoring as well as a re-evaluation on honey bees; mosquito risk assessment; and fly coil risk assessment. In the future, risk assessment will be integrated into the dossier requirements and the registration process. It is planned to publish the risk assessment approaches, refine existing approaches and to continue working on more protection goals. (See presentation under 3.2.2 on page 32)

¹ Carcinogen, mutagen and reproductive toxic

ACCESS TO REGISTRATION INFORMATION

Published risk assessment studies and pesticide evaluations from countries with comprehensive risk assessment procedures, as well as the justifications for regulatory decisions, are valuable resources for developing countries that want to reduce pesticide risks without conducting their own risk assessment studies. However, only few Asian countries regularly check the registration status of a pesticide in the EU or the USA.

An analysis of the list of registered pesticides (Annex 1) has shown, that there are 281 substances registered in Asia that have not been approved in the EU because of “unacceptable risk” to human health and/or the environment. Even though risk concerns and levels of exposure differ between Europe and Asia, risk assessments and registration decisions from Europe and other countries provide important information for assessing the risks in Asia.

To encourage countries to access registration information from the EU or the USA, two guidance documents have been produced:

Access to registration information from the EU

The Swedish Chemicals Agency (KemI) has produced a guidance document on how to access and interpret registration information from the EU. After comments from various users, a second version of the guidance document is now being produced.

In the EU, active substances are evaluated at EU level and either approved or not approved. Substances are not approved if there is an “unacceptable risk” to human health and/or the environment. The national governments then may register products containing approved active substances for use in their own territory.

The easiest way to get registration information is to use the pesticide data base on the website of DG SANCO. The database also contains the review reports with information on evaluated uses, areas of concern, data gaps and risk mitigation measures. The best way to find information on GHS classification of chemicals is to search in the classification data base made available by ECHA. (See presentation under 3.2.3 on page 37)

Access to pesticide registration information from US-EPA





A document has been prepared to provide guidance on what information on pesticides can be found on the USA-EPA website that could be useful as reference material to pesticide registrars in countries with less advanced review systems. There is no single list of approved active ingredients, but information about the registration status of individual products can be searched using the US-EPA *Chemical Search* or the *National Pesticide Information Retrieval system* (NPIRS) which is operated by Perdue University. A complete list of approved active ingredients for use in California is available on-line. Even though it is not a full reflection of all products approved by the US-EPA, it probably is quite close and thus could provide a useful indication. There is no list of banned products since hazardous products may have their registration cancelled rather than being banned.

The websites can also be used to find risk assessment reports, MRLs information and copies of approved labels. Older pesticides that have been registered before 1984 have been re-evaluated with regard to their human health and ecological risks, and the results from these reviews are available online. There is also a list of minimum risk products that are exempt from registration. Users are encouraged to contact US-EPA if they need assistance. (See full document under 3.2.4 on page 40)

3.2 PRESENTATIONS

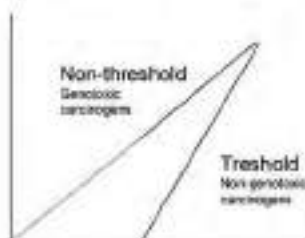
3.2.1 Introduction to health and environmental risk assessment

by Lilian Törnqvist and Jenny Rönngren, KEMI

<p>Introduction to Health and Environmental Risk Assessment</p>  <p>Lilian Törnqvist and Jenny Rönngren Swedish Chemicals Agency May 2014, Nanjing, China</p> <p>KEMI</p>	<p>Content:</p> <ol style="list-style-type: none">1. Why conduct a risk assessment?2. Basic concepts of risk assessment<ul style="list-style-type: none">– human health– environment3. Current issues under discussion <p>KEMI</p>
<p>Why make a risk assessment?</p> <p>Important tool for decision making based on predicted effects on human health or the environment</p> <p>Requirements:</p> <ul style="list-style-type: none">• Hazard assessment• Estimation of exposure• Decision criteria <p>→ Possibility to make a risk assessment and to take some sort of decision (rejection, request for more data, approval, restrictions etc.)</p>  <p>KEMI</p>	<p>Hazard versus risk:</p> <ul style="list-style-type: none">• Hazard = ability to cause damage or harm (intrinsic hazardous properties)• Risk = probability for damage or harm to occur  <p>Risk = Hazard x Exposure</p> <p>KEMI</p>
<p>How to reduce the risk</p> <ul style="list-style-type: none">➢ Use less hazardous substances➢ Reduce exposure  <p>Risk = Hazard x Exposure</p> <p>KEMI</p>	<p>Hazard assessment</p> <p>Look at the intrinsic properties of a substance or formulation</p> <p>E.g.:</p> <ul style="list-style-type: none">– Acute toxicity to humans– Corrosivity– Carcinogenicity– Degradability– Bioaccumulation– Toxicity to aquatic organisms <p>KEMI</p>
<p>Standardised test methods</p> <p>Advantages:</p> <ul style="list-style-type: none">• The method has been scrutinised by experts and is well documented• Comparable results• Possibility to set up criteria for decision making• Data can be collected from several laboratories and create a larger database that can be used for other purposes, e.g. QSAR <p>KEMI</p>	<p>Standardised test methods</p> <p>Disadvantages:</p> <ul style="list-style-type: none">• Not designed for particular substances or specific questions• Adjustments might therefore be necessary <p>KEMI</p>

Carcinogenicity

Evidence that exposure increases the incidence of tumours



KEMI

Reproductive toxicity

- Adverse effects on sexual function and fertility
- Adverse effects on the development of the offspring
 - Prenatally
 - Postnatally
- Effects on or via lactation

KEMI

Developmental toxicant

May affect:

- Growth
- Development
- Acquisition of normal organ function between conception and puberty

May cause:

- Death (in utero or postnatally)
- Structural defects
- Growth retardation
- Functional defects
- Childhood cancer

Confounding factor: maternal toxicity

KEMI

Health Hazard Classification in GHS

- Acute toxicity
- Skin corrosion/irritation
- Serious eye damage/eye irritation
- Respiratory or skin sensitisation
- Germ cell mutagenicity
- Carcinogenicity
- Reproductive toxicity
- Specific Target Organ Toxicity (STOT)
 - Single exposure
 - Repeated exposure
- Aspiration hazard

CMR

KEMI

Joint Meeting on Pesticide Management (JMPM)

As a first step in the development of a risk reduction programme, the [FAO/WHO Joint Meeting on Pesticide Management \(JMPM\)](#) was requested to provide a working definition for highly hazardous pesticides.

Working definition:

- Classes 1A or 1B of the WHO classification; (or category 1 and 2 of GHS)
- Carcinogenicity Cat. 1A or 1B GHS
- Mutagenicity Cat. 1A or 1B
- Reproductive toxicity Cat. 1A or 1B
- Annexes A or B or paragraph 1 of Annex D in the Stockholm Convention
- Montreal protocol
- High incidence of severe or irreversible adverse effects

KEMI

Pesticides (Plant Protection Products) in EU

- New regulation on PPP: Regulation No. 1107/2009; Applicable from 14 June 2011
 - New cut off criteria: CMR category 1A and 1B, endocrine disruptors and very persistent and bio-accumulating substances not to be approved (→ "serious danger to plant health", 5 years extra, but not cat. or repro. cat. 1A)
 - Substitution by comparative assessment of products
 - Zonal authorization
 - Safeners and synergists to be approved according to the same procedure as for active substances.
 - A work plan established by 14 December 2014
 - Co-formulants: Negative list Annex II

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We are all individuals

Physiological factors

- Age
- Gender
- Body weight
- Skin surface area
- Physical condition
- Disease
- Genetics

Behavioural factors

- Time-activity patterns
- Life-style factors
- Socio-economics
- Nutritional status
- Physical activity

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Vulnerable groups, such as children, need to be considered

- Rapid metabolism
 - Higher consumption of food and water per unit body weight
 - Higher inhalation volume per unit body weight
 - Higher respiratory rate
- Development
 - Immature organ system
 - Immature metabolism
- Behaviour
 - Hand-to-mouth activity, sucking and biting
 - Spend much time on the ground



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Establishment of reference values

Effect data + dose response data \Rightarrow "NOAEL" \Rightarrow

1. AOEL (Acceptable Operator Exposure Level)

AOEL (mg/kg bw/day) = NOAEL/100

(safety factor, 10 x 10 for inter individual x inter species variation; lowest NOAEL chosen)

2. ADI (Acceptable Daily Intake)

3. ARD (Acute reference Dose)

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Exposure pathways



KEM

Risks to consumers from residues in food

- Residue levels at time of consumption (at the market, at harvest)
- Too high residues can occur:
 - by using too large dose
 - application too close to harvest (after the recommended PHI)
- Important endpoints based on NO(A)EL + Assessment factors:
 - ADI (Acceptable Daily Intake) mg a.s./kg bw/day (lifetime)
 - ARD (Acute Reference Dose) set for acutely toxic substances mg a.s./meal or <24 hours

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Consumers: Maximum Residue Limits (MRL) in EU

European diet



MRL is based on field studies carried out according to the GAP for a product

MRL set for about 1100 substances and 315 agricultural products (EU)

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Operator Risk Assessment

- Compare **estimated exposure** in mg/kg body weight and day (mg/kg bw/day) (body weight 60 kg) with AOEL (mg/kg bw/day)
- Exposure should be less than AOEL
- To reach a value less than AOEL personal protection equipments are added, one by one, in a step-wise approach:
 - no protection \Rightarrow gloves \Rightarrow overall suit \Rightarrow protective mask
 - a) for mixing and loading procedures
 - b) during application procedure (mostly spraying) different types of spraying devices
- Route of exposure: a) through inhalation b) through skin

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Exposure to Health and the environment at spraying



KEM

Well protected farmer



KEM

Knapsack hand-held sprayer using protection equipment



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High risk: mixing and loading



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Operator Risk Assessment – northern zone

1. AOEL
2. Exposure assessment (simulated)
using input data on: the type of product (solution, powder etc.),
concentration of active substance in product and in spraying
solution. Data from exposure models, (built on measured data)
% skin absorption of product/solution

⇒ Risk assessment

The following exposure models are acceptable:

- UK POEM
- German model (75th percentile)
- Dutch model (greenhouses)
- Seed Tropex model (seed treatment)

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Workers, northern zone

The following exposure calculations and input parameters are acceptable:

- EURO POEM II Worker Re-entry Model 2
- Work duration: 6-8 hours depending on activity
- Work duration for crop inspection (cereals): 2 hours
- Body weight: 60 kg (adult)

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Bystander, northern zone

The following exposure calculations and input parameters are acceptable:

- EURO POEM II Bystander Exposure to Pesticides or comparable calculations
- Exposed body surface: 2 m² for adults and 0.66 m² for children
- Duration of exposure: 60 min but refinements can be done in higher tier assessment
- Body weight: 60 kg (adult)

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Environmental exposure assessment

Estimation of the concentrations/doses to which organisms in environmental compartments (aquatic, terrestrial, feed) are or may be exposed to.

PEC – Predicted Environmental Concentration

KEMI

Exposure Assessment – relevant compartments



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Exposure Assessment – estimate concentrations



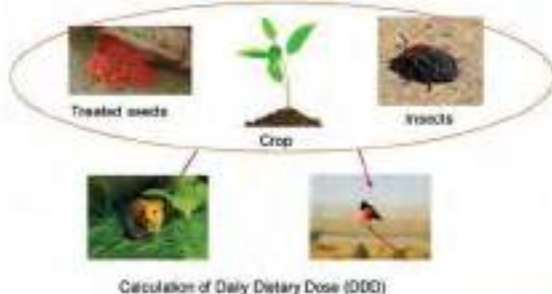
KEMI

Predicted Environment Concentration

- Surface water (PEC_{sw})
- Soil (PEC_{soil})
- Groundwater (PEC_{gw})

KEMI

Exposure Assessment – birds and mammals



KEM

Standard organisms

Surface water



Soil



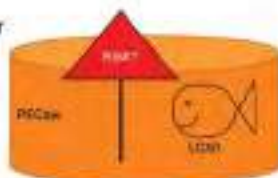
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Risk assessment

1. Compare estimated concentration in the environment with effect concentrations = calculation of Toxicity Exposure Ratio (TER)
2. Compare with safety factor

TER > safety factor → OK

TER < safety factor → RISK



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Safety factors – environment

TER values are "precautionary values", not scientifically based

Examples from EU:

- Acute toxicity to aquatic organisms: TER 100
- Acute toxicity to earthworm: TER 10
- Long-term toxicity to birds: TER 5

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Refinement – toxicity data

Laboratory tests with more species



More realistic tests / field tests (mesocosm)



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Refinement – toxicity data

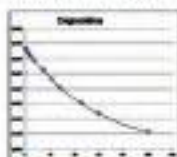


Reduce the safety factor, margin of safety

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Refinement – exposure assessment

More realistic exposure estimations



Focus degradation kinetics



Estimate spray drift (buffer zones)

More complex models (FOCUSgw and FOCUSpe)



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PEC groundwater in EU

PEC_{gw} should not exceed 0.1 µg/l.

- is the same value for all substances and for relevant metabolites (P_{gw}) i.e. which has a biological activity
This is a politically decided endpoint
- this means that it is not compared with ADI
- WHO has set other values for individual substances based on ADI

At monitoring of drinking water limit is set to:

- 0.1 µg/l for a single active substance and RM
- 0.5 µg/l when you have more than one substance or RM

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Current issues under discussion (1)

1. Neonicotinoids ("neonics")

- Substances: thiamethoxam, clothianidin and imidacloprid
- Identified as one of several reasons for the decline in the number of bees according to the European Food Safety Authority's (EFSA) risk assessment and a large number of reports.
- In May 2013 the [European Commission](#) decided to prohibit placing on the market of seeds treated with neonics. Exception: use in greenhouses.



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Current issues under discussion (2)

2. Endocrine disrupting substances (EDs)

- Criteria for identification of Eds is being developed by the European Commission and should have been presented in December 2013. The work has been delayed.
- A new database "Endocrine Active Substances Information System (EASIS)" will be published soon.



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Current issues under discussion (3)

3. Combination effects of chemicals ("cocktail effect")

- Current regulatory approaches are usually based on the evaluation of single substances, chemical by chemical.
- Concerns that this approach does not provide sufficient security and that the combination effects of chemicals should be addressed in a more systematic way.
- Study from 2009: [State of the Art Report on Mixture Toxicity](#)
- Development of guidance documents is on-going but very little has been finalised.



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Take home message:

- Do a stepwise risk assessment.
- Start simple!
- Use information that is already available!

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Useful links

Risk assessments reports:

Pesticide risk assessments (EFSA conclusions):
http://ec.europa.eu/pesticides/public/index.cfm?event=activeSubstance_selection

Or Google search "EFSA conclusion + name of the active substance"

Risk assessments for biocides (assessment reports):
<http://echa.europa.eu/information-on-chemicals/coordinated-biocides-assessments>

Risk assessments for substances in Annex II, Rotterdam convention (Decision Guidance documents):
http://www.pic.int/TheConvention/Chemicals/DecisionGuidanceDocuments/DecisionGuidanceDocuments_en.htm

Guidance documents on exposure and risk assessments:

http://ec.europa.eu/pesticides/public/index.cfm?event=activeSubstance_selection_documents_en.htm

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Thank you for your attention!



KEMI

3.2.2 Risk assessment in China by Tao Chuan-Jiang

Pesticide Risk Assessment in China

Health Division of ICAMA TAO Chuan-jiang

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Tel: 86 10 28191818; Fax: 86 10 28191818

Focal point of pesticide management changes from quality control to safety management

Projects on risk assessment methods development

Projects/Funding Agencies	Field	Time
Asia Facility for China/US Dutch collaboration	Env.	2006-2010
Dutch MDA & Embassy in China	Env.	2006-2008
Introduction of Foreign Advanced Technology /SAFEA	Occup. & Env.	2007-2010
Pesticide Safety Monitoring and Evaluation / Chinese MDA	Dietary, occup. & Env.	2009
Sino-US Cooperation / Chinese MDA & USEPA, USDA	Dietary, occup. & Env.	2007-2010
Scientific Research for Public Welfare / Chinese MDA & MOST	Dietary, health & Env.	2008-2015
11 th , 12 th Science & Technology Pillar Program / MOST	Dietary, health & Env.	2006-2015

Current status

- **Health**
 - Dietary risk assessment
 - Occupational risk assessment, under development
 - Residential risk assessment, mosquito coil, mat, liquid
- **Env. / Eco**
 - Groundwater
 - Aquatic ecosystem
 - Silkworm
 - Birds
 - Honeybee
 - Beneficial arthropods

Risk assessment scheme

```

graph TD
    A[Toxicity/ Endpoint Endpoints] --> C[Hazard / Effect assessment]
    B[Uncertainty Factors] --> C
    C --> D[Acceptable Threshold]
    C --> E[Exposure]
    F[Residue/ Data data] --> G[Exposure Models]
    H[Baseline Data/ Scenarios] --> G
    G --> E
    D -- Criteria --> I[Risk Characterization]
    E --> I
    I --> J[Registration Decision]
  
```

Dietary risk assessment

- Follow FAO/WHO JMPR approaches
 - Toxicological review, ADI establishment
 - Supervised residue trials with GAP: Median residue, High residue
 - Exposure analysis
 - $MEQ = \sum [SDMR \times (STMR \times F)]$
 - $TMQ = \sum [MRU \times F]$
 - Risk characterization
 - $Risk (\%) = MEQ / TMQ \times (ADI \times 60) \times 100\%$
 - Criteria: 100%
- Establishment of Maximum Residue Limit (MRL)

Occupational – operator risk assessment

Hazard assessment of Occupational

- Toxicological review
 - Short, intermediate, long-term
 - Oral, dermal, and inhalation
- Point of Departure (POD): NOAEL, LOAEL, BMDL
- Acceptable Operator Daily Exposure Level, AODEL
 - $AODEL = NOAEL / UF$



Farmer interview / farm survey



- Farmer interview in 16 provinces, 550 families
 - Land acreage, crop types
 - Pesticide application equipments
 - Pesticide use pattern, rates, frequency
 - Maximum daily application acreage / volume / hours
 - Personal protective equipment (PPE)
 - Post application activities
- Agronomic practice survey in every provinces
 - Normal crops, crop calendar
 - Plant protection activities
 - Pesticide use pattern, period, frequency



Exposure scenario formulation



- Scenario formulation
 - Application equipment + crop + PPE
- Crop grouping
 - Height
 - Density
 - Crop stage



Unit Exposure (UE) testing, backpack sprayers



Whole Body Dosimetry



Inhalation Sampling

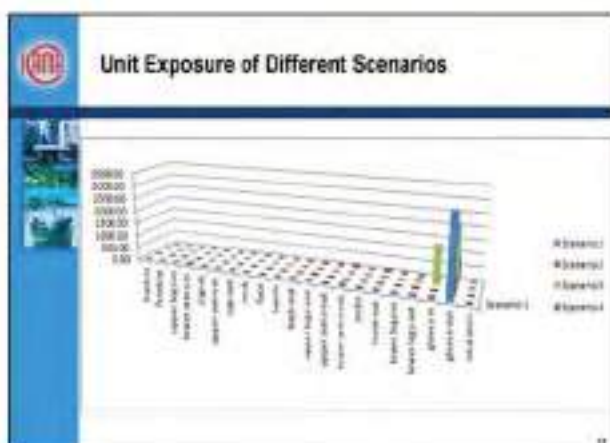


3 heights \times 6 locations \times 8 persons



Sampling





Exposure calculation

$$\text{Amount handled per day} = \text{Application rate} \times \text{Area Treated}$$

$$(\text{kg ai} / \text{day}) \quad (\text{kg ai} / \text{ha}) \quad (\text{ha} / \text{day})$$

$$\text{Exposure} = \text{Amount handled per day} \times \text{Unit Exposure Value}$$

$$(\text{mg} / \text{day}) \quad (\text{kg ai} / \text{day}) \quad (\text{mg ai} / \text{kg ai handled})$$

$$\text{Dose} (\text{mg} / \text{kg} / \text{day}) = \text{Exposure} (\text{mg} / \text{day}) \times \text{Absorption Factor}$$

$$\text{Body Weight (kg)}$$

18

- ### Exposure model
- Input data
 - Pesticide basic information and tox values
 - Crop
 - Use pattern: method, rate
 - Background data
 - Scenarios
 - Crop grouping
 - Agriculture practice
 - Working duration
 - PPEs
 - UEs
 - Output: Exposures inhalation, dermal
- 19

- ### Hazard Assessment and Risk characterization
- Risk Quotient (RQ)

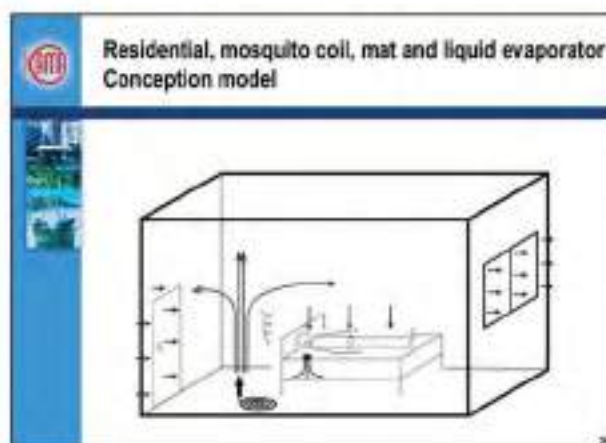
$$\text{RQ} = \text{Exposure} / \text{AODEL}$$
 - $\text{RQ}_{\text{total}} = \text{RQ}_{\text{inh}} + \text{RQ}_{\text{der}}$
 - Criteria = 1
- 20




- ### Hazard assessment
- Toxicological review
 - Short, intermediate, long-term
 - Oral, dermal, and inhalation
 - Point of Departure (POD): NOAEL, LOAEL, BMDL
 - Acceptable Residential Daily Exposure Level, ARDEL

$$\text{ARDEL} = \text{NOAEL} / \text{UF}$$
- 22


- ### Residential, family survey
- 1 500 families in 15 provinces
 - Family composition
 - House type, age, height
 - Hours staying home of every family member
 - Information collected
 - Target: mosquitoes, flies, cockroaches, ants ...
 - Types of pesticide chosen
 - Mostly rooms used
 - Use frequency: Days a years & Hours a day
 - Open or close
 - Staying hours at home
 - Children
- 23



Exposure routes and main drivers




- Exposure route
 - Inhalation: air
 - Dermal: deposition
 - Oral: deposition

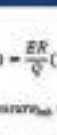


- Main drivers
 - AI content
 - Use life
 - Exposure time
 - Room size
 - Air exchange rate
 - Inhalation rate
 - Body weight
 - Deposition
 - Transfer Coefficient
 - Children hand to mouth

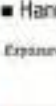
Main calculations



- Inhalation exposure
 - Air concentration curve
 - Integration with inhalation



- Dermal exposure
 - Deposition curve
 - Integration



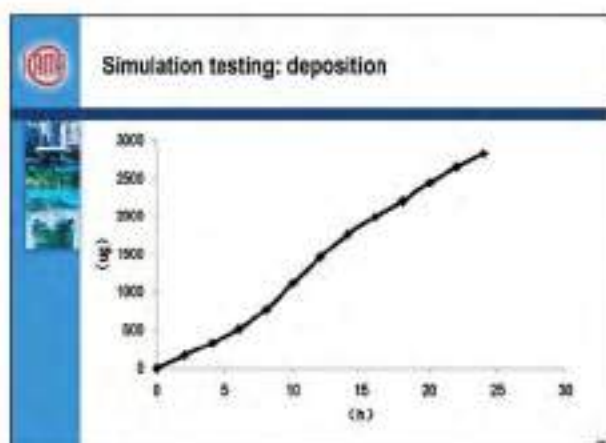
- Hand to mouth exposure

$$C(t) = \frac{ER}{V} (1 - e^{-\lambda C(t)})$$


$$Exposure_{inh} = \frac{IR}{24} \int_0^{24} C(t) dt$$

$$AdR = \frac{AD \times V}{A} \times \int_0^{24} C(t) dt$$

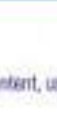
$$Exposure_{der} = \frac{AdR \times F_p \times TC}{BW}$$

$$Exposure_{h2m} = [IR \times (V_h \times SA_h) \times (ET \times N_{h2m}) \times (1 - (1 - SE)^{\frac{C(t) \times IR}{N_{h2m}}})]$$


Computer Model




- Input data
 - Pesticide information
 - Formulation, use pattern, content, use life from label




- Data fixed in model
 - Body weight
 - Inhalation rates
 - Home activities and timing
 - Room size
 - Air exchange rate
 - ...

■ Output: exposure inhalation, dermal, oral

Risk characterization



- Risk quotient (RQ)
 - $RQ = Exposure / ARDEL$



- $RQ_{total} = RQ_{inh} + RQ_{der} + RQ_{oral}$

■ Criteria = 1

Environmental risk assessment

Protection goals selected



- Groundwater, to human health
 - Dry land in North China: 10 m
 - Rice area in south China: 2 m



- Aquatic ecosystem
 - Natural ponds in south China
 - Lower 3 drainage channels of south China
 - Lower 7 rivers in north China

■ Silk worm

■ Mulberry leaves

■ Birds

■ Honey bee

■ Beneficial arthropods



Effect assessment

- Eco-tox endpoints
 - LC50, LD50, NOEC
- Uncertainty factor, UF
 - Intra- and inter-species variation of toxicity data
 - Short-term to long-term / chronic toxicity extrapolation
 - Extrapolation of mono-species laboratory data to field impact on ecosystems
- Result
 - Predicted No Effect Concentration (PNEC)
$$PNEC = \text{Eco-tox endpoint} / UF$$

Exposure analysis

- E-fate
 - degradation, absorption
- Climate
 - precipitation, temperature
- Hydrology, geography
- Soil property
- Agriculture
 - farm distribution, crops
 - pesticide application
- Outcome
 - Predicted Exposure Concentration (PEC)

Copyright Elsevier 2013.08.07

Risk characterization

- Risk quotient (RQ)

$$RQ = PEC / PNEC$$
- Criteria: 1

Effect assessment of Groundwater

- Protection goal: drinking water, for human health
- PNEC
 - Guidelines for Drinking-water Quality 3rd Edition, WHO

$$GV = \frac{TMDI \times bw \times P}{C}$$

GV = Guidance value
 TMDI = Tolerable Daily Intake/Acceptable Daily Intake, mg/kg bw
 bw = Bodyweight, kg
 P = fraction of the TDI allocated to drinking water, 20%
 C = daily drinking water consumption, L

Fate models for groundwater

- Dry land in North China
 - China-PEARL
 - 6 scenarios
 - 90th %ile = 90th %ile annual avg. rainfall + 90th %ile soil
- Rice area in South China
 - PaddyPEARL
 - 2 scenarios
 - 90th %ile = 90th annual avg. percolation + 90th soil

Effect assessment of aquatic organisms in surface water

- Effect assessment: PNEC
 - Endpoint: LD / LC / EC50, NOEC, Based on eco-tox data
 - Uncertainty factors

PNEC _{fish}	EdP	LC ₅₀
	UF	100
PNEC _{invertebrates}	EdP	EC ₁₀ / LC ₅₀
	UF	100
PNEC _{algae}	EdP	EC ₁₀
	UF	10

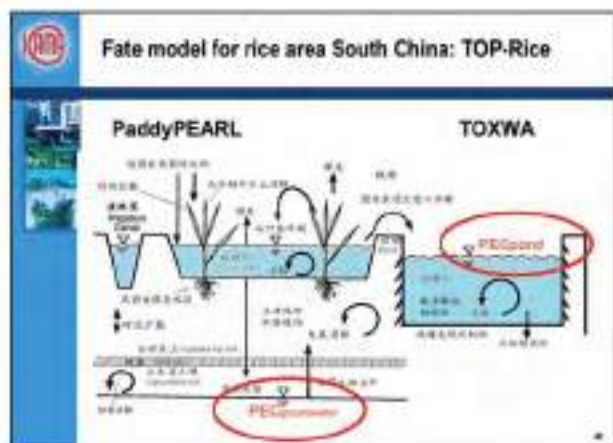
EdP = End Point UF = Uncertainty factor

China-PEARL

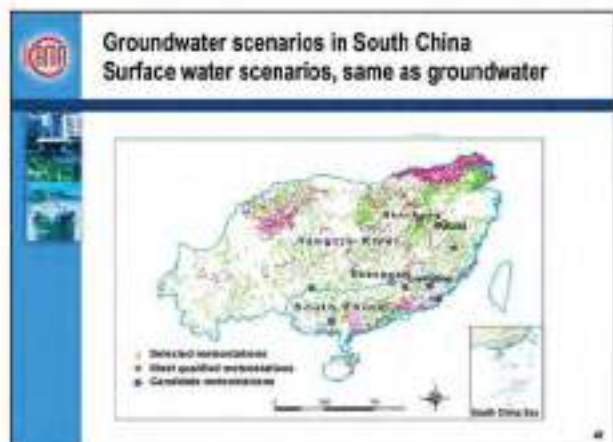
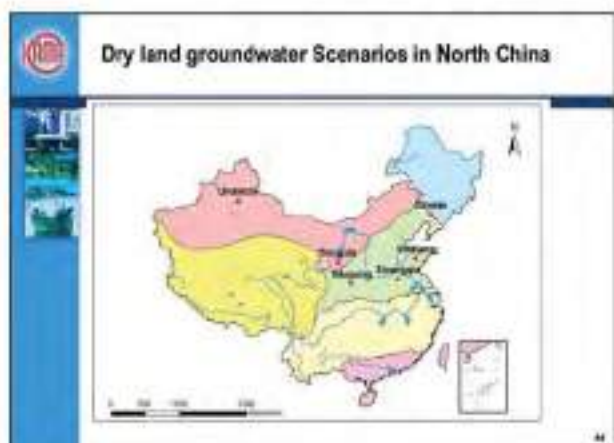
ChinaPEARL 1
 ChinaPEARL 1.1.1 Copyright © 2008 by RIVM, Bilthoven, The Netherlands

China-PEARL

China-PEARL 1.1.1 Copyright © 2008 by RIVM, Bilthoven, The Netherlands



- TOP-Rice**
- Surface water in pond
 - TOP-Rice = TOXWA + PaddyPEARL + Drift_PRI
 - 2 scenarios:
 - 90% %ile Conc.
 - = 90% %ile rainfall + irrigation + height outlet
 - + 50% %ile overflow events



Silkworm, Effect assessment

- Toxicity endpoints
 - Acute: LC50 with Uncertainty factor 70
 - Long term: NOEC with Uncertainty factor 10
- Uncertainty factor inter-strain

Pesticide	LC ₅₀ (mg a.i. kg ⁻¹ leaf)		平均 HC ₅₀ (mg a.i. kg ⁻¹ leaf)	Ratio of sensitivity	
	most sensitive strain	least sensitive strain		least/ most	least/ HC ₅₀
dimethoate	15.9	23.4	15.5	1.5	1.5
imidacloprid	0.13	0.29	0.12	2.2	2.4
cypermethrin	8.015	0.064	0.0094	4.3	6.8
Monocrotophos	0.20	0.36	0.18	1.8	2.0

CropLife America 2013-04-07

Exposure analysis

- Scenario 1 spray on mulberry tree

$$PEC_{sw} = AR \times EUD_{50} \times MAF \times DF_{50}$$

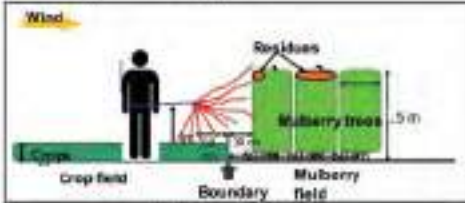
$$MAF = \frac{(1-e^{-aK})}{(1-e^{-aK})}$$

$$DF_{50} = e^{-\left(\frac{DTSD}{DTSD} \times PH\right)}$$

AR = Application rate, kg a.i. / ha
 EUD₅₀ = 50% A.i. residue units dose
 DF₅₀ = Degradation factor
 MAF = multi application factor
 a = Number of applications
 K = Application interval, days
 DTSD = half-life, days
 PH = Pre-harvest interval, days

Exposure analysis

- Scenario 2: Drift from neighbour field to mulberry trees
- Drift model IDEFICS calculates residues on 1st row and 2nd row with single or multi applications



Exposure Analysis 2013-44-37

Use of the methods developed

- MRLs establishment
- Registration review of new compounds
- Pesticide Safety Monitoring and Evaluation Project
 - Residue monitoring
 - Groundwater monitoring
 - Surface water monitoring
 - Reevaluation on honeybee
- Mosquito risk assessment
- Fly coil risk assessment

Future

- To Integrate risk assessment into dossier requirements and registration process
- To publish risk assessment approaches
- To Refine existing approaches
- To Continue working on more protection goals

谢谢! THANKS!


Health Division of ICAMA TAO Chuan-jiang

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3.2.3 Access to information from the pesticide registration process in the EU

by Lilian Törnqvist and Jenny Rönngren, Kemi

Access to information from the pesticide registration process in EU



Lilian Törnqvist and Jenny Rönngren
Swedish Chemicals Agency
May 2014, Nanjing, China

KEMI

Content of the presentation

1. Overview of the review process for active substances in EU.
2. Live demonstration of search for information

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Guidance document on how to access information from the EU registration process

- + Document drafted by Kemi
- + Aim:
 1. Give an overview of the procedures for evaluation and decision making for active substances in EU
 2. Give guidance on how to find information produced within the EU system
- + Version 1 → University of Cape town, FAO, ITP
- + Comments → Version 2



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History

- + Since early 1990's, active substances are evaluated at EU level
- + Harmonised data requirements, criteria and guidance documents
- + Decision on **approval** or **non-approval** of active substances at EU level
- + 900 active substances → around 640 (lack of support from industry or incomplete dossier)

KEMI

Pesticides in EU 2009

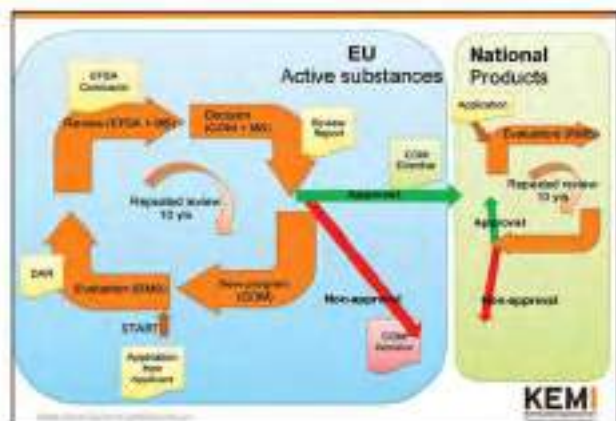
- http://ec.europa.eu/sanco_pesticides/public/index.cfm



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Decision making

- + European Commission drafts a proposal for decision based on the EFSA conclusion
- + A standing committee with all Member States votes



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Approval

- The risk assessment has shown that a representative product can be used with "acceptable risk" to human health and the environment
- Approvals might include extensive risk mitigation measures
- Possibility to approve active substances without a full risk assessment due to lack of data, if likely that the risk assessment would show "acceptable risk". Confirmatory data specified.

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Non-approval

- "Unacceptable risk" to human health and/or the environment
- Withdrawal of the substance from the review process
 - Knowledge of "unacceptable risks"
 - Large data gaps

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Live demonstration

Example product:

Name	Roundup
Active substance	glyphosate
Concentration of active substance	750 g/L
Intended use	Concentrated use
Application rate	400 g/ha
Number of applications	1
Interval between applications	14 days
Application method	Spray

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Status in EU



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Status in EU

Enter the EU pesticide database:
http://ec.europa.eu/sanco_pesticides

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Comparability



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Comparability

Check supported uses in Appendix 2 of the review report. Review reports can also be found via the pesticide database.

http://ec.europa.eu/sanco_pesticides

All evaluated uses (intended uses) can be found in the EFSA conclusion. Uses with "unacceptable" risks are marked in grey.

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Areas of concern and classification



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Areas of concern

Check:

- "Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing halosulfuron" in the [review report](#).

or

- Information under "specific provisions" in the [regulation](#) that approves the substance.

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Classification

Check:

- EU pesticide database
or
- Classification and labelling inventory database at the European Chemicals Agency's (ECHA) website:
<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>

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Data gaps



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Data gaps

Check:

- "List of studies to be generated" in the review report
or
- Information under "specific provisions" in the regulation that approves the substance.

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Risk mitigation measures



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Risk mitigation measures

Check:

- "Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing halosulfuron" in the [review report](#).
- Exposure scenarios in the EFSA conclusion report

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Decision making



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Thank you for your attention
and
good luck!

KEMI

3.2.4 Pesticide registration information from US-EPA

by Harry van der Wulp, Senior Policy Officer (Pest and Pesticide Management), FAO, and Kimberly Nesci, Chief, Microbial Pesticides Branch, Office of Pesticide Programs, US-EPA

This document aims to provide brief guidance on what information on pesticides can be found on the US-EPA website that could be useful as reference material to pesticide registrars in countries with less advanced review systems.

Overview

Main webpage for the EPA Office of Pesticide Programmes:

<http://www.epa.gov/pesticides/>

New home page for pesticide registration information:

<http://www2.epa.gov/pesticide-registration>

Registration status of pesticides in the US

There is no single list of approved active ingredients, but information about the registration status of individual products can be searched for at Chemical Search or NPIRS as explained below.

Chemical search

The Chemical Search page allows users to search by pesticide name to find out the registration status of the active ingredient. The database covers both registered products and products for which the registration is pending.

<http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1>

Guidance about the use of Chemical Search can be found at:

<http://www.epa.gov/opp00001/regulating/part-180.html#general-name>

In short: Type in the common name. If you get a list, click on the common name. Then click on the chemical name. You will see the regulatory status. Click on the Regulatory Actions Tab to see more details.

National Pesticide Information Retrieval System (NPIRS)

NPIRS can also be used to find pesticide registration information.

<http://ppis.ceris.purdue.edu/>

Type the active ingredient in the appropriate box. Click on display companies. Select the company you are interested in and click on display products. One then can see which products that contain the active ingredient are registered by the company concerned. Clicking on the small EPA-logo will open a link to the label page for that product. The label lists the approved uses of the product concerned.

To check a specific product, one can also directly enter the trade-name on the start page.

Products of which registration is pending

As part of the registration process the draft review and decision are made available for comment by stakeholders and the public. This is called a Docket open for comment. Such dockets can be found at: <http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:34:11968475201623>

Conditional registration

If EPA finds that a pesticide meets the standard for registration, but there are outstanding data requirements, the Agency may, under certain circumstances, grant a conditional registration after it has determined that use of the pesticide would not significantly increase the risk of unreasonable adverse effects on the environment during the time needed to generate the necessary data. A list of products with conditional registration can be found at: http://www2.epa.gov/sites/production/files/2014-04/documents/conditional_registration_status_4-15-2014.pdf. The list also indicates which environmental studies are still outstanding for each product.

Registration status of products in the State of California

The State of California makes available a complete list of active ingredients approved for use in California at: <http://www.cdpr.ca.gov/docs/label/actai.htm>

States can be more strict, but not less strict, than the federal government. States can only approve products that have been approved by EPA at the Federal level, but states have the possibility to deny registration of products that were approved for federal registration, or impose additional restrictions. Although the California list is thus not necessarily a full reflection of all products approved by EPA, it probably is quite close and thus could provide a useful indication.

Special categories

Re-registration status of older products

In 2008, EPA completed a review of older products (registered before November 1984). This process was called re-registration and aimed to review human health and ecological risks. It also involved reassessment of residue tolerances. The results of the re-registration review can be found at: <http://www.epa.gov/pesticides/reregistration/status.htm>

If a RED has been signed, it means that the active ingredient is eligible for registration. This means that companies can apply for registration of products that are based on the a.i. concerned.

Banned pesticides

The US does not maintain a list of banned pesticides. There only is a positive list. Products are only permitted for registered uses. Non-registered products or uses are prohibited.

Restricted Use Pesticides

The “Restricted Use” classification restricts a product, or its uses, to use by a certified pesticide applicator or under the direct supervision of a certified applicator. The label of a product will indicate whether it is a Restricted Use Product (RUP). A list of all RUPs can be found at: <http://www.epa.gov/opprd001/rup/rupreport.pdf>

Minimum risk products

Minimum Risk products are products that are exempted from registration if certain conditions are met. The list of exempted substances can be found at: http://www.epa.gov/opbtpd1/biopesticides/regtools/25b_list.htm#activeingredients

Risk assessment reports

Reports of risk assessments that have been conducted as part of the registration process can be found through <http://www.regulations.gov/#!home>. This webpage provides access to all US Government rules, proposed rules, and notices and allows for public comment. One can find risk assessments for specific chemicals by typing the chemical name and the words “risk assessment” into the search box.

Risk assessment can also be found through Chemical Search or by requesting information from the relevant US-EPA staff as explained below.

Pesticide residues (tolerances/MRLs)

Information on tolerances or Maximum Residue Limits can be found at:

<http://www.epa.gov/opp00001/regulating/part-180.html#tolerance-commodity>
The webpage includes instructions on how to search.

Other search tools are provided at:

<http://www.epa.gov/pesticides/food/viewtols.htm>

International MRL database (requires registration)

<http://login.mrl database.com/>

Pesticide labels (and approved uses)

Labels for all approved products can be found at:

<http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1>

Search by trade names of products registered in the US. If the product still has an active registration, you will get a link to the currently approved label, plus links to previous versions of the label. The label lists the approved uses of that product. If you do not get a link, the product likely no longer has an active registration.

Contacts for further assistance

Registrars looking for specific risk assessments or other information and who are not sure about where to look or how to interpret what they found, are explicitly encouraged to contact US-EPA for assistance.

Overview of contacts in the Office of Pesticide Programmes

<http://www.epa.gov/pesticides/contacts/index.htm>

Registration Division Contacts

The Registration Division handles the approval of new conventional pesticides and new uses of previously registered pesticides. The ombudsperson and the special assistants listed can help you locate a contact for a specific active ingredient.

http://www.epa.gov/opprd001/contacts_rd.htm

Biopesticides and Pollution Prevention Division (BPPD) Contacts

BPPD handles the approval and reevaluation of biopesticides, including biochemicals and microbial pesticides.

http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm

3.3 SUMMARY AND CONCLUSIONS

Summary observations

- Almost all countries consider risk during the registration procedure; in most cases, they assess the pesticide hazard based on a review of toxicological data;
- Fewer countries conduct a full risk assessment that includes the assessment of exposure data; only three countries have specific surveillance programmes to monitor pesticide exposure within the country;
- Countries generally consider hazard and risk information published by FAO/WHO and consult the lists issued by the international Conventions;
- Only few countries regularly check the registration status of a pesticide in the EU or USA;
- There are 281 substances registered in Asia that have not been approved by the EU because of “unacceptable risk” to human health and/or the environment;
- After the expiration of the registration validity period, pesticides are often re-registered without a review or with only a partial review that may involve checking international treaties or the registration status in other countries; only five countries conduct full reviews of the application dossier;
- For conducting risk assessments, the following shared information from reference countries would be useful: registration status; lists of banned and restricted products; residue data, MRLs and PHIs; exposure data; target crops and pests; pesticide use patterns and user precautions.
- Risk assessments from other countries would need adjustment with regard to dietary data, residue data, use patterns, exposure, occupational risk and application technique.

Conclusions

- Risk assessments are important to justify regulatory decisions, particularly with regard to highly hazardous chemicals;
- It is not necessary for all countries to conduct full risk assessments as much of the information is available and can be shared or adapted;
- Only few countries have the expertise and resources to carry out comprehensive risk assessments;
- Countries with insufficient expertise and resources can make use of internationally available information;
- Registration authorities can check whether a particular pesticide is registered in another country; they can access review reports and regulatory justifications to help them with their own decision making.

4. PHASING OUT OF HHPs

4.1 STATUS OF HHPs IN ASIA

Definition of HHP

The questionnaire results showed that there was a high level of agreement among Asian countries about the criteria for identifying HHPs (Figure 10). Almost all responding countries included the WHO Class I and Convention pesticides in this category. Also, a wide consensus existed for highly carcinogenic and mutagenic substances, as well as for pesticides with high reproductive or environmental toxicity (11 countries). The lowest level of agreement (9 countries) was for endocrine disrupting substances which are still under investigation internationally. Such a broad consensus is a good foundation for a common approach to phasing out HHPs in Asia.

Information sources on HHP

To identify substances that fall under the HHP categories, registration authorities rely on published hazard information. The most frequently consulted sources were the FAO/WHO pesticide information and the Convention lists (Figure 11). Registration data from the EU, USA or other countries were less frequently accessed. Fewer than half the countries regularly checked the more specific IARC carcinogen or the PAN HHP lists. These results show that even though the countries agree on the definition of HHP, their management would differ because they do not rely on the same information sources. The adoption of the GHS with its unified label classifications for substances that are carcinogenic, mutagenic, reproductive toxic or hazardous to the environment, would therefore be a useful step toward harmonizing HHP management in the region.

Phasing-out steps

When a new pesticide is added to one of the Convention lists and should therefore be considered an HHP, all countries reported that they would review the registration in order to decide whether to restrict, phase-out or cancel the registration (Figure 12). Most countries also would stop import and production, or encourage the producer to withdraw the product voluntarily from the market.

Figure 10: HHP definition

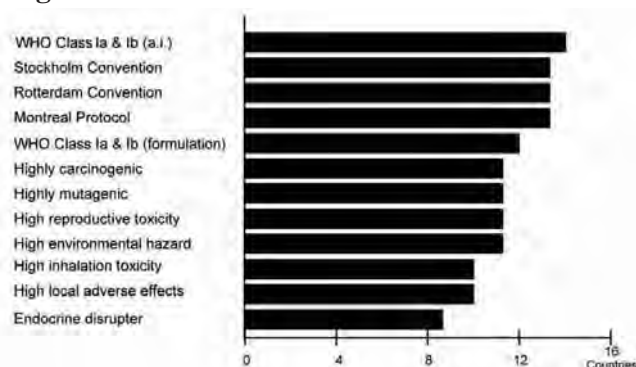


Figure 11: HHP Information Sources

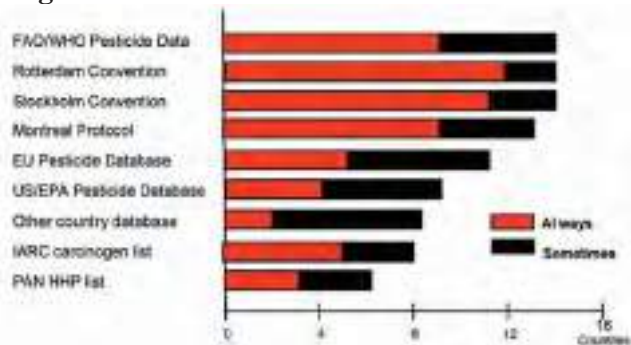


Figure 12: Common phasing-out steps

1. Review product/explore alternatives
2. Announce decision and inform stakeholders
3. Stop production/importation
4. — Recall product for disposal (4 countries)
— Allow phasing-out period (6 countries)
5. Cancel registration/prohibit sales
6. Monitoring and enforcement

The majority of countries allow phasing-out periods ranging from six months to two years. However, four countries prefer to recall the products after cancellation of the registration and dispose of them. After a product has been phased out, countries generally monitor compliance and initiate enforcement actions, if necessary.

Registrations of HHP

The first step toward phasing out HHPs is to identify these products among the registrations and initiate regulatory actions. The survey showed that about half the countries had already prepared such lists and restricted the uses of some of these products. However, an analysis of five HHP lists showed no common approach to HHP management. Only 16 of the total of 104 pesticides were listed by two or more countries. The most often named chemicals were Carbofuran, Acephate and Monocrotophos which appeared on 3 or 4 lists.

An analysis of the regional data set of registered pesticides showed that all countries had registrations of active ingredients that belong to WHO Classes I or O (obsolete) (Figure 11). While eight countries had eliminated all obsolete pesticides, one still had as many as 19. Likewise, the number of registered WHO Class I products ranged widely from 1 to 25 per country. While three countries had fewer than five registrations of WHO Classes I or O pesticides, six Asian countries still had 20 or more.

Likewise, all countries had registrations of Convention pesticides. Overall, there were 17 Rotterdam and 4 Stockholm Convention pesticides, in addition to Methyl Bromide of the Montreal Protocol. The number of registrations per country ranged from 1 to 20, with three countries having more than 10 registrations. These results differed slightly from the registration status results reported on page 10 because of inconsistencies between the questionnaire responses and the lists of registered pesticides. It should also be noted that the data sets of registered pesticides normally include restricted use pesticides and those that are under review or have been targeted for phasing out.

With regard to the pesticides that have not been approved in the EU because of unacceptable risk to human health and/or the environment, there were 281 of these products registered in Asia. In addition to WHO Classes I, O or Convention pesticides, this number also contains pesticides that belong to the CMR¹ category 1A and 1B, endocrine disruptors, very persistent and bio-accumulating substances

¹ carcinogen, mutagen and reproductive toxic

Figure 13: Number of registered pesticides of WHO Classes Ia, Ib and O*

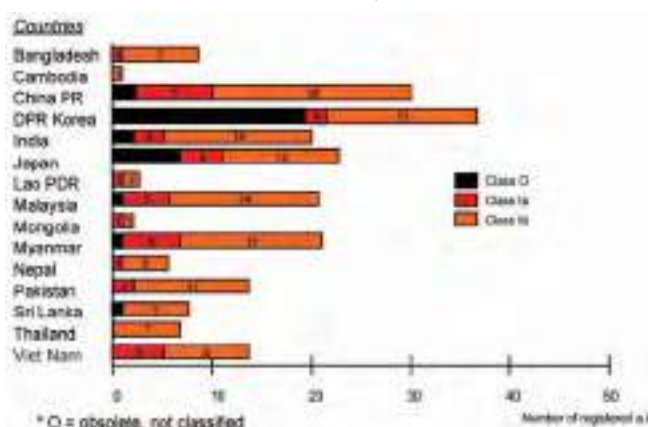
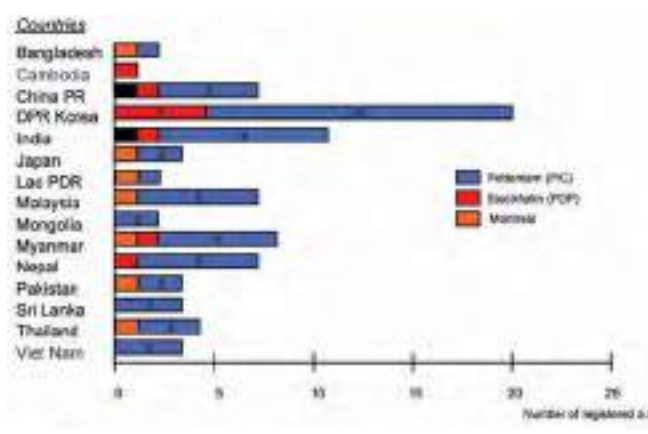


Figure 14: Number of registered Convention pesticides



that are not yet regulated as HHP in all Asian countries. The difference of 21 between the EU “not approved” total and the overall total includes 13 WHO Class I pesticides that are approved in the EU and eight pesticides that had not been evaluated in the EU, but belonged to one of the other two HHP categories.

Table: Number of HHP registrations in Asia

	Total	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Total registered a.i.	1 172	144	155	581	220	249	502	79	282	76	241	107	255	110	206	359
Total WHO Classes I and O	77	8	1	28	34	20	23	3	20	2	22	6	13	8	7	13
Total Conventions	22	2	1	8	20	11	3	2	7	2	11	5	3	3	4	3
Total EU “not approved”	281	50	38	148	99	76	141	24	77	9	86	34	74	33	58	100
Total* WHO + Conventions + EU “not approved”	302	54	39	159	105	85	150	27	86	12	93	38	79	37	62	106

* Note that some pesticides appear in several categories; thus the overall total is not the sum of the three individual totals.

These numbers only give an indication of possible HHPs in a country; final decisions would require country-specific risk assessments. However, the table shows that in order to phase out all potential HHPs in Asia, all countries would have to review as many as 16 to 39 percent of their current pesticide registrations. The phasing out of WHO Classes I and O, and of Convention pesticides would be a more realistic first goal.

Some Asian country experiences with phasing out HHPs are given below in more detail.

Phasing out of HHPs in China

When phasing out an HHP, ICAMA first collects information and evidence of adverse effects and initiates research projects to assess the risk. Based on the results, the Pesticide Registration and Evaluation Committee makes a decision to mitigate risk via label changes or withdrawal of registration. Registration and phasing out information is available online. So far, China has banned 34 active ingredients and one inert substance. In the phasing out programme are 16 substances that have shown a high incidence of adverse effects or chronic toxicity. Furthermore, 30 pesticides have been restricted for use on certain crops or the registration was cancelled except for export. Continuous efforts are made to harmonize and revise data requirements for human health and environmental considerations, and to re-evaluate based on significant new information. Science based decisions will be made in a tiered approach. Furthermore, China promotes 50 alternative, low-toxicity pesticides and over 160 use patterns, and gives price subsidies to farms that use low toxicity and biological pesticides.

The experience in China has shown the importance of collaboration between the different ministries of agriculture, trade, finance and customs. The phasing out is not only a decision by the pesticide registration authority, but other ministries have to be stimulated to take action in order to achieve a positive impact, and local governments have to monitor the market to enforce the decision.

The Chinese experience also demonstrated the importance of local incidence reports. The decision to restrict or phase out a product was taken based on documented accidents (e.g. banning of Fipronil which caused deaths of bees and fish); regularly exceeding of MRLs (leading to the cancelling of the registration on vegetables); or when records showed consistent misuse (the use of Paraquat as a suicide tool, which led to the cancellation of the liquid formulation). (See presentation on page 49)

Phasing out of HHPs in China – Industry Experience

Over the years, the China pesticide industry has grown to become the world's largest pesticide producer. In 2013, its output was 3.19 M tons with about 300 technical products produced by more than 1800 factories. Herbicides make up more than 50 percent of the production. Over the last 50 years, the major formulation types changed from solid to liquid to now mainly environmentally friendly formulations. The decisions to ban certain pesticides caused strong reactions in the industry and CCPIA negotiated compromise solutions to proposed regulatory actions, e.g. for banning Fipronil and Paraquat, or for phasing out EC formulations because of hazardous solvents. There have been numerous pesticide incidences which have been publicized in the media and caused great public concern. The industry supports the strategy to limit the “san gao – three highs” pesticides which exhibit *high toxicity, high pollution* or *high residues*. Producers have responded to the phasing out of HHPs with their own efforts for new product development, automation or quality control. While there were hardships, there were also great opportunities for the industry in terms of greater innovation, structural adjustments and greater market competitiveness. This has placed China products in a much better position on the global market and made the industry and agricultural production more sustainable. Having learned from this experience, CCPIA now works together with the authorities, communicates the decisions to its members, collects feedback, and gets involved in finding solutions to issues. The industry now has proactive programs, a robust R&D system, a practical strategy, user training and a good supervision system. (See presentation on page 53)

Phasing out of HHPs in Malaysia

Following a decision by the Pesticide Board, the Minister will issue a directive to ban a product. This directive is communicated to the producers and users, and a grace period of normally six months is granted to sell off the product. Resistance from the industry may result in delaying the decision. During this period, the Pesticide Section collects information on economic impact, effectiveness and availability of alternative products which are also passed on to the producers. Experience has shown that it would be better if these facts and figures were already available at the time of ban announcement, and if all stakeholders were involved during the process. (See presentation on page 56)

Phasing out of HHPs in Thailand

Thailand uses nine criteria for identifying HHP: (1) chronic toxicity, (2) bioaccumulation, (3) persistence, (4) high acute toxicity, (5) high residues, (6) toxic to useful insects, (7) causing outbreaks, (8) banned in other countries, and (9) in PIC and POP lists. A working group on phasing out HHPs collects the data and the Committee of Hazardous Substances makes the regulatory decision. In Thailand, there are presently 29 HHPs registered for restricted use, two products are on a watch list (selected for risk assessment) and 98 are banned. The banned list contains products that are carcinogens, persistent in the environment, cause high residues in products or have a high acute toxicity. Banned products must be delivered within 15 days to one of the eight regional offices of the DAO which will destroy them by incinerator. (See presentation on page 58)

4.2 PRESENTATIONS

4.2.1 Progress of high hazardous pesticide management in China

by Zhang Wei



Progress of High Hazardous Pesticide Management in China

Pesticide Registration Division
ICAMA
Nanjing 2014/5/19-22



Contents

- Regulatory Framework and Organizations
- Progress of High Hazardous Pesticide Management
- Continuous Improvement



Regulatory Framework and Organizations

- Regulatory Authorities
- Regulatory Acts
- Registration Framework
 - Registration Policies and Guidance
 - Registration System
 - 3 Stages of Registration



Regulatory Authorities



Ministry of Agriculture (MOA)
Registration & Use
Pesticide Registration
Certification

Ministry of Industry and Information Technology (MIIT)
Manufacturing Products
Pesticide Manufacturing
License

Ministry of Agriculture (MOA)
Quality Supervision, Inspection and Testing (AQSIQ)
Quality Monitoring
Pesticide Quality
Inspection




Regulatory Acts

- Laws
 - Administrative License Law of the People's Republic of China
 - Food Safety Law of the People's Republic of China
 - Law of the People's Republic of China on Quality and Safety of Agricultural Products
 - Trademark Law of the People's Republic of China
 - Standardization Law of the People's Republic of China
 - Patent Law of the People's Republic of China



Regulatory Acts



- Regulations
 - Regulation on Pesticide Administration (Revising)
 - Regulation on Agrochemicals Administrative Protection
 - Regulation on Industrial Products Manufacturing License
 - Regulation on Hazardous Chemicals Administration




Registration Framework

Under "the Regulations on Pesticide Administration", the MOA issues regulatory policies and guidance documents to assist the public and regulated entities.


- Pesticide Registration Data requirements (Revising)
- Regulatory Principles of Pesticide Registration
- Restricted or prohibitive Use-Pesticide
- Regulation on Pesticide Label and Instruction (Revising)
- Pesticide Distribution Licenses

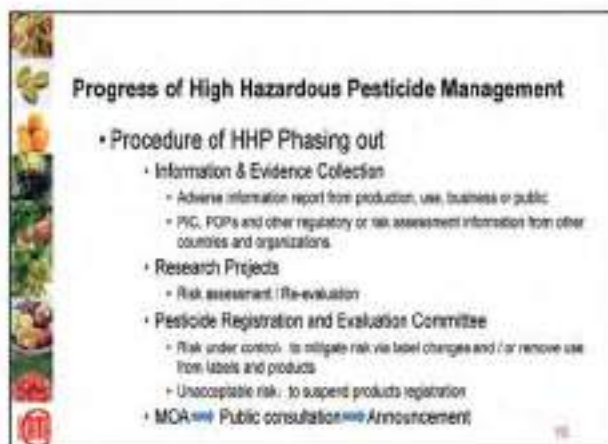
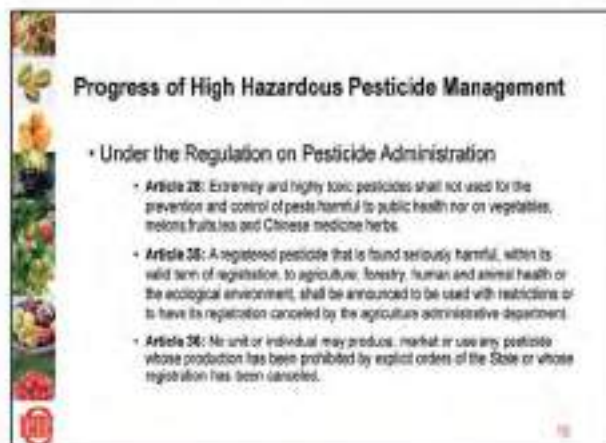
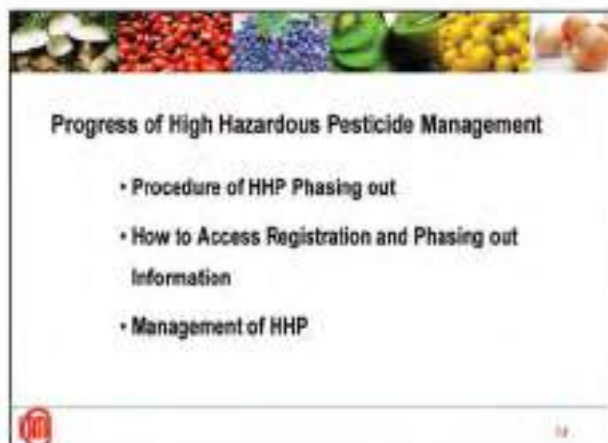
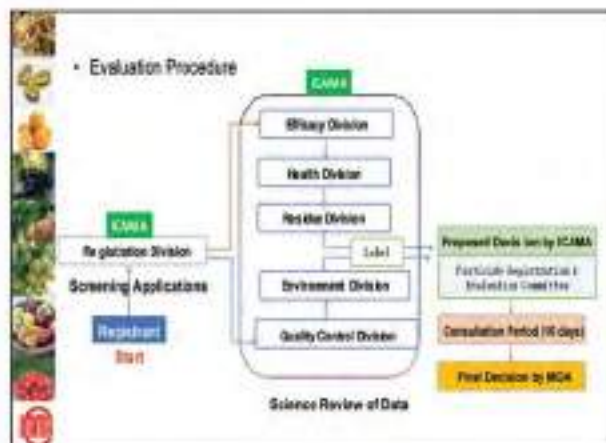
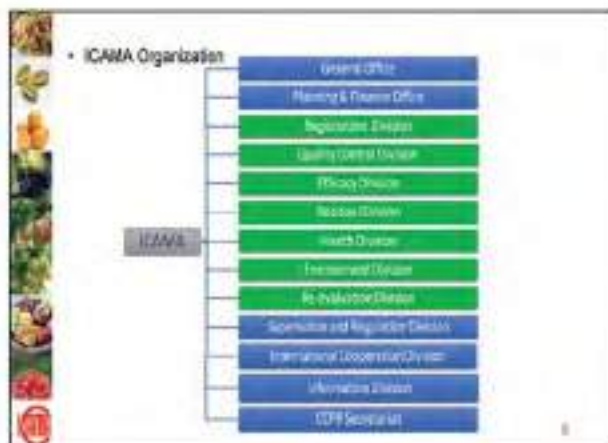


Registration Framework



- Pesticide Registration Systems
 - MOA (the Ministry of Agriculture, China)
 - MOA is a component of the State Council in charge of agriculture and rural economic development
 - ICAMA (the Institute for Control of Agrochemicals, the Ministry of Agriculture)
 - ICAMA, mandated by MOA, responsible for pesticides evaluation, registration, risk assessment, policies enforcement, market supervision, international cooperation and public service
 - Local ICAs (the branches of ICAMA in 31 provinces)
 - 31 ICAs, responsible for the regional service on pesticides evaluation, registration (license, advertisements permits), policies enforcement and public issues





How to Access Registration and Phasing out Information

- MDA : english.agri.gov.cn/
 - Pesticide registration information (Chinese version)
 - Pesticide regulatory laws, regulations and announcements (Chinese & English version)



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How to Access Registration and Phasing out Information

- ICAMA: www.chinapesticide.gov.cn/en/
 - Information on pesticides evaluation, registration, risk assessment, policies enforcement, market supervision, international cooperation and public service



Publication Website

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How to Access Registration and Phasing out Information

- Regional ICAs:
 - Local information on pesticide evaluation, registration renewal, advertisements permission, policies enforcement and public issues



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Progress of High Hazardous Pesticide Management

- Management of HHP
 - Banned Pesticides (34 active substances +1 inert substance)
 - Phasing out Pesticide (16 active substances)
 - Restricted Pesticides (30 active substances)
 - Others

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Progress of High Hazardous Pesticide Management

- Banned Pesticides
 - Before 2002, No.195 Announcement (15)
 - BHC, DDT, camphochlor, dibromochloropropane, chlorobenzene, styrene dibromide, rotenone, aldrin, dieldrin, mercury compounds, arsenic compounds, lead compounds, (乐果), fluorethamide, glyphosate, tetramine, sodium fluoroacetate, alachlor

- ★ High acute toxicity
- ★ Long-term toxic effect at chronic exposure
- ★ Persistence in environment
- ★ Accumulation in food chain

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Progress of High Hazardous Pesticide Management

- Banned Pesticides
 - 2002-2008, 4 Announcements: No. 194/2733221-2008 (5)
 - methamidophos, parathion, parathion-methyl, monocrotophos, phosphamidon

Suspended registration in 2002 → Gradually withdrew registration and cancelled use from 2003 to 2007 → Banned in 2008

- ★ High acute toxicity of Organ phosphorus pesticides
- ★ Long-term toxic effect at chronic exposure

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Progress of High Hazardous Pesticide Management

- Banned Pesticides
 - 2006, No. 747 Announcement
 - Octachlorodipropyl ether (inert ingredient)
 - 2011, No. 1596 Announcement (13)
 - fenamiphos, fenitrothion, phosalone-methyl, calcium phosphide, magnesium phosphide, zinc phosphide, cadusafos, coumaphos, surfacap, terbufos


- ★ High acute toxicity

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Progress of High Hazardous Pesticide Management


- Phasing Out Pesticides
 - Withdrawn registration in 2013, cancel use and market in 2015. (2013, No. 2032 Announcement)
 - dactaniluron, altemetulfuron
 - ★ High incidence of tumors or carcinogenic adverse effects on rotational crops
 - isoxmethyl, urticide
 - ★ Long-term toxic effects at chronic exposure
 - ★ High environmental concerns through toxicity

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Progress of High Hazardous Pesticide Management

- **Phasing Out Pesticides**
 - **Suspended registration and production**
 - 2011, No. 1585 Notification (13):
 - malathion, phorate, isofenphos-methyl, carbofuran, methidathion, effoprophos, aldicarb, aluminium phosphide, omethoate, isocarbophos
 - ★ **High scale toxicity**
 - methyl bromide ★ **Montreal Protocol (the Ozone Layer depletion)**
 - Endosulfan ★ **Stockholm Convention (Persistent Organic Pollutants)**




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Progress of High Hazardous Pesticide Management

- **Restricted Pesticides**
 - **Cancelled use, unregistered pesticides only for export**
 - paraquat AS (2012, No. 1745 Announcement)
 - ★ **Health risk on misuse, poisoning and occupational exposure**
 - Suspended registration and product license of TK and AS
 - To withdraw registration since the 1st of July, 2014 (2 years transition period for manufacturers)
 - To cancel use and market since the 1st of July, 2016 (4 years transition period for market)



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Progress of High Hazardous Pesticide Management

- **Restricted Pesticides**
 - **Cancelled use, unregistered pesticides only for export**
 - metsulfuron-methyl (**Crop Phytotoxicity**)
 - Ispionil (**Environmental risk to aquatic organism**)
 - Restricted use as the public health insecticides, seed coating agents or unregistered for export.




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Progress of High Hazardous Pesticide Management

- **Restricted Pesticides**
 - **Cancelled use on the vegetables, fruits, tea and other crops (6)**
 - omethoate: cabbage, citrus
 - dicofol: tea
 - fenvalerate: tea
 - Aldicarb: apple
 - carbendazim: citrus
 - terbufos: sugarcane




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Progress of High Hazardous Pesticide Management

- **Restricted Pesticides**
 - **Cancelled use on the vegetables, fruits, teas and other crops (8)**
 - daminozide: peanut
 - isocarbophos: citrus
 - methidathion: apple, citrus, tea
 - cadusafos: citrus, cucumber
 - endosulfan: apple, tea
 - methyl bromide: strawberry, cucumber
 - Chlorpyrifos: vegetables
 - triazophos: vegetables




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Progress of High Hazardous Pesticide Management

- **Restricted Pesticides**
 - **Cancelled use on the vegetables, fruits, teas and Chinese herbs (14)**
 - phorate, isofenphos-methyl, terbufos, phospholan-methyl, sulfotep, demeton, carbofuran, aldicarb, ethoprophos, phospholan, coumaphos, fenoxfos, isazofos, fenamiphos




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Progress of High Hazardous Pesticide Management

- **Others**
 - **<30% glyphosate formulations (**Environmental risk—low**)**
 - 2012, No. 1744 Announcement
 - Withdrawn registration of products which glyphosate below 30% (m/v)
 - Increasing glyphosate content equal or over 30% (m/v)
 - **Suspended registration (**Comments from the Pesticide Registration & Evaluation Committee**)**
 - Medical antibiotics used as agrochemicals fly cot, PCP-Na
 - clove oil, linalyl acetate
 - ★ **Potential risk to human health**



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Continuous Improvement

- **Effective Practice for Regulation**
- **Safety Considerations**
- **Re-evaluation**



34

- Effective Practices for Registration



Protective goal	Protective goals for human health and the environment to meet societal expectations.
Data	Harmonized data requirements for hazard and exposure characterization.
Risk assessment	Universal principles and methods, applied to produce coherent assessments whilst respecting local conditions of use.
Mitigation or refinement	Mitigation of risk or refinement with more complex approaches depending on local/individual circumstances.

- **Safety Considerations—Use assessment**

- farmer practices and application methods
- economic benefits and public health benefits



- Safety Considerations—Human Health

- **Toxicology**
 - Identify possible human health effects of pesticides and establish the levels at which humans can be exposed to the products without any harm
- **Occupational exposure**
 - Defines the level of exposure to a pesticide considering all possible sources and assess risk to workers
- **Consider all potential routes of human exposure**



- Safety Considerations—Food

- **Dietary/food residue & MRLs**
 - Determine the risk posed to various population groups via exposure to pesticide residues on treated food commodities and sets limits to levels of residues allowed on treated foods (MRLs)



• Safety Considerations—Environment

- **Eco-Toxicology**
 - Based on accepted (e.g. OECD) protocols with surrogate test species.
 - Identify sensitive organisms and predicts adverse effects on non-target organisms.
- **Fate**
 - Estimates the potential exposure to plants and animals from pesticide residues in water, food, soil and air.
 - Includes information on how often, how long and the amount of pesticide to which an organism may be exposed.
 - Based on environmental fate and transport data as well as modeling and field monitoring information.



- Re-evaluation

- Significant new information
- Substance available with improved benefits or reduced adverse effects
- Significant changes in use or quantity

- Other Activities

- Alternatives (50 pesticide, over 160 use patterns)
- Government procurement and price subsidy to farms of low toxicity pesticides and biological pesticides
- Monitoring and enforcement

4.2.2 Phasing out of HHPs: Chinese pesticide producers' experiences and lessons by Xia Feng

Phasing out HHPs

Chinese Pesticide Producers' Experiences and Lessons

China Crop Protection Industry Association (CCPIA)

Shirley Xia (Xia Feng)
May 21, 2014

Development of China Pesticide Industry

Period	Product	Producer	Output
1949-1983 (35 years)	Product: 8 Producer: 4 Output: 100+ mt/a	Product: 100+ Producer: 200+ Output: 200,000 mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a
1983-1999 (16 years)	Product: 300+ Producer: 1000+ Output: 1.5 M mt/a	Product: 1000+ Producer: 1600+ Output: 1.5 M mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a
1999-2013 (14 years)	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a	Product: 1000+ Producer: 1600+ Output: 1.5 M mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a

Development of China Pesticide Industry

Period	Product	Producer	Output
1949-1983	Product: 8 Producer: 4 Output: 100+ mt/a	Product: 100+ Producer: 200+ Output: 200,000 mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a
1983-1999	Product: 300+ Producer: 1000+ Output: 1.5 M mt/a	Product: 1000+ Producer: 1600+ Output: 1.5 M mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a
1999-2013	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a	Product: 1000+ Producer: 1600+ Output: 1.5 M mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a

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1999-2013	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a	Product: 1000+ Producer: 1600+ Output: 1.5 M mt/a	Product: 300+ Producer: 1600+ Output: 1.5 M mt/a

Phasing-out HHPs

Year	Key event
1983	Banned production & use of Organophosphorus
1985	Banned production & use of Organochlorine
2007	Banned production & use of 5 organophosphorus
2011	Limit and Ban 23 high toxic pesticides

Phasing-out HHPs

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1983	Banned production & use of Organophosphorus
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Phasing-out HHPs

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Phasing out HHPs

Year	Key event
1983	Banned production & use of Organophosphorus
1985	Banned production & use of Organochlorine
2007	Banned production & use of 5 organophosphorus
2011	Limit and Ban 23 high toxic pesticides



Reason of phasing out HHPs

- In 1992, case of pesticide poisoning 141 79063 and 8643 people died in China
- In 2000 Spring Festival, rate of over standard of pesticide residues was 25.20% in 17 kinds of veg. and fruits from 11 provinces
- In 2011 Q3, pesticide residues in 85 out of 191 veg. samples was higher than MRL
- In 2014, 1000+ poisoning in only one county (Zhaoqing)

100

Reason of phasing out HHPs

Three cases

"Du Jiang Gou"
2010.1, Hainan, methamidophos and isocarbophos was detected in cowpea

"Du Jiu Cai"
2010.4, Qingdao, 9 people were poisoned because Organophosphorus pesticide was overused for allium tuberosum

"Du Shen Jiang"
2011.5 Shandong, aldicarb was found to illegally use for ginger

100

Strategy of phasing out HHPs

- First LIMIT and then BAN
- First NO PRODUCTION and then NO SALES & USE
- First TECH. and then FORMULATION
- First NO MORE SALES and then NO EXPORT
- First NO NEW CAPACITY and then NO EXISTING

100

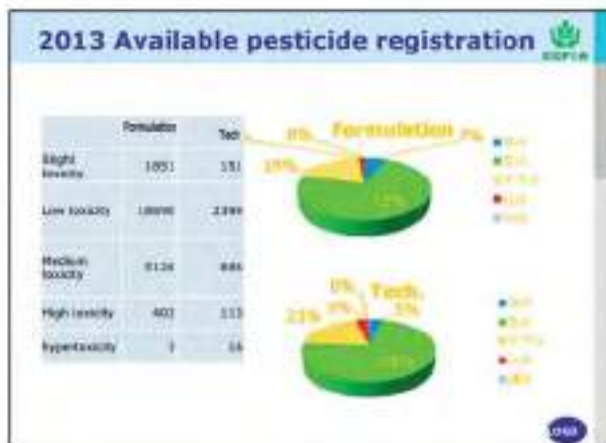
Producers with HHPs

Public awareness
Demand of safe consuming
More new products

**Ban: 33
Limit: 17**

100% 70% 2%

100



Challenge of phasing out HHPs

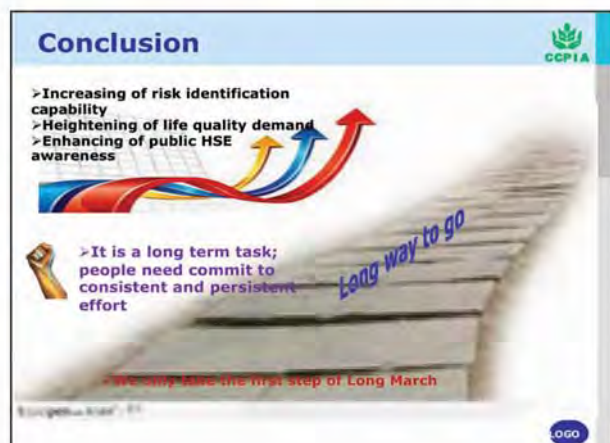
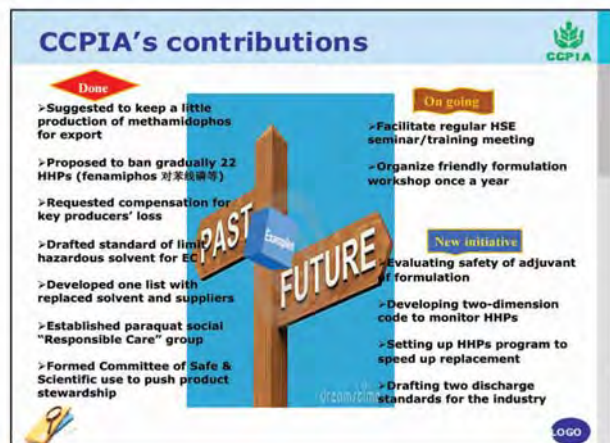
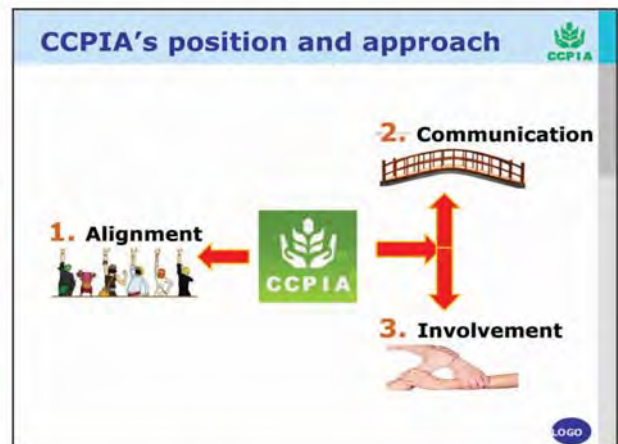
1. Survival crisis of many producers
2. Not enough replaceable products
3. Capital shortfall of some producers
4. Blindness of new product selection
5. Marketing re-segmentation and product re-positioning
6. Farmers' adherence to tradition

100

Producers response

- R&D capability
- Strength reinforcement
- Automation
- Risk reduction
- Quality control
- RE Improvement
- Safe use

100



4.2.3 Phasing out of HHPs in Malaysia by Madam Atika Abdul Kadir Jailani



Phasing out HHPs in Malaysia

Atika Abdul Kadir Jailani
Deputy Director
Pesticides Control Division
Department of Agriculture, MALAYSIA

Regional Workshop on "Practical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
Nanjing, China, 19-22 May 2014

What is HHPs

Highly Hazardous Pesticide:-

- I) Highly Toxic Pesticides listed in the Pesticides Regulations (Highly Toxic Pesticides) 1996
 - Paraquat and its mixtures
 - Monocrotophos
 - Calcium cyanide
 - Metamidophos

Regional Workshop on "Practical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
19-22 May 2014, Nanjing, China

What is HHP

- II) Annex 3 of the Rotterdam Convention
- III) HHPs listed under the Stockholm Convention
- IV) Schedule 1a and 1b of the WHO Hazard Classification
- V) Pesticides under the Montreal Protocol
- VI) Any other pesticides which have been shown to cause adverse effects under local conditions.

Regional Workshop on "Practical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
19-22 May 2014, Nanjing, China

List of HHPs

MALAYSIA - List of HHPs
[Malaysia - Banned / Restricted Pesticides List.doc](#)

Regional Workshop on "Practical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
19-22 May 2014, Nanjing, China

Policy

Based on:

- Normal review for registration by the Malaysian Pesticides Board – monthly
- Post-registration monitoring
- Review on specific active ingredient
- Regulatory actions taken under international system (Rotterdam & Stockholm Convention, Montreal Protocol etc.

Regional Workshop on "Practical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
19-22 May 2014, Nanjing, China

Phasing Out HHPs...Procedures

- I) Directive from Management / Minister
- II) Issuance of circular to inform stakeholders on the decision to phase out a particular pesticide – with conditions attached, e.g. limited usage, limited or no promotion / advertisement; and penalty / action taken to non-compliance

Regional Workshop on "Practical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
19-22 May 2014, Nanjing, China

Phasing Out HHPs...Procedures

Communication:

- to producers and distributors by circulars, internet-announcement in website
- to users through extension agent, flyers and announcement in website

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
16-22 May 2014, Beijing, China

Phasing Out HHPs...Procedures

- III) Grace period for registrant to sell off their product in the market (normally 6 months)
- inspectors – to monitor and take action on registrant who does not comply to the conditions set.

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
16-22 May 2014, Beijing, China

Phasing Out HHPs...Alternatives

- ❖ Before making decision to phase out a particular pesticide, the Pesticides Board will ensure that there are cost-effective alternatives available
- ❖ this is done during the process of reviewing by the Technical Committee of the Board
- ❖ consideration on alternatives based on cost, effectiveness and availability.

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
16-22 May 2014, Beijing, China

Phasing Out HHPs...Issues

- ❖ Resistant from industries
economic reasons in relation to their industry / company
- To resolve:
- Take into consideration their opinion
 - Delay decision – gather more information locally & internationally

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
16-22 May 2014, Beijing, China

Phasing Out HHPs...Lesson Learned

- ❖ Get ready with fact and figures on alternatives
 - cost
 - effectiveness
 - availability
- ❖ To involve all stakeholder during the process

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
16-22 May 2014, Beijing, China



*Thank You For Your
Attention*

Regional Workshop on "Technical Aspects of Pesticide Risk Assessment and Phasing Out of Highly Hazardous Pesticides"
16-22 May 2014, Beijing, China

4.2.4 Phasing out of HHPs in Thailand by Panida Chaiyanboon

Phasing out of HHPs in Thailand

Ms. Panida Chaiyanboon
Department of Agriculture
Bangkok, Thailand

FAO-RAP: Regional Workshop on:
"Practical aspects of pesticide risk assessment and phasing out of Highly Hazardous
Pesticides (HHPs)" 19-22 May 2014, Nanjing, China

Content

1. Criteria
2. Responsibilities
3. Phasing out Process
4. Phasing out of HHPs in Thailand
5. Conclusion

1. Criteria

Criteria for considering as high hazardous pesticides

Criteria
1. Chronic Toxicity
- Neurotoxicity studies
- Reproductive toxicity studies
- Teratology studies
- Mutagenicity studies
- Carcinogen
2. Accumulation in Food Chain
3. Persistence in Environment

1. Criteria

Criteria
4. High Acute Toxicity
- Class 1a, Class 1b (FAO/WHO)
5. High Pesticide residue in Agricultural Products
6. Toxic to useful insects
7. Pesticides which be banned in the other countries
8. Cause outbreak of pests
9. Pesticides in PIC and POP

2. Responsibilities



2. Responsibilities

Responsibilities	Activities
Working group for Phasing out HHPs (Dept. of Agriculture)	- Collect data and/or study of risk assessment - Propose pesticide for watch list by risk assessment data
Sub-committee (Dept. of Agriculture)	- Propose name of Pesticide and risk assessment data to Committee of Hazardous substances.
Committee of Hazardous substances (Committee concern The Hazardous Substance Act)	- Judgment for Ban HHPs

3. Phasing out Process



3. Phasing out Process

Process	Responsibilities	Activities
Restrict use	Dept. of Agriculture	Prohibited to use in some commodities/area
Watch list	Working group for Phasing out HHPs (Dept. of Agriculture)	select high hazardous pesticide by considering risk assessment
	Dept. of Agriculture	Collect/study for risk assessment data of watch list pesticides
Ban	Committee of Hazardous substances	- Judgment list of pesticide
	Dept. of Agriculture	- doing the ban process

Ban process

Notification of Department of Agriculture
(published in Royal Gazette)

" Management for Hazardous Substances Type 4 "
(banned pesticide)

1. The owner have to notify the quantity of hazardous substances within 7 days
2. The owner have to deliver all of substances to DOA within 15 days

4. Phasing out of HHPs in Thailand

Item	Number	Remark
Restrict use	19	Reurgence in paddy field
Watch list	2	Carbofuran Methomyl
Banned list	98	New list in 2014 EPN and dicotophos

Banned list Carcinogen

2,4,5-T	chlorobenzilate	hexachlorobenzene
2,4,5-TP	chlorophenols	leptophos
chlordane	copper arsenate hydroside	lindane
amitrol	daminozide	MCPB
aramite	DGCP	metoprop
BHC	DDT	mirex
kinapocryl	dinoseb	phenothiol
cadmium	ESD	strobane
captafol	endrin	TDE
carbon tetrachloride	ethyl hexylene glycol	toxaphene
chlordecone	ethyl oxide	
chloroform	ethylene dichloride	

Banned list

Persistent in Environment

2,4,5-T	hexachlorobenzene
chlordane	lindane
aldrin	mercury compound
beta-HCH	mirex
DDT	pentachlorophenol
dieldrin	strobane
endrin	TDE
heptachlor	toxaphene

High residues in products

EPN	methamidophos
dicotophos	monocrotophos

Banned list

High Acute Toxicity

aminocarb	cloterb	nitrofen
acinghos ethyl	disulfoton	perathion ethyl
acinghos methyl	DNOC	peris green
bramophos	endosulfan	pentachlorophenol
bramophos ethyl	fenosulfathion	phorate
calcium arsenate	fenitro	phosphamidon
carbon tetrachloride	fluoroacetamide	prothioate
chlorothiophos	fenofos	pyrinuron
copper arsenate hydroside	mephosfolan	schardan
cycloheximide	mercury compound	sodium fluoroacetate
demaphion	methamidophos	sulfotep
demeton	mevinphos	TEPP
dimefox	monocrotophos	thallium sulfate

4. Conclusion

Pesticide Registration and Phasing out of HHPs
in Thailand

Phasing out of HHPs

- watch list 2 compounds
- Banned list 98 compounds

4.3 SUMMARY AND CONCLUSIONS

Summary observations

HHP definition

- There is a general consensus with regard to the criteria for identifying HHPs;
- All countries consider WHO Class I pesticides as HHPs;
- Almost all countries consider the Montreal Protocol, Stockholm and Rotterdam Convention pesticides as HHPs;
- To identify HHPs, most countries consult FAO/WHO pesticide information and Convention lists;
- Registration information from other countries or lists of carcinogenic compounds are consulted to a lesser degree.

Regulatory action

- All countries have some registered HHPs that are either obsolete, highly toxic (WHO Class I) or are listed by international Conventions;
- All countries take some sort of action after a pesticide has been added to an international Convention;
- Most countries allow a phasing-out period when a registration has been withdrawn.

Phasing out of HHP

- There is a commonly applied procedure for phasing out HHPs similar to the steps recommended by the Code of Conduct: (1) first review registered products and identify those that meet the criteria of HHPs; (2) assess whether their availability is really necessary and whether there are alternatives; (3) take regulatory action to phase out the products concerned and provide guidance about alternative where needed; (4) consider what risk mitigation action can be applied if the product cannot be phased out; and finally (5) establish, strengthen and maintain a monitoring and reporting systems for health and environmental impacts of pesticides.
- Complaints from industry/dealers and farmers against a regulatory actions are common;
- Most countries explore alternatives prior to a regulatory action;
- There were no reports of pest outbreaks as a result from phasing out a HHP;
- Issues with phasing out HHPs and possible solutions are:

Issues	Solution
Lack of unified criteria for HHPs	<ul style="list-style-type: none">• Recommend regional priority list for phasing out• Inform producers and users on status of HHPs
Lack of documented poisoning cases or environmental problems	<ul style="list-style-type: none">• Strengthen monitoring system• Follow up on incidences reported in the media• Follow up on alerts from other countries• Collect data on specific products• Must have enough evidence for banning
Lack of risk assessment	<ul style="list-style-type: none">• Review characteristic and make decision• Do or use risk assessment from others countries• Alternatives must be identified in advance• Investigate to finding alternative of pesticide

continued...

Issues	Solution
No specific procedure for phasing out	<ul style="list-style-type: none"> • Develop procedures and regulations • Review registration validity • First restrict use in some crops, then ban
Resistance and pressure from stakeholder	<ul style="list-style-type: none"> • Conduct stakeholder meetings • Communicate legal framework or procedure • Involve other ministries • Multifactorial problems need multifactorial solutions
Lack of disposal facilities	<ul style="list-style-type: none"> • Allow a phasing out period or make manufacturer or importer responsible

Conclusions

- Adoption of the GHS will help in identifying most HHP hazard categories;
- Countries can support each other by sharing data from monitoring and reporting systems for health and environmental impacts of pesticides and sharing experiences on successful phasing out of particular chemicals, including information about alternatives.
- Experience has shown no negative effects to agricultural production or the industry as a result from phasing out HHPs; in China, regulatory actions on HHPs have challenged the industry to strengthen their product development efforts and make structural adjustments. This has placed the Chinese pesticide industry in a much better position on the global market.
- Phasing out HHPs is important for sustainable agricultural production and a competitive agrochemical industry.

5. FAKE AND SUBSTANDARD PESTICIDES

5.1 STATUS IN ASIA

The questionnaire results showed that almost all countries check the quality of pesticides at registration, importation, manufacture, retail or in the field to look for fake or substandard products. However, the analytical capacities to carry out such checks vary widely between the countries. For example, in 2013 only five countries had analyzed sufficient samples for a systematic and representative quality control monitoring (Figure 15). Of these, Thailand and Vietnam predominantly analyzed registration and import samples, while Pakistan and India focussed on market and field data. Only China equally checked both registration and field samples.

Most countries had received alerts about fake or substandard pesticides, mostly from sources within the country. Only two countries were alerted from other countries. Almost all respondents found these alerts helpful and wished to receive more.

Most countries regarded fake, counterfeit or substandard pesticides a minor problem (Figure 16). Only 1-2 countries considered them a major problem. On the other hand, illegal pesticides without a registration number or with foreign language labels were reported a major problem in four countries.

Without more information it is difficult to assess the severity of fake, counterfeit and substandard pesticides in the region. About half the countries acknowledged not having sufficient data.

Figure 15: Quality analyses in 2013

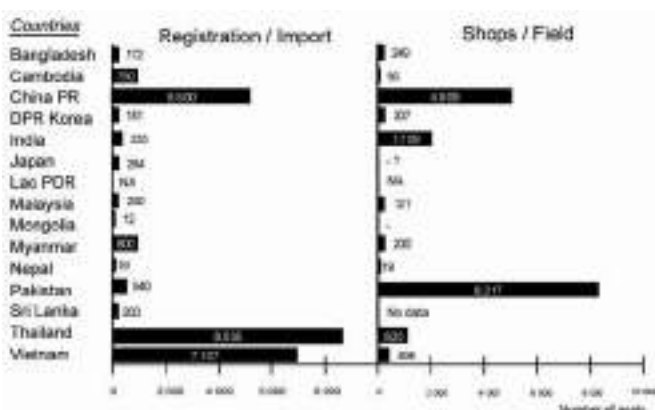
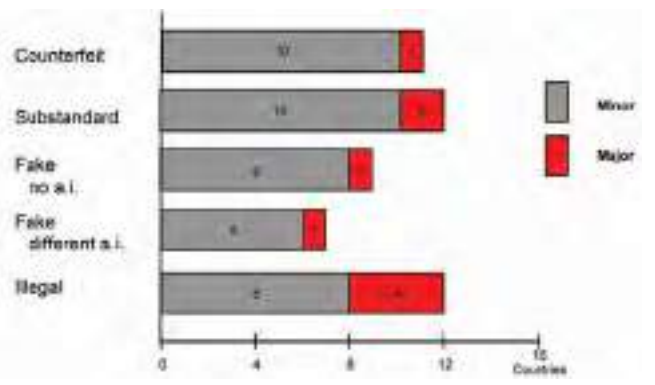


Figure 16: Quality problem assessment



Quality control and implementation in China

The “One Implementation Practice” refers to the joint issuance of import and export certificates by the MOA and the General Administration of Customs (GAC). Quality control involves three divisions of ICAMA: Supervision and regulation division, quality control division and international cooperation division. Overall, there are about 90 quality inspection facilities and 20 laboratories, of which eight are accredited by OECD countries while the remainder follow ISO standards. For pesticide quality, there are 136 national and 116 industry standards. Annually, about 15 000 market samples are collected. In 2013, there were 21 unqualified products and 16 pesticide production enterprises were blacklisted.

In 2013, China imported 62 200 t with a value of 700 M USD and exported to 170 countries or regions a total of 1.62 M t with a value of 8.5 billion USD. China produces 1 157 chemicals which make up 98 percent of all pesticides registered in the world. The import/export control of these materials aims to be transparent, standardized and tractable. Each consignment receives a certificate that the shipment is registered in China. The import or export of pesticides without a clearance notification is strictly prohibited. Special certificates are issued for Thailand, Lebanon, Indonesia, etc. according to their requests. Recently, an electronic law enforcement network has been established which allows the online application and issuance of certificates. An importing country can check through the ICAMA Pesticide Information NetWork whether a product is registered in China. Possible areas of future cooperation are joint actions to crack down on illegal trade and to facilitate the verification of certificates whether they are real or fake, and whether analyses have been conducted by official laboratories. (See presentation on page 64)

Quality control and implementation in Japan

Registrations are issued on a formulation basis and importers must submit the same information as manufacturers for registration application. Quality inspections are carried out at the site of manufacture verifying the manufacturing process, concentration of the active ingredient, physico-chemical properties and the label of the information. In case of irregularities, the registration will be cancelled and the product recalled from the market. In the case of pesticide imports, it is not possible to inspect the manufacturing site and another system is needed to ensure the quality of pesticide products that are manufactured and labelled outside Japan. Pesticides that are produced in Japan solely for export are not regulated, but the exporter must show the approval for import from the other country. There is a provision that prohibits the export of chemicals listed in the Conventions, and manufacturers are advised not to export the 27 active ingredients that are banned in Japan. (See presentation on page 68)

Quality control and implementation in Malaysia

Quality control in Malaysia includes pre-registration analysis and post-registration monitoring by random sampling from pesticide retailers. Imported pesticides are required to have a permit. In 2004, a committee was formed on curbing unregistered pesticides. Every year, the department seizes pesticides that do not conform to the label information, e.g. Paraquat which exceeded the allowable concentration of 13 percent; Endosulfan which had been banned; pesticides with foreign language labels or pesticides without a registration number. Penalties are imposed to such offences. (See presentation on page 70)

Quality control and implementation in Thailand

The responsibility for quality control lies with the MOA. Control measures include the collection of samples at various sites. In 2013, 646 samples were collected at points of entry, 176 at production sites, and 820 at pesticide shops or market stalls. Samples were checked for compliance with the FAO specifications for pesticides. Three substandard samples were found among each of the import and production site samples, and 51 among the market samples. (See presentation on page 72)

5.2 PRESENTATIONS

5.2.1 Quality control and implementation in P.R. China

by Zhang Wenjun

Quality control and implementation in P.R. China

Mr. Zhang Wenjun
International Cooperation Division
ICAMA

Regional workshop on Practical aspects of pesticide risk assessment and
phasing out of Highly Hazardous Pesticides (HHPs)
May 19-22, 2014 Nanjing China

Outline

1. Legal System on Quality Control
2. Control of Import and Export
3. Pesticide International Trade
4. Further Suggestions for Cooperation

1. Legal System on Quality Control

1.1 Definition of Quality Control of Pesticides

- **Quality control of pesticides** refers to the inspection of pesticide products imported, manufactured and/or available in the market to check whether they meet the desired requirements including packaging and specifications as well as to identify for non conformities and take the necessary corrective actions.

1.2 Relevant laws and regulations

- **Product Quality Law** issued on February 22, 1993, and revised in 2000 and 2013.
- **Standardization Law** issued on December 29, 1988.
- **Regulation on Pesticide Administration (RPA)** issued by State Council in 1997, and revised in 2001. The latest revision is in progress.
- **The Implementation Method of Regulation on Pesticide Administration (IMRPA)** issued by MOA in July, 1999 and revised in 2002 and 2007.

1.2 Relevant laws and regulations (especially for control of import and export)

- The Customs Law of the People's Republic of China
- Foreign Trade Law of The People's Republic of China
- The Law of the People's Republic of China on Export and Import Commodity Inspection
- Regulation of the People's Republic of China on Control of Import and Export
- Rotterdam Convention (PIC) and Stockholm Convention (POPs) enter force in 2005
- **One Implementation Practice**

➤ One Implementation Practice

- **The Practice of Pesticide Import and Export Registration Certificates (PIERC)**, jointly issued by the Ministry of Agriculture (MOA) and the General Administration of Customs (GAC) in June, 1999.
- **Bulletin No. 1452 of MOA, GAC**, issued on Sept. 19, 2010, Clearance Notification for Registration Management on Import and Export of Pesticide Come into force on October 18, 2010

1.3 Authorities and Responsibilities

- **Departments:**
- **Ministry of Agriculture (MOA)** – Registration and Clearance notification import & export of pesticides
- **Ministry of Industry and Information and Technology (MIIT)** – Production License
- **General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)** – Standards of pesticide quality
- **State Administration of Industry and Commerce (SAIC) and MOA** – Market inspection and management
- **General Administration of Customs (GAC)** Control inward and outward means of transportation, goods and articles

1.3 Authorities and Responsibilities

- **ICAMA**
- **Supervision and Regulation Division:** Organize national market monitoring annually, inspect labels, deal with illegal cases
- **Quality Control Division:** Provide technical support, review chemistry data, develop data requirements and test guidelines related to product chemistry.
- **International Cooperation Division:** Formulate the management list for import and export of pesticides, and handle the Clearance Notification of pesticide registration and management for import and export, and help to combat illegal trade practices.

1.4 Test Facilities for Quality Control

- 3 National Quality Inspection Centers
- 90 Provincial Quality Inspection Facilities
- 20 laboratories for 5 batches analysis for pesticide registration certified by MOA, among,
 - 13 laboratories comply with GLP principles for pesticide physical chemical testing,
 - 8 GLP laboratories accredited by OECD countries
- The laboratory quality Control system runs according to the relevant requirements of ISO17025
- The quality test of pesticides containing new active ingredients should be taken by 3 national centers, others can be done by either national or provincial quality inspection facilities

1.5 Product Quality Standards System



136 National Standards
116 Industry Standards

China has established a three-levels system of pesticide product quality standards including national standards, industry standards and enterprise standards

Post-registration Sampling Inspection Market Supervision for Quality control

- MOA – market sampling examination, 15,000 a year
 - label inspection, 50,000 a year
 - illegal cases investigation
 - notify results of quality supervision and spot check special circumstances
 - **black list** (Warning farmers and in case be deceived)
 - 2013, 21 unqualified products of 16 pesticide production enterprises – **black list**

2. Control of Import and Export

- Control Measures
- Record Filing and Registration of Pesticide Foreign Trade Operators
- List of Pesticides Subject to Import & Export Certificate Control
- The Clearance Notification for Registration Management on Import or Export of Pesticides
- ICAMA Certificate of Pesticide Registration
- Inspection and Quarantine

Transparent Standardized Traceable

2.1 Record Filing and Registration of Pesticide Foreign Trade Operators

- ✓ All companies operating international trade in China must firstly get record filing and registration with MOC.
- ✓ Traders that engage in the pesticide import and export have to apply to ICAMA for being recorded.
- ✓ Record and file the information on each pesticide trade operator to achieve tracking management.

2.2 List of Pesticides Subject to Import & Export Certificate Control

- ✓ jointly issued by MOA and GAC
- ✓ 1157 chemicals are included in the list, covering all the pesticide ais registered in China and 98% registered all over the world
- ✓ revised and promulgated annually jointly by MOA and GAC to actual needs

2.3 Clearance Notification for Registration Management on Import or Export of Pesticides

- ✓ All pesticide products of export or import need the Certificate
- ✓ Carried out jointly by GAC and MOA
 - Issued by MOA/ICAMA
 - Checked by Customs
- ✓ Basic Principles: **One Consignment, One Certificate**
 - Each shipment has to be determined by ICAMA if the shipped product is registered in China before the Customs release the goods.

2.3 Clearance Notification for Registration Management on Import or Export of Pesticides

- ✓ Any unit to import and export pesticides is obliged to apply to MOA, ICAMA is authorized to issue PIERC to qualified applicants
- ✓ PIERC is a must for customs handle pesticide import and export
- ✓ Imports or exports of pesticides without PIERC will be strictly banned
- ✓ The Certificate gives basic information on the common name of pesticide, HS code, quantity, country name, trader name, etc.
- ✓ Importation and exportation of pesticide products must comply with the content of the Certificate

Contents of Clearance Notification for Importation

- 1 and 3: Importer and its custom code
- 2 and 4: Notification No. and its validation
- 5: Terms of trade
- 6: Place of Clearance
- 7 and 8: Name of Commodity and its HS code
- 9: CAS NO. of active ingredients
- 10: Application of commodity
- 11 and 12: Quantity and Unit
- 13 and 14: Consignee and Manufacturer
- 15: Original Country or region
- 16: Departure country or region
- 17: Means of Package
- 18: Toxicity of products
- 19: Remarks
- 20: Issuing authority and signature date

Contents of Clearance Notification for Exportation

- 1 and 3: Exporter and its custom code
- 2 and 4: Notification No. and its expiry date
- 5: Terms of trade
- 6: Place of Clearance
- 7 and 8: Name of Commodity and its HS code
- 9: CAS NO. of active ingredients
- 10: Application of commodity
- 11 and 12: Quantity and Unit
- 13 and 14: Consignor and Manufacturer
- 15: Destination Country or region
- 16: Arrival country or region
- 17: Means of Package
- 18: Toxicity of products
- 19: Remarks
- 20: Issuing authority and signature date

➤ Certificate of Pesticide Registration

- ✓ Before accepting exports of pesticide products from China, many countries require a certificate from ICAMA to ensure whether the pesticide product is authorized for supply and use in China or not
- ✓ provides basic information on the registration status of exported products, scope of application, targeted pests, etc.
- ✓ ICAMA Certificate modification is being made according to requests of importing country, Thailand, Lebanon, Indonesia, etc.
- ✓ Important bridge of communicating between ICAMA and pesticide authority from other countries, India CIB

Latest Developments

- The first electric law enforcement network established between GAC and MOA ICAMA
 - Operate on Internet, including Applied, approved and issued;
 - MOA-ICAMA send information on approved Notification to Customs daily.
 - Customs release each shipment according to electronic information received from MOA-ICAMA

Flow chart of online operating



2.4 Certificates of Pesticide Registration

- Before accepting exports of pesticide products from China, many countries require a certificate from ICAMA to ensure whether the pesticide product is authorized for supply and use in China or not
- provides basic information on the registration status of exported products, scope of application, targeted pests, etc.
- ICAMA Certificate Modification is being made according to requests of importing country, such as Thailand, Lebanon, Indonesia, etc.
- Important bridge of Communicating between ICAMA and pesticide authority from other countries

International Cooperation

- Information exchange and cooperation on registration, GLP, GLR, etc.
 - EPA, BVL, APVMA, etc.
 - Thailand, Vietnam, Pakistan, Ukraine, Lebanon, etc.
 - India, Brazil, Egypt, etc.

ICAMA Certificate Sample



ICAMA Certificate Thailand



3. China Import and Export of Pesticides

3.1 Import

- > 2011
 - Volume: 43.9 thousand tons
 - Value: 521 million USD
- > 2012
 - Volume: 53.5 thousand tons, 21.8% Increased
 - Value: 564 million USD, 5.2% Increased
- > 2013
 - Volume: 62.2 thousand tons, 16.3% Increased
 - Value: 698 million USD, 23.8% Increased

3. China Import and Export of Pesticides

3.2 Export

- > Over the past 20 years, continue to grow in pesticide exportation
- > Exported to 170 countries or regions
- > 2013
 - Volume: 1.62 million tons, +1.4%
 - Value: 8.52 billion USD, +8.4%

3.3 Export to Aisan Countries

Year	Country	Volume (t)	Growth rate	Value (Million USD)	Growth rate
2013	Thailand	112415.08	3.80%	173.07	16.24%
2013	Vietnam	79289.77	3.42%	123.59	28.15%
2013	India	69941.66	4.30%	196.26	8.75%
2013	Philippines	30315.6	56.07%	173.46	19.17%
2013	Malaysia	44000.63	8.15%	155.17	24.29%
2013	Japan	27181.33	43.67%	128.28	10.37%
2013	Republic of Korea	5876.32	4.80%	89.32	6.50%
2013	Indonesia	24451.17	13.67%	81.36	7.26%
2013	Bangladesh	10783.57	22.89%	36.85	27.88%
2013	Myanmar	6564.88	13.96%	21.38	1.22%
2013	Cambodia	3875.65	188.83%	6.48	121.30%
2013	State of Laos	1706.45	74.08%	1.58	11.89%
2013	Montenegro	408.24	-18.38%	0.38	-81.99%
2013	Sri Lanka	1716.7	55.32%	0.79	24.70%
2013	Cape Verde	44.05	104.96%	0.18	158.13%

4. Further Suggestions for Cooperation

- To Crack down on the Illegal Trade
 - ✓ Pesticide monitoring program to improving the quality
 - ✓ Supplier registration program
 - ✓ Confirmation of registration information: products, registrants, traders, etc.
 - ✓ Prevent the antidumping
 - ✓ Jointly investigation and collecting evidence
 - ✓ Jointly practices

Thanks for Your Attentions!

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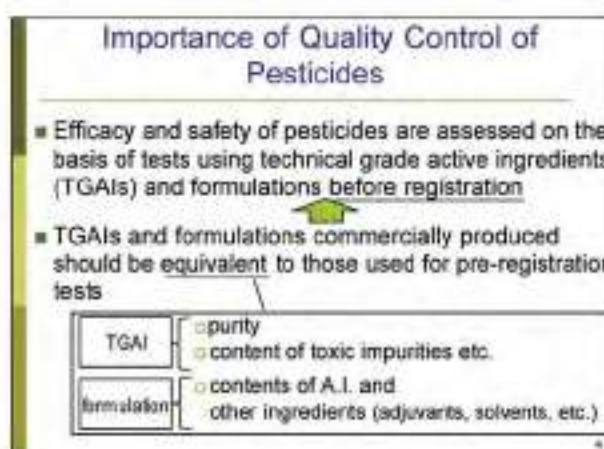
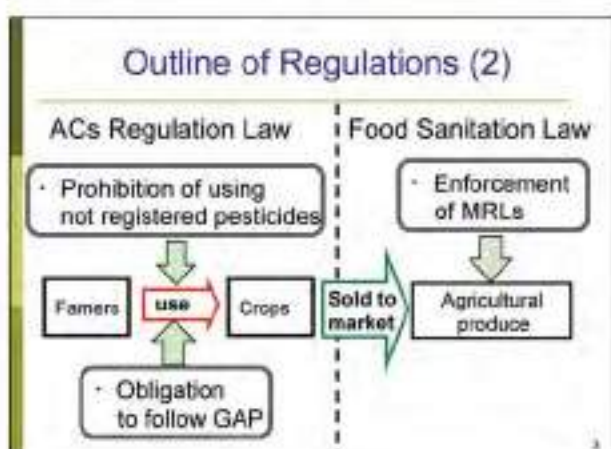
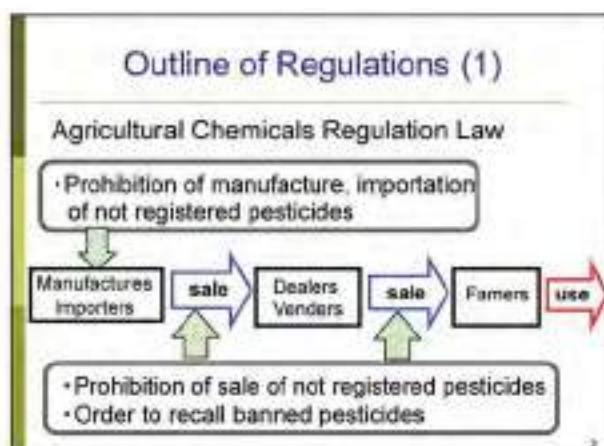
5.2.2 Introduction to Japan's quality control/inspection scheme and implementation by Yoshiyuki Takagishi

Introduction of Japan's Quality Control / Inspection Scheme & Implementation

Yoshiyuki TAKAGISHI
Agricultural Chemicals Office
Plant Products Safety Division
Food Safety and Consumer Affairs Bureau

MAFF
Ministry of Agriculture, Forestry and Fisheries

1



Registration of pesticides in Japan

- Pesticides are registered on a formulation basis
- If any of the following items differ, independent registration is necessary:
 - Formulation type
 - Content and type of a.i. (for mixed formulation, combination of a.i.)
 - Manufacturer or importer
- Importers must submit the same data package as manufacturers for registration application
- Manufacturer or importer shall submit the information on manufacturing process of TGAI and formulation

5

Inspections of Manufacturing Site

- Inspection of manufacturing site for each manufacturer
- 70-80 factories each year
- Check production line and quality control
- Check samples of formulation
 - concentration of a.i.
 - physico-chemical property
 - label

6

Actual Case: Substandard pesticides

- Inspection to a manufacturing site
- Findings from analysis of a product:
 - Concentration of the a.i. was less than half of that of registered pesticide
 - Some ingredients were identified that were not supposed to be formed by registered manufacturing process

manufacturing process changed without authorization

- Cancellation of the registration
- Recall of products on the market

Regulation of pesticides Imported into Japan

- Only registered pesticides can be imported and only the registrant can import the pesticides
- Certification of registration is required for customs clearance (ca. 90 applications / year)

Challenges for quality control

- Imported pesticides which are manufactured, labelled outside Japan
- ➔ Inspection of the manufacturing site is impossible
- Need for the system to ensure the quality of pesticide products manufactured outside Japan

Regulation of Pesticides exported from Japan

- Regulation of domestically manufactured pesticides solely for export from Japan is out of the scope of Agricultural Chemicals Regulation Law
- Nevertheless, prior notification to MAFF with the following information is required when a manufacturer wishes to export a pesticide that contains a.i. not registered in Japan
 - A document to show approval of import which is issued from the government of partner country; and
 - Summary of toxicological profile of a.i. [or formulation]

Regulation of unregistered pesticides

- In order to prevent distribution of unregistered pesticides, MAFF regularly collects information on "suspected" unregistered pesticides through:

- Notification from local governments / farming communities
- Information posted on the website of MAFF

- Analysis of products on the market
- Inspection to the manufacturing site

Actual case: Unregistered pesticides

- Information of a suspected product: a product without pesticide registration may contain certain a.i.
- Findings from analysis of a product:
 - A.i. without registration was detected
- Inspection to a manufacturing site

Unregistered pesticides manufactured and distributed

- Voluntary recall of products by the manufacturer
- Instruction to dealers / farmers by MAFF to return products to the manufacturer and not to use them*

Summary

- Each manufacturer or importer shall register each formulated product in Japan
- Inspections of each manufacturing site
 - checking manufacturing process, conc. of a.i., physico-chemical property, label of formulation
- Each importer shall submit certification of registration for customs clearance

5.2.3 Introduction of Malaysia's quality control/inspection scheme and implementation by Atikah Abdul Kadir Jailani



PESTICIDES ACT 1974

Pesticides (Highly Toxic Pesticides) Regulations 1996

- To control certain highly toxic pesticides which have been shown to cause problems but are considered to be required under local conditions
- Place greater accountability on employers who use these pesticides to minimize adverse effects caused by such pesticides

Quality Control

BASED ON:

- Pre-registration analysis (upon submission of new registration)
 - data on formulation, toxicology, efficacy, residue and analysis of pesticides sample
- 5 batch analysis report to be submitted upon new and reregistration
 - to ensure that the production complies with the standard submitted by the registrant

Quality Control

BASED ON:

- Post-registration monitoring by random sampling from pesticide retailers
 - market sampling and studies, monitoring of pesticides residue in food/agr. produce and the environment, monitoring of poisoning cases and enforcement activities

How do we do it???

1. Enforcement

- Inspection of premise
- Inspection of farm / plantation
- Road block / inspection at Entry Points
- Licensing of premises for sale and storage for sale of pesticides
- Licensing for manufacturing

STATISTICS ON SEIZURE OF PESTICIDES UNDER THE PESTICIDES ACT 1974

Year	Value of Seizure (RM)
2009	344 573
2010	335 711
2011	81 180
2012	640 062
2013	37 438

Prohibition of Sale of Class 1a and 1b Pesticides in Sundry Shops

(one of the licensing condition imposed)

In order to reduce the risks posed by pesticides, the Board decides that sundry shops would not be allowed to sell Class 1A and 1B pesticides

Inspection and control of imported pesticides

- Through Custom's e-permit system
- Only pesticides company who subscribed to the e-Permit system can get access to the information
 - Series of discussion with MAQIS and Malaysian Royal Custom to enable inspection of imported pesticides at the entry points

What did we find???

- EG OF SUBSTD, FAKE & UNREGISTERED PESTICIDES final.doc

How do we do it???

2. COMMITTEE ON CURBING OF UNREGISTERED PESTICIDES

- Formed on 17 February 2004 to solve issues on unregistered pesticides.
- Chaired by Director General of Agriculture
- Members include representatives from related government agencies, industries and NGOs.
- This committee provides a platform to strategies actions to address the problem of smuggling, manufacturing, sale and use of unregistered pesticides.

How do we do it???

3. PROSECUTION

Severe penalty is imposed on any person who commits an offence against the Pesticides Act or the rules or regulations under the Act

With regards to HHPs, penalty are as follows...

PENALTY

SECTION	OFFENCE	1 ST OFFENCE		2 ND AND SUBSEQUENT OFFENCE	
		IMPRISON- MENT	FINE	IMPRISON- MENT	FINE
13	Import or Manufacture – misbranded pesticide, – Unregistered pesticide	5 years, or	RM 50,000 or both	10 years, or	RM 100,000 or both

PENALTY

SECTION	OFFENCE	1 ST OFFENCE		2 ND AND SUBSEQUENT OFFENCE	
		IMPRISON- MENT	FINE	IMPRISON- MENT	FINE
20	Selling of pesticides without license and unregistered pesticides	3 years or statu	RM 10,000 or both	6 years or	RM 20,000 or both

PENALTY

SECTION	OFFENCE	1 ST OFFENCE		2 ND AND SUBSEQUENT OFFENCE	
		IMPRISON- MENT	FINE	IMPRISON- MENT	FINE
53	Giving or making false information or statement	1 year, or	RM 25,000 or both		

PENALTY

SECTION	OFFENCE	1 ST OFFENCE		2 ND AND SUBSEQUENT OFFENCE	
		IMPRISON- MENT	FINE	IMPRISON- MENT	FINE
3A	Possession or use of unregistered pesticides and unapproved use of pesticides	1 year or	RM 10,000 or both	3 years or	RM 20,000 or both

PENALTY

SECTION	OFFENCE	1 ST OFFENCE		2 ND AND SUBSEQUENT OFFENCE	
		IMPRISON- MENT	FINE	IMPRISON- MENT	FINE
56	General Penalty	6 months or both	RM 5,000 or both	1 year or	RM 10,000 or both

5.2.4 Introduction of Thailand's quality control/inspection scheme and implementation by Ms Panida Chaiyanboon

Pesticide Control in Thailand

Ms. Panida Chaiyanboon
Department of Agriculture
Bangkok, Thailand

Content

1. Responsibilities
2. Control Measure
3. Pesticide Formulation Analysis
4. Conclusion

1. Responsibilities

Department of Agriculture

Government Sectors	Activities
Office of Agricultural Regulation	<ol style="list-style-type: none"> 1. Do the legislations process 2. Inspect under control measure 3. Take product sample for analysis
Agricultural Production Science Research and Development Office	<ol style="list-style-type: none"> 1. Analysis for active ingredient 2. Check physical properties

2. Control Measure

Control points	Activities
At points of entry (Import)	<ol style="list-style-type: none"> 1. Take samples for analysis, results must be complied with registration standard before clearance 2. Check packaging 3. Check label
At production site	<ol style="list-style-type: none"> 1. Take samples for analysis 2. Check packaging 3. Check label 4. Inspect production/storage condition against factory standard

2. Control Measure

Control points	Activities
At the market	<ol style="list-style-type: none"> 1. Check for <ol style="list-style-type: none"> 1.1 Label (Thai language only) 1.2 Packaging size to comply with registration certificate 1.3 Container condition (leakage/distorted/deformed) 1.4 Registration number 2. Take samples for analysis

2. Control Measure

Control points	Activities
At the market	Shop Control for Agricultural Products <ul style="list-style-type: none"> - Fertilizers - Seeds - Pesticides

2. Control Measure

Control points	Activities
At the market	Pesticides Shops <ol style="list-style-type: none"> 1. license for sale is valid in 1 year 2. The shop owners/sellers must be trained by DOA, every 5 years 3. not sell fake, banned, substandard pesticides

3. Pesticide Formulation Analysis



Pesticide Research Group,
Agricultural Production Science
Research and Development Office

3. Pesticide Formulation Analysis

Analysis: : Active ingredient
by Gas Chromatography (GC-FID)
High Performance Liquid Chromatography
(HPLC-DAD)
: Physical Properties
Depend on pesticide formulation

Analysis Method: : CIPAC
Criteria: : FAO Specification



Gas Chromatography

High Performance Liquid Chromatography



3. Pesticide Formulation Analysis

Activities	Subsides from	Number of Samples	Number of Sub-standard samples	% Sub-standard samples
Control measure	Points of entry	646	3	0.3
	Production sites	176	3	1.7
	Markets	820	51	6.2
Total	Control measure	1,642	57	3.4
Registration	Registrants	2,107	38	0.3
Total	Control measure and Registrants	3,749	67	1.8

Sample Analysis during 1 Oct. 2012 to 30 Sep. 2013

4. Conclusion

Pesticide Control in Thailand

Pesticide Control

- At point of entry
- production site
- At the market
- control products
- control shops

5.3 SUMMARY AND CONCLUSIONS

Summary observations

Quality control

- Almost all countries monitor the quality of pesticides at registration, importation or manufacture;
- Most countries also monitor the quality of pesticides in shops or in the field;
- Where analytical results were reported, more than 99 percent of the registration, import or manufacture samples indicated no quality problems;
- Only a few countries collect and analyze sufficient samples for a systematic and representative quality monitoring at retail and field level.

Fake and substandard pesticides

- Most countries consider fake, counterfeit or substandard pesticides a minor problem;
- Four countries consider the sale of unregistered pesticides a major problem;
- Most registration authorities have received alerts from internal or external sources about fake, counterfeit or substandard pesticides and found them helpful; the information sources included all persons concerned about pesticides;
- Fake, counterfeit or substandard pesticides are mainly found in pesticide shops and in the field where monitoring is difficult and sporadic.

Conclusions

- Analytical results indicate few quality problems at registration, importation or manufacture;
- Most surveillance programmes may be inadequate for an effective supervision of the market;
- Criminal activities are hard to uncover and must involve the cooperation of different government departments;
- The country presentations provided some clues for potential areas of greater attention, such as a legal system for quality control, management system and laboratory facilities, development of relevant standards, verification of certificate, information for producer, monitoring of field use, etc.;
- More information exchange and regional cooperation may be helpful in fighting fake and substandard pesticides.

6. NEW REGIONAL DEVELOPMENTS

6.1 NEW DEVELOPMENTS IN CHINA AND JAPAN

Chinese experience with removing trade names from labels

In 2007, there were 2 400 enterprises in China selling 622 active ingredients in 23 000 pesticide formulations under 16 000 trade names. This confused farmers when selecting a pesticide since many trade names were similar to each other. Furthermore, many cheap formulations encouraged farmers to use pesticides repeatedly. Consequently, in 2007, six new regulations were issued, including regulations for label text and design. They included 1 024 approved abbreviations for common names; mixture names were limited to five Chinese characters. The company was allowed add its logo or trademark to identify the specific brand of active ingredient. As a result of these actions, the number of pesticide names was reduced from about 15 000 to 1 700. Presently, there are about 2 500 product names. The guiding principles behind these new regulations were the consumers' right to know and to avoid repeated use of pesticides. All companies were considered equal before the law and thus trade names were also treated equally. The change in label regulations lead to an increase in product quality and more compliant pesticide labels, and made the pesticide market more transparent and competitive. Companies have to earn the trust from their consumers through the development of new formulations and innovative technologies. Brand acceptance was no longer influenced by words like "well known trade mark" or "China top brand" as the best-selling brand should be decided by the market and not by Government authorizations. The type of pesticide formulation is indicated by a colour band, and the toxicity classification is prominently indicated on the label, including highly toxic active ingredients. The introduction of the GHS system is under consideration, but not considered urgent. (See presentation on page 76)

Update on the Reform of the Pesticide Registration System in Japan

Since 2007, the pesticide registration system in Japan has undergone a reform to incorporate new approaches and greater participation. The registration decision making was shifted from hazard-based to risk-based assessments of scientific data. Furthermore, Japan was seeking a greater involvement in international rule-making bodies such as Codex Alimentarius, OECD, etc. Risks were communicated to all stakeholders in a transparent manner. The required number of supervised trials was increased and certain trials from other countries are accepted. Japan also began registering uses for crop group, which may result in a potential decrease and simplification of registration requirements. OECD style dossiers and study reports in English are now accepted. On-going programs are the development of more crop groups; guidelines for livestock metabolism and animal transfer studies; evaluation of health effects of short-term intake of pesticides; enhancing the protection of consumer health; evaluation of health risks to operators and bystanders; and procedures for joint reviews and work sharing. (See presentation on page 82)

6.2 PRESENTATIONS

6.2.1 Chinese experience with removing trade names from labels

by Li Youshun

Chinese experience with removing trade names from labels

Dr. Li Youshun
Supervision and Regulation Division
ICAMA

Contents

- 1 Regulations and Definitions of Terms
- 2 Regulations on Trade name using and its problems
- 3 Regulations on Removing of Trade names from labels (For New Regulations)
- 4 Experience

Regulations and Definitions of Terms

- Trade name
 - Reflect the functions of the product
 - One trade name for one end-use product
- Trademark
 - As enterprise brand
 - Products of the same class

Regulations and Definitions of Terms

- CHINA TOP BRAND
 - A quality mark awarded by General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) for a prize of excellent enterprise
 - once a year since 2001



中国名牌产品证书
中国名牌产品

Regulations and Definitions of Terms

- well-known trademark
 - refers to enjoy a high reputation in China and widely known to the public
 - Affirmed by the State Administration of Industry and Commerce (SAIC)
 - 《Provisions for the determination and protection of well-known trademark》, SAIC Decree 5, 2003



Regulations and Definitions of Terms

- Key Regulations for Pesticide Registration/Label
 - Pesticide Management Regulation (RPA, May 8, 1997 the State Council issued, November 29, 2001 Amendment)
 - Measures for Implementation of Pesticide Management Regulation (April 27, 1999 issued by MOA, 2002, 2004, revised 2007)
 - Pesticide registration data requirements (1982 issued by MOA, 2001, December 2007 revised)
 - measures for management of labeling and specifications of pesticides (Decree no. 8 of the MOA)

Regulation on Trade name using

- Measures for Implementation of Pesticide Management Regulation (before revised in December 2007)
 - 第十三条 农药生产者申请办理农药登记时可以申请使用农药商品名称。农药商品名称的命名应当规范，不得描述性过强，不得有误导作用。农药商品名称经农业部批准后由申请人专用。
 - Article 13 Trade name can be used when pesticide manufacturing enterprise applying for pesticide registration, the trade name can only be used after approval by MOA

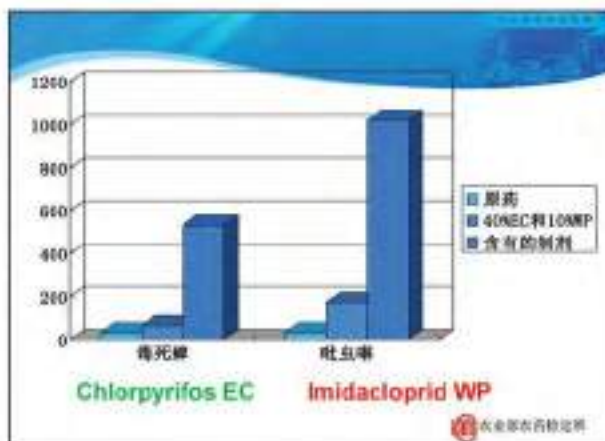
The initial purposes of using trade names

- To promote the enterprise brand
- Easy for farmers to remember

Problems Result in using trade names

- 622 a.i., 2400 enterprises, 23000 pesticide products, **16000** trade names
- Lots of names for one kind of pesticide product

农业部农药检定所



Problems Result in using trade names

- Trade names containing “一”:

一枝花、一支清、一招清、一窝清、一锅烩
 一扫除、一扑净、一平线、一品丰、一溜清
 一片青、一片倒、一喷净、一泡净、一叨三
 一炮响、一怀净、一把平、一把清、一打灵
 一炮轰、一粒宝、一利条、一利克、一串串
 一可灭、一顺星、一箭杀、一箭毒、一毒杀
 一溜净、一杀死、一绝功、一秀

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Problems

- Products containing the same a.i. have lots of different trade names, or similar trade names, but different a.i.
 - difficult for farmers to distinguish/choose/use
- to pursue short-term benefits, Enterprises use trade names for commercial speculation
- Huge numbers of low content products registered (low price, high competitive?)
- Repeated use of pesticides

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Problems Result in using trade names

- Low qualified rate of labels: lack of standardization
 - In 2007, the qualified rate was only **62.9%**!

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• How to do?

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Six new regulations

- Six new regulations were issued by MOA in Dec. 2007, effective in Jan. 2008
 - (1) Decision on Amendment of the Measures for Implementation of Pesticide Management Regulation (Decree No. 9)
 - (2) Measure for Management of Labeling and Specification of Pesticides (Decree No. 8)
 - (3) Regulation on Registration Data Requirements of Pesticides (Decree No. 8)

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Six new regulations

- (4) Removal of trade name from pesticide label (Announcement No. 944 of MOA)
- (5) Naming of Pesticide Products (Announcement No. 945 of MOA & NDRC)
- (6) Content of Active Ingredient in Pesticide (Announcement No. 946 of MOA & NDRC)

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Key point of rule on removal of trade name

- Decision on Amendment of the Measures for Implementation of Pesticide Management Regulation (RPA) (MOA Decree No. 9)
- 第十三条 农药名称是指农药的通用名称或简化通用名称。直接使用的卫生农药以功能描述词和剂型作为产品名称。农药名称登记核准和使用管理的具体规定另行制定。
- Article 13 the pesticide name was the pesticide common name or Simplified common name (short common name). The name of the directly used sanitary pesticide was "functional description term + formulation form".
- Means: forbid using trade name as pesticide name in reg. certificate & label

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Key points on Pesticide label

- Measure for Management of Labeling and Specification of Pesticides (Decree No. 8)
 - The new rule regulates both label text and design (art works)
 - Product name should be put in 1/3 upside and visible part of the label
 - A.I. content and formulation type may only be put in the part below product name and the word height $\geq 1/2$ of the product name
 - Trademarks only may be put in the corner and the edge of labels and the site (area) \leq the site (area) of product name
 - All word size ≥ 1.5 mm

农业部农药检定所

Key points of rule on pesticide naming

- Common names to be pesticide names, such as, Acento 250 g/L SC, new called Prooxystrobin.
- use "functional description term + formulation form" as the pesticide name for straight used sanitary insecticide, for example, electrothermal vaporizing liquid (电热蚊香液)
- Use shortening/abbreviation common name for mixture products if the total words is more than 5 Chinese words, such as "Lambda cyhalothrin-Emamectin benzoate" (高效氯氟氰菊酯-甲氨基阿维菌素苯甲酸盐) named "甲维-高氯氟"
- MOA has issued a list of abbreviation common name for mixture products: 1024 abbreviation common names

农业部农药检定所



6.2.2 Update on the reform of the pesticide registration system in Japan

by Yoshiyuki Takagishi



Update on the Reform of Pesticide Registration System in Japan

Yoshiyuki TAKAGISHI

Agricultural Chemicals Office
Plant Products Safety Division
Food Safety and Consumer Affairs Bureau

MAFF
Ministry of Agriculture, Forestry and Fisheries

Contents

- Principles of the Reformation
- Agreed New Approaches and On-going Works
- Promoting Participation in Joint Review / Work Sharing

Principles of the Reformation (2007-)

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

Revision of "Guidelines for Supervised Residue Trials" (effective from April 1, 2014)

- Increase of No. of trials
 - Major crops (22) 2 → 6 trials
 - Semi-major crops (34) 2 → 3 trials
 - Minor crops (others) 2 trials (unchanged)
- Acceptance of indoor trials conducted in other countries (same GAP)
- Harmonization of portions analyzed
- Quality assurance of analysis

Development of Crop Groups (ongoing)

- Based on the Codex Classification
- Reflecting the reality in Japan
- Harmonization of portions to be analyzed with those of Codex

➡ Leading to potential decrease of requirements

For more information, please see the following website:
http://www.maff.go.jp/j/nyuuyaku/n_sassin/sakumoru.html

Example of Draft Crop Groups (ongoing)

- Stone fruits

Subgroups	Crops
Peaches	Peach ; Nectarine
Plums	Apricot ; Japanese apricot, Plum, Japanese ; Plum ; Prunes ; Sloe ; Plum, Damson, Bullace ; Cherry plum ; Plum, Chickasaw ; Jujube, Chinese ; Plumcot
Cherries	Cherry, Sweet ; Cherry, Sour, Morello ; Korean cherry ; Cherry, Nanking

Selection of Representative Crops (ongoing)

- Representative crop(s) for each crop group for group MRL and registration
- Taking actual use of pesticides in Japan into consideration
- No. of trials for each representative crop
- Stepwise process for crop groups

➡ Simplification of requirements for registration

Guidelines for Livestock Metabolism and Animal Transfer Studies (to be enforced from May 2017)

- Required for new pesticides whenever residues are detectable on feed crops
- For existing pesticides, data submission prioritized taking account of maximum theoretical dietary burden and fat-solubility
- Animal Feeding Table already established and provided to OECD

Evaluation of Health Effects of Short-term Intake of Pesticides (ARfD and NESTI) (ongoing)

- General agreement to establish ARfD and conduct short-term exposure assessment on a routine basis
- Prioritization criteria for the evaluation under discussion among relevant authorities and stakeholders
 - ➔ **Enhanced protection of consumer health**
- Challenges:
 - Possible data gaps for existing pesticides
 - Need for alternative GAP when the NESTI exceeds the ARfD

Evaluation of Health Risk to Operators / Bystanders (ongoing)

- Establishment of model for estimation of operator exposure
 - Measurement of pesticides on body surfaces and in the inhaled air (field study)
- Establishment of acceptable operator exposure levels (AOELs)
 - Development of procedure to derive AOELs

Joint Review / Work Sharing (ongoing)

- Necessary for saving resources and streamlining approvals while ensuring higher protection of human health and the environment
- Measures taken to promote participation in Global Joint Review / Work Sharing:
 - Harmonization with OECD test guidelines
 - Introduction of OECD-style dossier
 - Acceptance of electronic files
 - Acceptance of study reports in English
 - Training courses for evaluators

Thank you for listening

6.3 SUMMARY AND CONCLUSIONS

Summary observations

China

- Many different names and products for the same pesticide substance confuse farmers;
- Many similar names for different pesticides confuse farmers;
- Large numbers of cheap and low content formulations encourage farmers to use more pesticides than necessary.

Japan

- Registration decision making was shifted from law- and hazard-based assessments to risk-based assessments taking into account the magnitude of different risks;
- OECD style dossier and study reports in English are now accepted;
- When residues are detectable on feed crops, livestock and animal metabolism studies are required for new pesticides;
- A model has been established for the estimation of operator exposure.

Conclusions

Pesticide labels

- All companies and trade names should be considered equal before the law; trade names should not distort market competition or confuse farmers;
- Consumer's right to know should be given priority over company's marketing strategies and short-term commercial speculation;
- To improve farmer's decision making and right to know, pesticide labels must be more transparent and clearly identify the product's contents;
- In China, changes in label regulations have made the pesticide industry more competitive and resulted in increased quality, innovative technologies and better formulations;
- China pesticide labels now carry the approved common name of the active ingredient and the company's logo or trade mark;
- New regulations in China resulted in a drastic reduction of trade names from 16 000 in 2007 to 1 700;
- New label regulations have increased the rate of compliance with label requirements;
- The introduction of GHS for classification and labelling will be addressed in the near future.

Registration

- Registering pesticides for crop groups instead of single crops may result in a potential decrease and simplification of registration requirements;
- Harmonization with international standards and guidelines saves resources while ensuring higher protection of human health and the environment.

7. CONCLUSIONS AND FOLLOW-UP ACTION

7.1 OVERALL CONCLUSIONS

In recent years, the focus of pesticide regulatory management has shifted from controlling the quality of products to assessing their human and environmental risks in order to safeguard human health and the environment from the potential harmful effects of these chemicals. As a result, many of the older toxic pesticides have become obsolete and have been phased out in most countries. However, there are still many products that are harmful to humans or the environment in various modes of actions. Therefore, risk assessment and phasing out of HHP are highly relevant topics for Asian countries, both for the present situation and challenges of the future. The workshop on *Practical aspects of pesticide risk assessment and phasing out of HHPs* in May 2014 made Asian countries aware of the new developments and encouraged them to join the international efforts to reduce pesticide risks and create a less toxic agricultural environment.

All presentations demonstrated that significant achievements have been made in the past five years. At the same time, discussion outputs exposed or indicated a number of issues for the way forward and areas of collaboration. Increased efforts for risk assessment are needed in many countries to justify regulatory decisions, particularly with regard to highly hazardous chemicals. Even though almost all countries consider risk as part of the registration procedure, only a few have the resources and capacity to carry out a full risk assessment that includes the assessment of local exposure data. Most registration authorities primarily assess pesticide hazards based on a review of toxicological data.

A comparison of pesticides registered in Asia and Europe showed that about one-quarter of the pesticides registered in Asia have not been approved by the EU because of “unacceptable risk” to human health and/or the environment. While pesticide risks cannot be directly compared, the difference between the EU and Asian countries points towards differences in the approach and management of risk assessment. While the EU countries have pooled their resources to evaluate pesticide risks and do not approve any substance that belongs to the CMR¹ category 1A and 1B, are endocrine disruptors, very persistent or bio-accumulating, Asian countries carry out risk assessments nationally and many authorities do not yet consider all potential HHP criteria in their regulatory management. This is likely to change in the future as registration authorities in Asia will be asked to apply the same health and environmental safety standards that are already applied in other countries. More and more countries realize that an agricultural system that is harmful to human health or the environment cannot be sustainable.

There was little disagreement among Asian countries with regard to the criteria that constitute highly hazardous pesticides. However, the focus was mainly on high acute toxicity (WHO Class I), persistent organic pollutants (POP, Stockholm Convention) and those requiring prior informed consent (PIC, Rotterdam Convention). However, an analysis of the pesticides registered in Asia showed 77 substances of WHO Classes IA, IB and O were registered, as well as 4 POP and 17 PIC chemicals. These pesticides may be given priority for phasing out in Asia, and this could be done without a full risk assessment procedure since their unacceptable risk is well documented and internationally agreed.

¹ Carcinogen, mutagen and reproductive toxic

For the other registered pesticides it would not necessary for all countries to conduct a full risk assessment as much of the information is available and can be shared and adapted. Countries with insufficient expertise and resources can make use of internationally available information. For example, registration authorities can check whether a particular pesticide is registered in another country and they can access review reports and regulatory justifications to help them with their own decision making.

While countries generally evaluate the risk of a pesticide at the time of first registration, they also need mechanisms to review the risk of already registered substances as new information becomes available. A good time for doing this would be at registration renewal in form of a re-registration process that includes a risk assessment which considers new data. Countries with unlimited registration validity periods would need other mechanisms to re-assess periodically the risk of their registered products.

Increased efforts are needed to supervise the pesticide market and the products that are sold, conduct research of their safety and risks, and regulate the international flow of these chemicals. For a successful economic and social development of the Asia region, countries need to work together. Risk assessment and the management of HHPs is an opportunity to exchange experiences between the countries and enhance closer cooperation for a safer agricultural production and ecological environment. For example, countries could share their lists of HHPs and alternatives, share reports on health and environmental incidences. Findings from monitoring for fake, counterfeit or substandard pesticides could lead to greater collaboration between importing and exporting countries on quality issues. A close cooperation among countries would be a strong continual driving force for achieving progress in strengthening regulatory management at both country and regional levels.

7.2 FOLLOW-UP ACTION

To facilitate information exchange in Asia, an *Electronic working group on pesticide risk reduction* was formed during the workshop on *Practical aspects of pesticide risk assessment and phasing out of HHPs* in May 2014. It will establish a platform for the exchange of information related to the following proposed subjects:

a. *Exchange of information*

- Inform each other about banning;
- Inform each other for restrictions and regulatory actions;
- Inform each other on major pesticide poisoning or environmental incidences;
- Assign focal points for the exchange of technical information.

b. *Technical information on risk assessment and phasing out of HHP*

- Exchange of information on country decisions or priorities for phasing out;
- Exchange information on alternatives;
- Exchange risk assessment results, justifications or related relevant information to be used for phasing out in other countries, e.g. China studies on Fipronil risk on rice ecosystem or Carbofuran toxicity to birds.

c. *Cooperation on cracking down on substandard products and illegal trade*

- Alert each other when one finds fake pesticides and illegal trade;
- Exchange information on the disposal of obsolete pesticides and pesticide packaging.

Each member country of the working group will nominate two contact persons, one for technical issues and one for official matters. As a first step, they will establish a priority list of issues and discuss possible other activities.

Countries were encouraged to take appropriate actions in reviewing the use of HHPs and in conducting basic risk assessment when considering registration of new compounds. This would not only reduce the risks to human health and the environment, but would also make their pesticide industry and agricultural sector more competitive and sustainable.

ANNEXES

List of registered pesticides

Pesticide active ingredients registered in Asia

■ = registered, approved

EU Status: 0 = not approved; P = pending; N = not plant protection product

WHO Class: IA, IB, II, III; O = obsolete; FM = fumigant

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
(+)-Absciscic acid (ABA)				0			■													1
1, 2-Benzisothiazolin-3-one												■								1
1, 3-Dichloropropene (cis)	FM			0					■	■										2
1-Methyl-cyclopropene (1-MCP)				■			■			■										2
1-Naphthylacetamide (1-NAD)				■						■										1
1-Naphthylacetic acid (1-NAA)	III			■			■												■	2
1-Triacontanol																			■	1
2-(1-naphthyl) acetamide	II							■												1
2-(1-naphthyl) acetic acid								■												1
2-(thiocyanomethylthio) benzothiazole												■								1
2, 4 buthyl ester																		■		1
2, 4 dimethyl ammonium																		■		1
2, 4 isobuthyl ester																		■		1
2, 4-D (2, 4-dichlorophenoxy acetic acid)	II			■		■	■	■	■	■	■	■	■				■		■	10
2, 4-D 2-ethylhexyl						■						■								2
2, 4-D 2-ethylhexyl ester												■	■							2
2, 4-D amine salt														■						1
2, 4-D butyl												■								1
2, 4-D butyl ester (butylate)						■	■					■								3
2, 4-D dimethyl amine salt						■						■				■				2
2, 4-D dimethylammonium										■		■								2
2, 4-D ethyl ester										■					■					2
2, 4-D iso-butyl ester												■								1
2, 4-D isopropylamine												■								1
2, 4-D isopropylammonium										■										1
2, 4-D sodium						■						■						■		3
2, 4-D sodium monohydrate												■								1
2, 4-D sodium salt															■			■		2
2-Methyl-4-isothiazolin-3-one												■								1
2-Phenylphenol (incl. sodium salt orthophenyl phenol)				■		■						■								2
3-chloropropan-1, 2-diol (3-MCPD)	IB					■														1
3-iodo-2-propynyl butyl carbamate												■								1
4-CPA (4-chlorophenoxyacetic acid = PCPA)				0				■		■										2
4-Indol-3-ylbutyric acid							■	■												2
6-Benzylaminopurine							■			■										2
Abamectin (aka avermectin)				■	■	■	■	■		■	■	■		■	■	■	■	■	■	13
Acephate	II			0	■	■	■	■	■	■	■	■		■	■	■	■	■	■	13
Acequinocyl				P						■										1
Acetachlor	III				■															1
Acetamiprid				■	■	■	■	■	■	■		■		■	■	■	■	■	■	13
Acetochlor				0			■	■			■			■		■		■		7
Acibenzolar-S-methyl (benzothiadiazole)				■															■	1
Acifluorfen	II			0			■													1
Acifluorfen, sodium salt														■		■				2
Acrinathrin	U			■						■									■	2

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
<i>Adoxophyes orana fasciata granulosis virus</i>																				1
Agrifos																				1
<i>Agrobacterium radiobacter</i>																				1
Alachlor	II		0																	10
Alanycarb	II		0																	1
Albendazole																				1
Aldicarb	IA		0																	2
Aldrin	O		0																	1
Allantoin																				1
Allethrin; Bioallethrin	II		0																	5
Alpha-Cypermethrin (aka alphamethrin)	II																			14
Alphamethrin																				1
Alpha-naphthyl acetic acid (a – NAA)																				3
Aluminium phosphide	FM																			11
AMBAM																				1
<i>Amblyseius (Neoseiulus) californicus</i>																				1
<i>Amblyseius cucumeris</i>																				1
Ametroctradin																				1
Ametryn	II		0																	6
Amicarbazone																				1
Amicarbazol																				1
Amidosulfuron																				2
Amino acid																				1
Aminocyclopyrachlor																				1
Aminopyralid triisopropanolammonium																				1
Amisulbrom																				2
Amitraz	II		0																	9
Ammonium-o-nitrophenolate																				1
Ammonium-p-nitrophenolate																				1
Amobam																				2
<i>Ampelomyces quisqualis</i>																				1
Anabasine																				1
Anilazine	O		0																	1
Anilofos, Anilophos	II		0																	6
Annonin																				1
<i>Aphelinus asychis</i>																				1
<i>Aphidius colemani</i> Viereck																				1
<i>Aphidoletes aphidimyza</i> (Rondani)																				1
Artemisinin																				1
Asadirachtin																				1
Asomate			0																	2
Aspirin																				1
Asulam	III		0																	1
Atonik																				1
Atrazine	III		0																	12
attenuated virus of pepper mild mottle virus																				1
Aureofungin																				1
Auxins																				1
Avermectin																				2
Azadirachtin (Neem)																				9
Azamethiphos	II		0																	4
Azimsulfuron	U																			4
Azinphos-methyl	IB		0																	1
Azocyclotin	II		0																	4
Azoxystrobin	U																			10
<i>Bacillus cereus</i>																				1
<i>Bacillus licheniformis</i>																				1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
<i>Bacillus simplex</i>																				1
<i>Bacillus sphaericus (incl.H5a5b)</i>				0																3
<i>Bacillus subtilis</i>																				4
<i>Bacillus thuringiensis</i>	III																			5
<i>Bacillus thuringiensis subsp. aizawai</i>																				3
<i>Bacillus thuringiensis subsp. israelensis</i>																				3
<i>Bacillus thuringiensis subsp. kurstaki</i>																				6
<i>Bacillus thuringiensis var. 7216</i>																				1
<i>Bacillus thuringiensis var. galleriae</i>																				1
<i>Bacillus thuringiensis var. H-14</i>																				1
<i>Bacillus thuringiensis var. T 36</i>																				1
Barbosulfan Carbofuran?																				1
Barium carbonate	O																			1
<i>Bathyplectes anurus</i>																				1
Beauveria																				1
<i>Beauveria bassiana</i>																				5
<i>Beauveria brongniartii</i>				0																1
Benalaxyl	III																			3
Benazolin-ethyl	III																			2
Bendiocarb	II			0																2
Benfuracarb	II			0																7
Benfuresate	III			0																1
Benomyl	U			0																10
Bensulfuron	U																			2
Bensulfuron-methyl	U																			12
Bensultap	II			0																2
Bentazone	II																			4
Bentazone-sodium																				2
Benthiavdicarb-isopropyl																				1
Benthiocarb																				1
Benziothiazolinone																				1
Benzobicyclon				0																1
Benzoic acid																				1
Benzyladenin																				1
Berberine																				1
beta-Cyfluthrin; Cyfluthrin	IB																			10
beta-Cypermethrin				P																8
beta-Naphthol																				1
beta-Naphthoxy acetic acid																				1
Bethrodine																				1
Bialaphos sodium																				1
Biethylenedio-carbamic acid zinc salt																				1
Bifenazate	U																			3
Bifenthrin	II																			12
Bioallethrin	II			0																2
Bioresmethrin	U			0																4
Bismerthiazol																				4
BispyrIbac-sodium	III																			11
Bistrifluron				0																4
Bisultap																				2
Bitertanol	U																			4
Borax; disodium tetraborate decahydrate	II																			2
Bordeaux mixture																				4
Boric acid				0																2
Boron ethanolamin																				1
Boscalid (formerly nicobifen)	U																			2
Brassinolide																				3

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
Brevibacterium																				1
Brochantite																				1
Brodifacoum	IA		0																	4
Bromacil	U		0																	6
Bromadiolone	IA																			10
Bromobutide	U																			1
Bromopropylate	U		0																	3
Bromothalonil																				2
Bromoxynil	II																			2
Bromoxynil octanoate	II																			1
Bromuconazole	II																			1
Bronopol	II		0																	3
Buprofezin	III																			12
Butachlor	III		0																	12
Butamifos	II		0																	1
Butralin	II		0																	5
Cadusafos (aka ebufos)	IB		0																	6
Cafenstrole			0																	1
Calcium carbonate																				1
Calcium chloride			0																	1
Calcium cyanamide	O																			2
Calcium formate																				1
Calcium oxide (quick lime)			0																	2
Calcium peroxide																				1
Calcium phosphide																				1
Calcium polysulfide																				2
Calcium sulfate																				1
Camphor																				1
Cantharidin																				1
Captan	U																			9
Carbam																				1
Carbam sodium																				1
Carbaryl	II		0																	12
Carbendazim	U																			13
Carbensulfan?																				1
Carbofuran	IB		0																	8
Carbon dioxide																				1
Carbon disulphide	O		0																	1
Carbon tetrachloride																				2
Carbophenothion	O		0																	1
Carbosulfan	II		0																	12
Carboxin	III																			5
Carfentrazone-ethyl																				7
Carpropamid	U		0																	3
Cartap	II		0																	8
Cartap hydrochloride																				6
Casugamicina																				1
<i>Celastrus angulatus</i>																				2
Chaetomium cupreum																				2
Chitosan																				2
Chlomethoxyfen	O		0																	1
Chlopyrifos-ethyl																				2
Chloramine phosphorus																				1
Chlorantraniliprole	U																			8
Chlorbenzuron																				2
Chlordane	II		0																	1
Chlordecone	O		0																	1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
Chlorella extract																				1
Chlorfenapyr	II		0																	7
Chlorfenson (aka chlorfenizon)			0																	1
Chlorfenvinphos	IB		0																	1
Chlorflazuron	U		0																	9
Chlorflurenol (chlorflurecol)	O		0																	1
Chlorimuron-ethyl	III																			4
Chlormequat (-chloride)	II																			4
Chlorobromo isocyanuric acid																				1
Chloroisobromine cyanuric acid																				1
Chloroneb	O		0																	1
Chlorophacinone	IA		0																	2
Chlorophthalin																				1
Chloropicrin	FM		0																	2
Chlorosulfonic acid																				1
Chlorothalonil	U																			14
Chlorpenapyr																				1
Chlorphonium (chloride)	O		0																	1
Chlorpropham	U																			3
Chlorpyrifos	II																			14
Chlorpyrifos-methyl	III																			6
Chlorsulfuron	U																			3
Chlorthiamid	O		0																	2
Chlortoluron																				1
Chlothianidin																				1
Chltosan																				1
Choline																				1
Choline chloride			0																	1
Chromafenozide			P																	6
<i>Chrysoperla carnea</i>																				1
Cinmethylen																				1
Cinmethylin	III																			2
Cinosulfuron	U		0																	4
Citrus oil																				2
Clamazone																				1
Clethodim																				8
Clinoptilolite																				2
Clodinafop-propargyl																				6
Clofentezine	III																			4
Clomazone	II																			7
Clomeprop	U		0																	1
Clopyralid	III																			5
Cloquintocet-mexyl			N																	1
Cloransulam-methyl																				1
Clothianidin																				6
Cnidiadin																				2
<i>Conidioblous thromboides</i>																				1
<i>Coniothyrium minitans</i>																				1
Copper acetate																				1
Copper ammonium carbonate																				1
Copper calcium sulphate																				1
Copper chloride																				1
Copper citrate																				1
Copper compounds (incl. succinate + glutarate + adipate)																				3
Copper hydrochloride																				1
Copper hydroxide	II																			11
Copper nonylphenol sulfonate																				1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
Copper oxychloride	II																			14
Copper oxysulfate																				1
Copper sulfate	II																			7
Copper sulfate (anhydride)	II																			1
Copper sulfate (basic, tribasic)	II																			2
Copper sulfate (pentahydrate)	II																			2
Cottonseed oil																				1
Coumachlor	O		0																	1
Coumaphos	IB		0																	1
Coumatetralyl	IB		0																	5
Coumoxystrobin																				1
Cover?																				1
cuaminosulfate																				1
Cumyluron																				1
Cuppric nonyl phenolsulfonate																				1
Cuprous oxide or copper oxide	II																			8
Curcumol																				1
Cyanamide (H & Ca cyanamide)			0																	2
Cyanazine	II		0																	2
Cyanophos	II																			1
Cyantraniliprole			P																	3
Cyazofamid																				4
Cycloprothrin	U																			2
Cyclosulfamuron	U																			6
Cycloxydim	III																			2
Cyenopyrafen			0																	1
Cyflufenamid																				1
Cyflumetofen																				2
Cyfluthrin	IB																			9
Cyhalofop-butyl	U																			12
Cyhalothrin	II		0																	2
Cyhalothrin, gamma																				1
Cyhalothrin, lambda	II																			1
Cyhexatin	II		0																	1
Cymoxanil	II																			10
Cypermethrin	II																			14
Cyphenothrin	II																			4
Cyproconazole	II																			6
Cyprodinil																				2
Cyromazine	III																			8
Cytokinin (Zeatin)																				1
Cytosinepeptidemycin																				1
d, d, t-cyphenothrin																				1
<i>Dacnusa sibirica</i> Telenga																				1
Daimuron	U																			1
Dalapon	U		0																	1
d-allethrin	II																			3
d-allethrin (75/25)	II																			1
Daminozide	U																			3
Danmihuanglong																				1
Dazomet	II																			5
DBEDC																				1
d-Camphor																				1
d-Catechin																				1
DCIP																				1
DCPTA																				1
d-Cyphenothrin																				1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
DDT (Dichloro Diphenyl Trichloroethane)	II			0																2
Decylalcohol																				1
Deltamethrin (Decamethrin)	II																			13
Dendrolimus punctatus cytoplasmic polyhedrosis virus																				1
Denotefuran																				1
Desmedipham	U																			3
d-Furamethrin																				1
Diafenthiuron	III		0																	7
Diatomaceous earth																				1
Diatomite																				1
Diazinon	II		0																	12
Dicamba	II																			7
Dicamba-dimethylamine																				1
Dicamba-potassium																				1
Dichlobenil	III		0																	1
Dichlofluanid	U		0																	1
Dichloran																				1
Dichloro-2-n-octyl-4-isothiazolin-3-one																				1
Dichloropropane (in DD mixture)																				1
Dichlorprop	II		0																	1
Dichlorvos	IB		0																	8
Diclocymet																				1
Diclofop-methyl																				2
Dicloran	III		0																	2
Dicofol	II		0																	5
Didecyldimethylammonium chloride			0																	1
Dienochlor	O		0																	1
Diethofencarb	U																			3
Diethyl aminoethyl hexanoate																				1
Diethyl toluamide, N, N Diethyl M Toluamide	III																			3
Difenoconazole	II																			12
Difenzoquat	II		0																	1
Diiflubenzuron	III																			11
Diiflufenican	III																			3
Diiflumetorim																				1
<i>Diglyphus isaea (Walker)</i>																				1
Dimefluthrin																				4
Dimehypo																				1
Dimepiperate	II		0																	2
Dimetachlone																				1
Dimethacarb																				1
Dimethametryn	III																			2
Dimethenamid	II		0																	2
Dimethenamid-P																				1
Dimethoate	II																			13
Dimethomop																				1
Dimethomorph	U																			11
Dimetsulfuron																				1
Dinex																				1
Diniconazole	II																			5
Diniconazole-M			0																	1
Dinocap	II		0																	3
Dinoseb, its acetate and salts	O		0																	1
Dinotefuran			0																	9
Dioxacarb	O		0																	1
Dioxathion	O		0																	1
Diphacinone	IA		0																	3

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Diquat (dibromide)	II																			4
Disodium octaborate tetrahydrate	III			0																1
Disulfoton	IA			0																1
Dithianon	II																			3
Dithioether																				1
Dithiopyr	U			0																2
Diuron	III																			11
d-Limonene																				1
Dodecyl sodium sulphate																				1
Dodine	II																			1
Doxycycline																				1
DPA																				1
d-phenothrin																				2
d-Phenothrin																				1
d-phenothrin (25/75)																				1
<i>Drechslera monoceras</i>																				1
d-Resmethrin																				1
DSMA (methylarsonic acid)	II																			2
d-Tetramethrin																				2
d-trans allethrin																				4
d-trans allethrin (75/25)																				1
d-trans-cyphenothrin																				1
d-trans-tetramethrin																				1
EBP																				1
EDB																				1
Edifenphos	IB			0																7
Ehlorepenthrin																				1
Emamectin (Abamectin-aminomethyl)																				2
Emamectin benzoate																				13
<i>Empedobacter brevis</i>																				1
Empenthrin	III																			1
Enadenine (2iP)																				1
<i>Encarsia formosa Gahan</i>																				1
Endosulfan	II			0																4
Endothal-disodium	II																			1
Endrin	O			0																1
Enestroburin																				2
EPN	IA			0																1
Epoxiconazole																				7
<i>Eretmoceris eremicus</i>																				1
<i>Eretmoceris mundus Mercet</i>																				1
<i>Erwinia carotovora subsp. Carotovora</i>																				1
Erythromycin																				1
Esbiothrin; S-Bioalletrin	II																			2
Esfenvalerate	II																			10
Esprocarb	III			0																1
Esters of botanical oil																				1
Ethaboxam				0																3
Ethachlor																				1
Ethalfuralin	U			0																1
Ethametsulfuron				P																1
Ethaprochlor																				1
Ethephon	III																			9
Ethion (aka diethion)	II			0																5
Ethiprole				0																8
Ethirimol	U			0																1
Ethofumesate	U																			1

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Ethoprophos; Ethoprop	IA																			2
Ethoxysulfuran																				1
Ethoxysulfuron																				10
Ethychlozate			0																	1
Ethyl butylacetylaminopropionate	U																			2
Ethylene dichloride; 1, 2-Dichloroethane	FM																			2
Ethylene oxide	FM		0																	1
Ethylcin																				1
Etobenzanid																				1
Etofenprox; Ethofenprox	U																			10
Etofumezat																				1
Etoxazole																				2
Etridiazole	III																			2
Eucalyptol																				2
Eugenol																				2
Extract of cashew nut shell oil																				1
Extract of Lentinura edodes mycelium																				1
Extract of mixed crude drugs																				1
Famoxadone	U																			5
Fatty acids, glyceride																				1
Femesafen																				1
Fenamidone																				4
Fenaminosulf	O		0																	2
Fenamiphos (aka phenamiphos)	IB																			3
Fenarimol	III		0																	4
Fenazaquin	II																			6
Fenazin, Isopropyl-fenazine																				1
Fenbuconazole	III																			4
Fenbutatin-oxide	III																			5
Fenclorim	U		N																	2
Fenhexamid	U																			1
Fenitrothion	II		0																	11
Fenobucarb (BPMC)	II		0																	12
Fenothiocarb	II		0																	1
Fenoxanil																				5
Fenoxaprop-P; Fenoxaprop-p-ethyl																				11
Fenoxycarb	U																			2
Fenpropathrin	II		0																	9
Fenpropimorph	III																			1
Fenpyrazamine	II																			1
Fenpyroximate																				8
Fenthion	II		0																	9
Fentin acetate; Triphenyltin acetate	II		0																	2
Fentin hydroxide; Triphenyltin hydroxide	II		0																	2
Fentrazamide			0																	3
Fenvalerate	II		0																	12
Ferbam	U		0																	1
Ferimzole																				1
Ferimzone	II																			1
Ferric ammonium methylarsonate																				1
Ferric phosphate																				1
Fipronil	II																			14
Flazasulfuron																				3
Flocoumafen	IA		0																	4
Flonicamid (IKI-220)																				6
Florasulam	U																			4
Florfenicol																				1

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Fluacrypyrim				0																1
Fluazifop-butyl																				8
Fluazifop-P; Fluazifop-p-butyl	III																			5
Fluazinam																				5
Flubendiamide				P																10
Flucarbazone-sodium	U			0																2
Flucetosulfuron																				4
Fluchloralin	II																			1
Flucythrinate	IB			0																1
Fludioxonil	U																			5
Flufenacet (formerly fluthiamide)	II																			2
Flufenoxuron	III			0																8
Flufenzin (ISO: diflovidazin)				0																1
Flufinam																				1
Flumethrin																				2
Flumetralim																				1
Flumetralin	U			P																1
Flumetsulam				0																1
Flumiclorac-pentyl																				1
Flumioxazin																				2
Flumioxazin																				1
Flumorph																				2
Fluometuron	U																			2
Fluopicolide																				3
Fluopyram																				2
Fluoroglycofen-ethyl																				2
Fluoroimide	O																			1
Flupoxam				0																1
Fluquinconazole																				1
Fluroxypyr	U																			2
Fluroxypyr-meptyl																				2
Fluroxypyr-methyl																				1
Flurprimidol	II			0																1
Flursulamid																				1
Flusilazole	II			0																6
Flusulfamide				0																3
Fluthiacet-methyl	U																			2
Flutianil				P																1
Flutolanil	U																			4
Flutriafol	II																			6
Fluvalinate	III																			3
Fluxapyroxad																				1
Folpet	U																			3
Fomesafen	II			0																7
Fonofos	O			0																1
Foramsulfuron																				1
Forchlorfenuron																				4
Formaldehyde	FM			0																2
Formetanate hydrochloride																				2
Formothion	O			0																1
Fosetyl	U																			1
Fosetyl-aluminium																				10
Fosthiazate																				3
<i>Frankliniopsis vespiformis</i>																				1
Fthalide (Phthalide)																				5
Fugavic acid																				1
Fulvic acid																				1

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Fumaric acid																				1
Fungous Proteoglycan																				3
Furalaxyl	II			0																1
Furametpyr																				1
Furan carbonic acid																				1
Furframid																				1
Gamma-cyhalothrin			P																	6
Garlic extract																				1
Gentamicin sulfate																				1
Gibberellic acid	U																			9
Gibberellic acid A4, A6																				1
Gibberellic acid (GA3)																				1
Glufosinate	II																			2
Glufosinate-ammonium																				8
Glufosinate-p-sodium																				1
Glutamic acid																				1
Glyphosate (incl trimesium aka sulfosate)	III																			12
Glyphosate ammonium																				6
Glyphosate ammonium salt																				3
Glyphosate isopropylamine salt																				3
Glyphosate isopropylammonium																				4
Glyphosate monoammonium																				1
Glyphosate potassium salt																				4
Glyphosate sodium																				2
Glyphosate trimesium																				1
Guazatine	II			0																1
<i>Gynaesius liturivorus</i>																				1
Halosulfuron methyl																				3
Haloxypop	II			0																2
Haloxypop-methyl (unstated stereochemistry)																				3
Haloxypop-R-methylester																				5
<i>Harmonia axyridis Pallas</i>																				1
Harpin protein																				1
HCB																				1
HCH	II			0																1
Heptachlor	O			0																1
Hexaconazole	III			0																13
Hexaflumuron	U			0																4
Hexazinone	II			0																7
Hexythiazox	U																			13
Hiper?																				1
<i>Homona magnanima granulosis virus</i>																				1
Humic acid																				2
Hydramethylnon	II			0																3
Hydrel																				1
Hydrogen cyanamide	FM																			4
Hydroxyisoxazole	III																			1
Hydroxypropyl starch																				1
Hymexazol	III																			7
Hyrogenated starch hydrolysate																				1
Icaridin																				2
Idaziflam																				1
Imazalil (aka enilconazole)	II																			2
Imazalil sulfate																				1
Imazamox																				2
Imazamox-ammonium																				1
Imazapic				0																5

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Imazapyr	U			0																3
Imazapyr isopropylammonium																				1
Imazaquin	U																			2
Imazethapyr	U			0																8
Imazethapyr-ammonium																				1
Imazosulfuron																				2
Imibenconazole	U			0																4
Imicyafos				0																1
Imidacloprid	II																			15
Imidaclothiz																				1
Iminoctadine	II			0																1
Iminoctadine acetate																				1
Iminoctadine tris (albesilate)																				3
Imiprothrin																				5
Indanofan				0																3
Indaziflam				0																3
Indol-3-ylacetic acid																				2
Indolylacetic acid (aka auxins)				0																1
Indoxacarb	II																			11
Indoxacarb-MP																				1
Iodosulfuron-methyl-sodium																				5
Ioxynil	II																			1
Ipconazole				P																3
Ipfencazone																				1
Iprovalicarb																				2
Iprobenfos	II			0																10
Iprodione	III																			11
Iprovalicarb																				4
Isazofos	O			0																2
Isocarbophos				0																2
Isofenphos-methyl				0																1
Isoprocab	II			0																8
Isoprothiolane				0																11
Isoproturon																				3
Isotianil				0																1
Isouron	II			0																1
Isoxaben	U																			1
Isoxaflutole																				3
Isoxathion	IB			0																2
Ivermectin																				1
Jingangmycin																				1
Jingangmycin A																				1
Kanamycin sulfate																				1
Karanjin																				1
Karbutilate	O			0																1
Kasugamycin	U			0																11
Kasugamycin hydrochloride hydrate																				1
Kinetin																				1
Kresoxim-methyl																				9
Lactofen				0																4
lambda-Cyhalothrin	II																			11
Ledosing																				1
Lenacil	II																			1
LeNPV																				1
Lepimectin				0																1
Levamisol hydrochloride																				1
Lime sulphur (calcium olysulphide)																				3

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Lindane (gamma-HCH)	II			0																1
Linuron	III																			6
Liuyangmycin																				1
Lufenuron																				11
Magnesium phosphide	FM																			7
Malathion	III																			13
Maleic hydrazide	U																			3
Mancozeb	U																			14
Mandipromid?																				1
Mandipropamid	U																			6
Maneb	U																			6
Manzeb																				1
Matiram																				1
Matrine																				5
MCPA (methyl chlorophenoxy acetic acid)	II																			9
MCPA ethyl																				1
MCPA isoctyl																				1
MCPA isoctyl ester																				1
MCPA isopropyl																				1
MCPA isopropylamine																				1
MCPA potassium																				1
MCPA sodium																				2
MCPA sodium salt monohydrate																				1
MCPB	II																			1
MCPB-ethyl																				1
MCPB-ethylate																				1
Mecoprop-demethylamine																				1
Mecoprop-p-isopropylamine																				1
Mecoprop-polyglycol																				1
Mecoprop-potassium																				1
Mecoprop-p-potassium																				1
Mefenacet	U			0																5
Mefenoxam																				2
Mencozeb																				1
Mepanipyrim	U																			1
Meperfluthrin																				4
Mepiquat chloride																				6
Mepronil	U			0																1
Mesosulfuron-methyl																				3
Mesotrione																				5
Metaflumizone				P																6
Metalaxyl	II																			14
Metalaxyl-M																				6
Metaldehyde	II																			12
Metam (incl. -potassium and -sodium)	II																			2
Metamifo (Matari)																				1
Metamifop				0																4
Metamitron	II																			2
<i>Metarhizium anisopliae</i>																				1
<i>Metarhizium anisopliae</i> (var. major)																				5
<i>Metarhizium anisopliae</i> var. <i>anisopliae</i>																				1
<i>Metarhizium anisopliae</i> var. <i>acidum</i>																				1
Metazachlor	III																			2
Metazosulfuron																				1
Metconazole	II																			2
Methabenzthiazuron	III			0																2
Metham																				1

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Methamidophos	IB			0																4
Methidathion	IB			0																6
Methiocarb (aka mercaptodimethur)	IB																			1
Methomyl	IB																			6
Methoprene	U			0																1
Methothrin																				1
Methoxy Ethyl Mercury Chloride (MEMC)																				1
Methoxyfenozide	U																			8
Methyl rsenic acid (or) DSMA																				1
Methyl bromide	FM			0																9
Methyl eugenol																				2
Methyl iodide																				1
Methyl isothiocyanate	II			0																1
Methyl-2methylbutanoate																				1
Methylamine avermectin																				1
Methylenebisthiocyanate				0																2
Metiram (complex)	U																			8
Metobromuron	U			P																1
Metofluthrin																				3
Metolachlor	III			0																9
Metolcarb	II			0																3
Metominostrobin				0																2
Metosulam	U																			1
Metoxadiazone																				1
Metribuzin	II																			13
Metsulfuron	U																			1
Metsulfuron-methyl	U																			12
Milbemectin																				3
minyak bawang putih garlic oil																				1
Mirex	O			0																1
Mismarthiozol=bismerthiozol?																				1
Molinate	II																			4
Monalide	O			0																1
Monocrotophos	IB			0																5
Monomehypo																				2
Monosodium methane arsonate																				1
Monosodium methylarsonate MSMA																				2
Monosultap																				3
Morantel tartrate																				1
Moroxydine hydrochloride																				1
Muscalure																				1
Myclobutanil	II																			8
Naled	II			0																2
Napropamide	U																			5
Naptalam	U			0																1
Nemadectin																				1
<i>Neochrysocharis ormosa</i>																				1
Nereistoxin																				2
Niclosamide	U																			4
Niclosamide ethanolamine																				2
Niclosamide ethanolamine salt																				1
Niclosamide olamine																				3
Nicosulfuron	U																			8
Nicotine	IB			0																3
Ningnamycin																				4
Nitenpyram				0																7
Nitrofen	O			0																1

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Nitrophenol																				2
Novaluron	U			0																8
Noviflumuron	U																			1
NPV of <i>Autographa californica</i>																				1
NPV of <i>Ectropis obliqua</i>																				1
NPV of <i>Helicoverpa (Heliothis) armigera</i>																				3
NPV of <i>Spodoptera littoralis</i>																				1
NPV of <i>Spodoptera litura</i>																				2
Nucleotide																				2
Oligo-alginate																				1
Oligoglucan																				1
Oligo-saccharit																				1
Oligosaccharins																				3
Omethoate	IB			0																4
<i>Orius strigicollis Poppius</i>																				1
Orthosulfamuron				P																7
Orysastrobins				0																1
Oryzalin	U																			2
Osfencarb (BPMC)																				1
Oxadiargyl																				8
Oxadiazon	U																			12
Oxadixyl	II			0																3
Oxamyl	IB																			2
Oxaziclomefone																				4
Oxine-copper	U			0																4
Oxolinic acid																				3
Oxpoconazole-fumarate																				1
Oxycarboxin	III			0																1
Oxydemeton-methyl	IB			0																4
Oxyadenine																				1
Oxyfluorfen	U																			9
Oxymatrine																				2
Oxytetracycline				0																3
Paclobutrazol	II																			6
<i>Paecilomyces fumosoroseus</i>																				1
<i>Paecilomyces lilacinus</i>																				3
<i>Paecilomyces tenuipes</i>																				1
Paenibacillus polymyza																				1
Paraffin oils; mineral oils																				3
Paraquat (dichloride)	II			0																12
Parathion	IA			0																1
Parathion-methyl	IA			0																3
<i>Pasteuria penetrans</i>																				1
PCP																				1
p-Dichlorobenzene				0																1
Pefurazoate				0																1
Penconazole	III																			5
Pencycuron	U																			7
Pendimethalin	II																			15
Penflufen																				1
Penoxanil? Fenoxalin?																				1
Penoxsulam	U																			7
Penoxulam																				2
Pentachlorophenol-sodium (PCP-Na)																				1
Pentacyclic triterpenoids alcaloid																				1
Penthiopyrad																				1
Pentoxazone				0																2

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Peracetic acid				0																1
Periplaneta fuliginosa densovirus (PFDNV)																				1
Permethrin	II			0																9
Permethrin 25/75 cis/trans																				1
Petroleum oils				0																5
Phenamidone																				2
Phenkapton	O																			1
Phenmedipham	U																			2
Phenothiol																				1
Phenothoate ?																				1
Phenothrin	U			0																1
Phenthoate	II			0																11
Pheromone																				1
Phorate	IA			0																3
Phosalone	II			0																8
Phosfolan-methyl																				1
Phosmet	II																			3
Phosphamidon	IA			0																3
Phosphine	FM																			1
Phosphonic acid				0																3
Phosphorothioate																				1
Phosphorous acid	U																			1
Phostin																				1
Phoxim	II			0																5
<i>Phytoseiulus persimilis</i>																				1
Picloram	II																			5
Picoxystrobin																				1
Pierisrapae granulosis virus (PrGV)																				1
Pinoxaden				P																3
Piperonyl butoxide	U			N																4
Pirimicarb	II																			3
Pirimiphos-methyl	II																			9
Plant activator protein																				1
Plifenate																				1
Plutella xylostella granulosis virus (PXGV)																				1
Polybutene				N																1
Polyoxin-B																				4
Polyoxins (complex)				0																3
Polyoxorim																				1
Polyphenol (from <i>Gleditschia australis</i> , <i>Siegesbeckia orientalis</i> , <i>Bidens pilosa</i> , <i>Parthenium hystherophorus</i>)																				1
Polyphenol (from <i>Litchi chinesis sonn</i>)																				1
Polyphenol (from <i>Mangifera indica L</i>)																				1
Polyphenol (from <i>Oroxylum indicum</i> , <i>Salix babylonica</i>)																				1
Polyphenol (from <i>Sophora japonica L. Schott</i>)																				1
Popiconazole																				1
Potassium 2, 4-dinitrophenolate																				1
Potassium bicarbonate																				1
Potassium oleate																				1
Potassium ortho-nitrophenolate																				1
Potassium para-nitrophenolate																				1
Potassium phosphite (mono-/di)-																				1
Potassium phosphonate																				1
Potassium polysulfide																				1
Prallethrin	II																			4
Pretilachlor	U			0																13
Probenazole	III			0																2

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
Prochloraz	II																			7
Prochloraz manganese chloride																				3
Procymidone	U		0																	4
Prodiamine	U																			1
Profenofos, Profenophos	II		0																	12
Profoxydim																				3
Profurite-aminium																				2
Prohexadione-calcium																				1
Prohydrojasmon			0																	1
Prometryn	III		0																	6
Propamocarb	U																			3
Propamocarb hydrochloride																				8
Propanil	II		0																	10
Propaquizafop	U																			4
Propargite	III		0																	11
Propetamphos	IB		0																	1
Propiconazole	II																			13
Propineb	U																			13
Propisochlor (ISO: 2-chloro-6'-ethyl-N-isopropoxymethylaceto-o-toluidide)			0																	2
Propoxur	II		0																	8
<i>Propylea japonica</i>																				1
Propylene glycol																				1
Propylene glycol monolaurate																				1
Propylene oxide																				1
Propyrisulfuron			0																	1
Propyzamide	U																			2
Prosuler																				1
Prosulfocarb	II																			2
Protein amylose																				1
Protein thủy phân																				1
Prothiofos	II		0																	4
<i>Pseudomonas fluorescens</i>																				6
<i>Pseudomonas rhodesiae</i>																				1
Pymetrozine																				8
Pyraclonil																				1
Pyraclostrobin																				10
Pyraflufen-ethyl																				3
Pyraoxystrobin																				1
Pyrazolate																				1
Pyrazosulfuron-ethyl																				12
Pyrazoxyfen	II		0																	1
Pyrethrin (+)																				1
Pyrethrins	II																			6
Pyribencarb																				1
Pyribenzoxim																				8
Pyributicarb																				1
Pyridaben	II																			8
Pyridalyl																				5
Pyridaphenthion	II		0																	3
Pyrifluquinazon			0																	1
Pyriftalid			0																	2
Pyrimethanil	III																			3
Pyrimidifen			0																	2
Pyriminobac-methyl																				2
Pyrimisulfan			0																	1
Pyriofenone																				1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
Pyripropanol																				1
Pyriproxyfen	U																			8
Pyriithiobac-sodium	III																			1
Pyroquilon	II			0																1
Pyroxsulam																				2
Pythium oligandrum																				1
Quaternary ammonium compounds				0																2
Quinalphos	II			0																11
Quinclorac	III			0																10
Quinoclamine	II																			1
Quinomethionate	III																			1
Quintozene	U			0																2
Quizalofop	II			0																1
Quizalofop-ethyl																				3
Quizalofop-p-ethyl																				11
Quizalofop-p-tefuryl	II																			6
Rapeseed oils																				1
Ribavirin																				1
Rich-d-t-cyphenothrin																				1
Rich-d-t-cyphenothrin																				1
Rich-d-t-prallethrin																				1
Rich-d-transallethrin																				1
Rich-d-t-tetramethrin																				1
Rimsulfuron (aka renriduron)	U																			3
Rotenone	II			0																3
S.S.S-Tributyl phosphorotrithioate																				1
Safflower oil																				1
Saflufenacil				0																1
Saisentong																				1
Salicylic Acid																				1
<i>Salmonella enteritidis</i>																				1
Saponin																				1
s-bioallethrin																				6
<i>Scorbitan-fatty acid ester</i>																				1
Selamectin																				1
Semiamitraz																				1
Sethoxydim	III			0																7
Sex phoromone																				1
Silafluofen				0																3
Silicon dioxide																				1
Silthiofam, Silthiopham																				1
Silver																				1
Simazine	U			0																5
Simeconazole				0																1
Simetryn	II																			3
Sirmate																				1
S-Metolachlor																				7
Sodium 1-naphthylacetate																				1
Sodium 1-naphthal acitic acid																				1
Sodium 2, 4-dinitrophenolate																				1
Sodium 4-CPA																				1
Sodium 5-nitroguaiacolate																				2
Sodium bicarbonate																				1
Sodium chlorate																				3
Sodium cyanide	IB																			2
Sodium dichloroisocyanurate																				1
Sodium diphacinone																				1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
Sodium ethyl xanthogenate																				1
Sodium huminate																				1
Sodium nitrogualacolate																				1
Sodium nitrophenol																				1
Sodium oleate																				1
Sodium o-nitrophenol																				1
Sodium pimaric acid																				2
Sodium p-nitrophenolate																				1
Sodium polysulfide																				1
Sodium salicylate																				1
Sodium-2, 4-dinitrophenol																				1
Sodium-O-nitrophenolate, Sodium-P-nitrophenolate																				2
Spinetoram	U																			6
Spinosad	III																			10
Spiroclufen																				5
Spiromesifen																				8
Spirotetramat	III																			5
Starch																				1
<i>Steinernema carpocapsae</i>																				1
<i>Steinernema glaseri</i>																				1
<i>Streptomyces lydicus</i> WYEC 107				P																1
Streptomycin				0																9
Streptomycin sulfate																				1
Succinic acid																				1
Sulcotrione																				2
Sulfentrazone				0																3
Sulfluramid	II																			1
Sulfosulfuron																				2
sulfosulfuron methyl																				2
Sulfotep	IA			0																1
Sulfoxaflo				P																4
Sulfuryl fluoride																				3
Sulphur	III																			15
<i>Talaromyces flavus</i>																				1
tau-Fluvalinate																				1
TDS																				1
Tebuconazole	II																			13
Tebufenozide	U																			4
Tebufenozide																				1
Tebufenpyrad	II																			3
Tebufloquin																				1
Tebuthiuron	II			0																2
Tecloftalam																				2
Teflubenzuron	U																			2
Tefluryltrione																				1
Tefluthrin	IB																			1
Temephos	III			0																7
Tepraloxymid																				1
Terallethrin																				1
Terbacil	U			0																1
Terbufos	IA			0																1
Terbutylazine	III																			2
Terbutryn	III			0																2
Tericlopyr																				1
Terpene acids																				1
Tetraconazole	II																			6
Tetracycline (hydrochlorid)																				3

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Tetradifon	U			0																4
Tetraflumethrin																				1
Tetramethrin	U			0																5
Tetramethylfluthrin																				1
Tetramycin																				1
Tetrapion																				1
Thaimethoxam																				2
Thallium sulphate	IB			0																1
Thenylchlor																				1
theta-Cypermethrin																				1
Thiabendazole	III																			3
Thiacloprid	II																			10
Thiamethoxam																				11
Thidiazuron	III			0																2
Thiodiazole copper																				1
Thifensulfuron-methyl	U																			3
Thifluzamide	U																			4
Thiobencarb	II			0																8
Thiocyclam	II			0																3
Thiocyclam-hydrogen oxalate																				3
Thiodiazole copper																				1
Thiodiazole zinc																				1
Thiodicarb	II			0																10
Thiomethoxain																				1
Thiometon	IB			0																1
Thiophanate (ethyl)	O			0																1
Thiophanate-methyl	U																			15
Thiosultap-sodium				0																1
Thiourea				0																2
Thiram	II																			10
Thiuram																				1
<i>Thphlodromips swirskii</i> Athias-Henriot																				1
Tiadinil				0																1
Tiba																				1
Tolclofos-methyl	U																			4
Tolfenpyrad				0																4
Tolylfluanid	U			0																1
Topramezone				P																2
Torula yeast																				1
Tralomethrin	II			0																4
Transfluthrin	U																			5
Triacantanol																				3
Triadimefon	II			0																8
Triadimenol	II																			4
Tri-allate	III																			2
Triasulfuron	U																			4
Triaziflam																				1
Triazophos	IB			0																9
Tribasic copper sulfate																				6
Tribenuron methyl																				3
Trichlorfon	II			0																9
Trichloroiso cyanuric acid																				1
<i>Trichoderma asperellum</i>																				1
<i>Trichoderma atroviride</i>																				2
<i>Trichoderma harzianum</i>																				2
<i>Trichoderma sp.</i>																				1
<i>Trichoderma sperellum</i>																				1

Pesticide	WHO Class	PIC	POP	EC Status	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Sum Asia
<i>Trichoderma virens</i>																				1
<i>Trichoderma viride</i>																				3
<i>Trichogramma dendrolimi matsumura</i>																				1
Trichlorofon																				1
Triclopyr	II																			2
Triclopyr butotyl																				2
Triclopyr butoxyethyl ester																				3
Triclopyr-amine																				1
Tricyclazole	II		P																	14
Tridemorph	II		0																	6
Trielopyr butoxye thylester																				1
Trifloxystrobin	U																			9
Trifloxysulfuron sodium																				5
Triflumizole	II																			5
Triflumuron	U																			2
Triflumuron																				1
Trifluralin	U		0																	8
Triforine	U		0																	5
Trimedlure			0																	1
Trinexapac (aka cimetacarb ethyl)																				4
Triptolide																				1
Trisiloxane ethoxylate																				1
Trisulfuran																				1
Triticonazole	III																			1
Uniconazole	II		0																	3
Urbacide																				1
Validamycin	U		0																	10
Validamycin A																				2
<i>Variovorax paradoxus</i>																				1
<i>Verticillium chlamydosporium</i> ZK6																				1
<i>Verticillium lecanii</i>																				3
Vertrine																				1
Vinclozolin	U		0																	2
Warfarin (aka coumaphene)	IB																			5
White oil																				2
Whole egg powder																				1
Xiaochongliulin																				1
Xylylcarb	II																			1
zeta-Cypermethrin	IB																			6
Zinc borate																				1
Zinc cyclohexane-carboxylate																				1
Zinc methanearsonate																				1
Zinc phosphide	IB																			9
Zinc sulfate																				1
Zineb	U		0																	11
Ziram	II																			8
Zucchini yellow mosaic virus ZY95																				1
Totals	456	17	4	576	144	155	581	220	249	502	79	282	76	241	107	255	110	206	359	1 172

List of banned and restricted pesticides

■ = banned; ■ = restricted use

Other: India: 3 = refused registration; 4 = pesticide withdrawn

China: 3 = phase-out scheme

PIC/ POP	Pesticide	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Banned	Restricted	Other
	1, 1, 2, 2-Tetrachloroethane		■													1		
PIC	2, 4, 5-T and its salts and esters		■		■	3	■	■	■	■			■	■	■	9		1
	2, 4, 5-TCP													■		1		
	2, 4, 5-TP (Fenoprop)		■											■		2		
	3-Chloro-2, 3-propanediol/alpha-Chlorohydrin		■													1		
	4-aminodiphenyl													■		1		
	4-nitrodiphenyl													■		1		
	Acephate				■												1	
	Acrolein		■														1	
PIC	Alachlor	■			■					■			■	■		3	3	
PIC	Aldicarb	■	■	■		■							■			5	2	
	Aldoxycarb		■													1		
POP, PIC	Aldrin	■	■	■	■	■	■	■	■	■	■		■	■	■	12	1	
	Allyl alcohol		■														1	
	Aluminium phosphide		■	■		■		■							■	1	4	
	Aminocarb		■											■		2		
	Amitraz		■													1		
	Amitrole		■											■		2		
	Ammonium sulphamate					3												1
	ANTU (1-Naphthylthiourea)		■													1		
	Aramite		■										■	■		2		
	Arsenic compound (AS)		■	■				■		■			■	■	■	7		
	Calcium arsenate		■			3		■						■		3	1	
	Copper arsenate hydroxide		■											■		2		
	Copper acetoarsenite (Paris Green)		■			■								■		3		
	Sodium arsenite		■					■						■		3		
	Asbestos-amosite													■		1		
	Asomate			3														1
	Azinphos ethyl		■			3								■		2	1	
	Azinphos methyl					3								■		2	1	
	Azocyclotin		■														1	
	Benomyl		■													1		
	Benzidine													■		1		
PIC	Binapacryl	■	■		■	3	■	■	■	■		■		■		8	1	
	bis (chloromethyl) ether													■		1		
	Blasticidin-S		■														1	
	Brodifacoum		■							■							2	
	Bromadiolone		■							■							2	
	Bromethalin		■													1		
	Bromophos		■											■		2		
	Bromophos ethyl		■									■		■		3		
	Bromoxynil butyrate		■														1	
	Bromoxynil heptanoate		■														1	
	Bromoxynil octanoate		■														1	
	Bromoxynil phenol		■														1	

PIC/ POP	Pesticide	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Banned	Restricted	Other
	Butocarboxim																1	
	Cadmium compound (Cb)															3		
	Cadusafos																1	
	Calcium cyanide (hydrogen cyanide)															3		
	Calcium phosphide															1		
	CAMA (calcium acid mothanearsonate)																1	
	Camphechlor (Toxaphene, Polychlorcamphene)															2		
PIC	Captafol															11	1	
	Captan															2		
	Carbaryl															1		
	Carbofuran															1	5	
	Carbon disulfide																1	
	Carbon tetrachloride															2		
	Carbophenothion					3										1		1
	Cinomethionate (Morestan)					3												1
POP, PIC	Chlordane															11	1	
POP	Chlordecone															4		
PIC	Chlordimeform															11		
	Chlorethoxyfos															1		
	Chlorfenvinphos (CVP)															3		
	Chlormephos															1		
	Chlornitrofen															1		
PIC	Chlorobenzilate															9		
	Chloropicrin																1	
	Chlorophacinone															1		
	Chlorophenols															2		
	Chlorpyrifos															1	1	
	Chlorsulfuron			3														1
	Chlorthiophos															4		
	Coumaphos															1	1	
	Crimidine															1		
	Crotoxyphos															1		
	CTC?															1		
	Cyanthoate															1		
	Cycloheximide															3		
	Cyhexatin															6		
	Cypermethrin																1	
	Cyromazine															1		
	Cytokinin																1	
	Dalapon					4										1		1
	Daminozide															3		
	Dazomet																1	
	DBCP (Dibromochloropropane)															6		
	DDD															1		
POP, PIC	DDT															11	3	
	Demephion-o															1		
	Demephion-s															2		
	Demeton (Demeton-o)															2		
	Demeton-s															3		
	Demeton-S-methyl															1		
	Diamidafos															1		
	Diazinon																1	
	Dichlorophene/Antiphen/Chlorophenol															2		
	Dichlorvos DDVP																1	
	Dicofol															1	2	
	Dicrotophos					3										1	2	1

PIC/ POP	Pesticide	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Banned	Restricted	Other
POP, PIC	Dieldrin															14		
	Difenacoum															1		
	Diferhialone															1		
	Dimefox															3		
	Dimetilan															1		
	Dinitrocresol															1		
PIC	Dinoseb and its salts and esters															5	1	
	Dinoterb															2		
	Dinoterb acetate/Dinitrobutyphenol															1		
	Dioxathion															1		
	Diphacinone																1	
	Disulfoton					3										3		1
PIC	Dinitro-ortho-cresol (DNOC) and its salts															5		
	DSMA (disodium methanearsonate)																1	
	Edifenphos															1		
PIC	EDB (ethylene dibromide)															7	1	
POP, PIC	Endosulfan															11	2	
	Endothion															1		
POP	Endrin															11	1	
	EPN					3										3	1	1
	Ethametsulfuron			3														1
	Ethoprophos			3												1		1
	Ethyl hexylene glycol															2		
	Ethyl mercury chloride															1		
PIC	Ethylene dichloride															6	1	
PIC	Ethylene oxide															5	1	
	Famphur															1		
	Fenamiphos															2		
	Fenbutathin oxide															1		
	Fenitrothion																1	
	Fensulfothion															2		
	Fenthion															1	4	
	Fentin acetate					3												1
	Fentin hydroxide					3										2		1
	Fenvalerate																1	
	Ferban					4												1
	Fipronil																1	
	Flocoumafen																1	
	Flucythrinate																1	
PIC	Fluoroacetamide															8		
	Folpet															1		
	Fonofos															3		
	Formetanate																1	
	Formothion					4												1
	Fosthietan															1		
	Furathiocarb															1		
POP, PIC	HCH/BHC (mixed isomers)															12	1	
POP	α -HCH															2		
POP	β -HCH															4		
POP, PIC	Heptachlor															12	1	
POP, PIC	Hexachlorobenzene HCB															7	1	
POP	Hexabromobiphenyl (HBB)																	
	Heptenophos																1	
	IPSP															1		
	Isazofos															1	1	
	Isobenzan															2		

PIC/ POP	Pesticide	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Banned	Restricted	Other
	Isocarbophos																1	
	Isodrin (Isomer of Aldrine)															2		
	Isofenphos																2	
	Isofenphos-methyl															1		
	Isoxathion															1		
	Lead arsenate					3										3		1
	Lead compound (Pb)															2		
	Leptophos					3										5		1
POP, PIC	Lindane (gamma-HCH/BHC)															11	1	
	Loxynil																1	
	MAA (methanearsonic acid)																1	
	MAFA (ammonium iron methylarsonate)																1	
	Maleic hydrazide															1	1	
	MAMA (monoammonium methanearsonate)																1	
	Magnesium phosphide															1	2	
	MCPB															2		
	Mecarbam																1	
	Mecoprop (MCP)															2		
	Menazon															1		
	Mephosfolan					3										1		1
	Medinoterb acetate															1		
	Mephosphoslan															1		
	Mercaptophosion (Dematon-o)															1		
	Mercuric chloride															1		
	Mercuric oxide															1		
PIC	Mercury compound (Hg)															12		
PIC	Mercuric Fungicides															2		
	Methamidophos															8	1	
	Methidathion			3												1	1	1
	Methiocarb															1		
	Methomyl															4	3	
	Methoxyethyl mercury chloride (MEMC)															1	1	
	Methyl bromide															1	8	
	Metoxuron															1		
	Metsulfuron-methyl			3														1
	Mevinfos					3										3		1
	Mexacarbate															1		
	MGK repellent/2-(octylthio) ethanol															2		
POP	Mirex															6	1	
	Molinate																1	
PIC	Monocrotophos															10	3	
	Monosodium methanearsonate/MSMA																1	
	Naphthylamine															1		
	Nickel chloride					4												1
	Nicotine																1	
	Nitrilacarb															1		
	Nitrofen															4		
	Octachlorodipropyl ether			3														1
	ODCB, o-dichlorobenzene															2		
	Omethoate																2	
	Oxamyl															2		
	Oxydemeton-methyl																1	
	Oxydeprofos (ESP)															1		
	Paradichlorobenzene					4												1
	Paraquat			3												2	1	1
	Paraquat dimethyl sulfate															1		

PIC/ POP	Pesticide	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Banned	Restricted	Other
PIC	Parathion															11	1	
	Parathion-methyl															11	2	
	PCNB (quintozone)															1		
POP	Pentachlorobenzene (PeCB)															1		
	Pentachloronitrobenzene (PCNB)															1		
	Pentachlorophenate sodium															2		
PIC	Pentachlorophenol/PCP and its salts and esters															7	1	
	Phenothiol															2		
	Phenylmercuric acetate (PMA)															2		
	Phorate															4		
	Phosalone																1	
	Phosfolan															1		
	Phosfolan-methyl															1		
	Phosphamidon															9	1	
	Phosphine																1	
	Phosphorus (white & yellow)															2		
	Pirimiphos-ethyl																1	
	Polybrominated biphenyls (PBBs)															1		
POP	Polychlorinated biphenyls (PCB)																	
	Polychlorinated triphenyls (PCTs)															1		
	Polychlorocamphene															2		
	Propanil															1		
	Propaphos																1	
	Propetamphos																1	
	Prothoate															1		
	Prothoate															1		
	Pyrinuron (piriminil)															2		
	Safrole															1		
	Schardan															3		
	Scilliroside															1		
	Selenium compound (Se)															3		
	Silatrane															1		
	Simazine					4											1	1
	Sodium Pentachlorophenate monohydrate															1		
	Sodium chlorate															3		
	Sodium cyanide															1	1	
	Sodium fluoroacetate															5		
	Sodium methane arsenate															1		
	Strobane (tepen polychlorinated)															4		
	Strychnine															1		
	Sulfotep															3		
	TDE															1		
	Tebupirimifos															1		
	Tefluthrin															1		
	TEPP															4		
	Terbufos															2		
	Tetradifon															1		
	Tetramine															1		
	Thallium compounds/sulfate															5		
	Thiofanox																1	
	Thiometon																1	
	Thionazin															1		
	Thiram															1		
POP, PIC	Toxophene															11	1	
	Triamiphos															1		
	Triazophos															1	1	

PIC/ POP	Pesticide	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Banned	Restricted	Other
	Tributyltin compounds incl. T. oxide (TBTO)															3		
	Tributyltin benzoate															1		
	Tributyltin chloride															1		
	Tributyltin fluoride															1		
	Tributyltin linoleates															1		
	Tributyltin methacrylate															1		
	Tributyltin naphthenate															1		
	Trichloroacetic acid (TCAA)															1		
	Trichloronat															1		
	Tris (2, 3-dibromopropyl) phosphate															1		
	Urbacide			3														1
	Vamidothion					3											1	1
	Vinyl chloride monomer															1		
	Warfarin					4												1
	Zeatin																1	
	zeta-cypermethrin															1		
	Zineb															1		
	Zinc phosphide									2						2	2	
TOTAL																		
37	295	24	209	57	43	67	31	54	29	46	15	28	30	100	45	219	95	34

Compilation of Questionnaire Responses on Practical Aspects of Pesticide Risk Assessment and Phasing out of HHPs

I. PESTICIDE REGISTRATION AND RISK ASSESSMENT

1. Registered pesticides and their status

Background

The number of registrations, validity period and regulatory actions indicate the approach to registration in a country.

Survey responses

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
How many active ingredients are currently registered in your country? (Please provide list as annex)	Min = 79 Max = >645	144	115	>645	219	246	561	91	284	79	244	108	322	122	207	378
How many formulated products are currently registered in your country?	Min = 119 Max = ∞	3 307	750	>29 700	346	∞	4 328	151	2 700	119	1 996	324	6 688		5 033	3 902
What is the normal validity period of a pesticide registration [years]?	Min = 2 Max = ∞	3	3	5	3	8	3	2	5	8	10	5	3	3	6	5
How many registrations have been restricted due to health or environmental concerns and can only be used in specific and controlled cases? (Please provide list as annex)	Min = – Max = 109	1	48	11	30	13	8	2	2	–	7	109	1	2	29	13
How many active ingredients have been banned for registration in your country? (Please provide list as annex)	Min = 4 Max = 163	23	163	47	13	29	27	55	31	4	39	15	26	30	98	29
Ratio formulations: a.i.		23	6.5	46	1.6	∞	7.7	1.7	9.5	1.5	8.2	3.0	20	6.6	24	2.4

Observations

- There is an 8-fold range in the number of registered active ingredients, and a more than 250-fold range in registered formulated products;
- The countries with the highest number of registered products in relation to the number of registered active ingredients (>20 times more formulations than a.i.) are India, China, Bangladesh, Pakistan and Thailand;
- The countries with the lowest ratio (<3 times more formulations than a.i.) are Viet Nam, DPR Korea, Lao PDR and Mongolia;
- The average period of registration validity is 3-5 years; one country has a 2 year period, while three countries have a 10 year or unlimited registration periods;
- The number of restricted use pesticides varies greatly from country to country from 1 to 109;
- The number of banned pesticides varies greatly from country to country from 4 to 163.

Analysis of data set on registered active ingredients

This information is based on the lists of registered active ingredients provided by the countries; the numbers in the following table may differ from other answers provided in the questionnaire.

Data set on registered active ingredients	Total	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Total number of registered active ingredients	1 172	144	155	581	220	249	502	79	282	76	241	107	255	110	206	359
Unique country-specific registration (a.i. not registered in any other country)	598	6	13	150	58	20	195	3	34	9	16	2	10	9	15	58
% of total	51%	4%	8%	26%	26%	8%	39%	4%	12%	12%	7%	2%	4%	8%	7%	16%
Number of a.i. names found in WHO list of classification	456	103	92	291	166	175	245	58	175	49	170	75	167	85	125	192
% of total	39% (65% av.)	72%	59%	50%	75%	70%	49%	73%	62%	64%	71%	70%	65%	77%	61%	53%
Number of a.i. with EU evaluation (approved and not approved)	576	123	115	356	164	198	326	64	202	56	187	90	211	95	166	255
% of total	49% (77% av.)	85%	74%	61%	75%	80%	65%	81%	72%	74%	78%	84%	83%	86%	81%	71%

Observations

- There are about 1 170 active ingredients registered in the region;
- On average, 65 percent of the pesticides registered in a country are listed in the *WHO Recommended Classification of Pesticides by Hazard*, and 77 percent have been evaluated in the EU;
- About half the total registered a.i. are registered in only a single country; the largest number is found in Japan with unique 195 pesticides that are not registered in any other country in the region; 77 percent of these pesticides are not found on the WHO or EU lists;
- The majority of single country registrations are rare chemical pesticides such as Agrifos, Picoxistobin, Prosuler, Simeconazole, theta-Cypermethrin, Urbacide, etc.;
- Single country registrations include about 100 bio-pesticide products, oils and plant extract, as well as more than 30 plant growth regulators, some plant stimulants and activators;
- Single country registrations also include 26 obsolete and 15 WHO Class I pesticides that have been out-phased elsewhere (e.g. Aldrin, Endrin, Mirex, Aldicarb, Parathion);
- Single country registrations may also include specific salts, esters or stereo-isomers that would not be considered a separate active ingredient in another country;
- Single country registrations include some specific local products and concoctions such as whole egg powder, starch, garlic powder, extract of mixed crude drugs or unspecified products such as amino acid, sex pheromone, auxins or the genus *Beauveria* and *Brevibacterium*;
- A few single country registrations are possible misspellings referring to real chemicals such as Asadirachtrin, Carbensulfan, Mandipromid, Phenothoate or Trisulfuron; or multiple registrations of the same chemical under different names (e.g. Alphametrin and alpha-Cypermethrin); or drugs such as Aspirin, Tetramycin or Streptomycin.

Conclusion

- Each country has registered some pesticides that are not found in any other country of the region. While some of these products are modern, state-of-the-art pesticides, others are outdated and rare products with limited risk information.

Analysis of data set on banned or restricted use active ingredients

This information is based on the lists of banned or restricted active ingredients provided by the countries; the numbers in the following table may therefore differ from other answers provided in the questionnaire.

Data set on banned or restricted active ingredients	Total	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Total number of restricted use registrations	112	1	48	24 [^]	30	13	2	2	2		7	0 [#]	1	1	5	13
Unique country-specific restricted use registrations (a.i. not restricted in any other country)	87	0	35	14	21	7	1	0	0		1	0	0	0	1	7
% of total	78%	0%	73%	58%	70%	54%	50%	0%	0%		14%		0%	0%	20%	54%
[^] China: The number includes pesticides under the phase-out scheme [#] Nepal restricts certain formulations to specific uses (household, public health, etc.), but it does not restrict the use of certain active ingredients to particularly qualified or trained persons																
Total number of banned pesticides	230	23	161	33	13	29	29	52	29		39	15	27	30	95	32
Unique country-specific bans (a.i. not banned in any other country)	117	0	60	8	2	19	4	3	1		0	0	2	3	14	1
% of total	51%	0%	37%	24%	15%	66%	14%	6%	3%		0%	0%	7%	10%	15%	3%

Preliminary observations

- There are a total of 112 active ingredients restricted and 230 banned in the responding countries;
- The majority of restricted use pesticides (78 percent) are restricted only in one country; only 8 pesticides are restricted in 3 or more countries, e.g. Methyl bromide is restricted in 8 countries, and Carbofuran in 5 countries;
- Half the banned pesticides (51 percent) are banned in only one country; 77 pesticides are banned in 3 or more countries.

Conclusion

- Countries apply different reasons and criteria for banning or restricting a pesticide;
- There is only limited consensus with regard to which pesticides should be banned or restricted.

Survey responses to registration status of pesticides listed under the Rotterdam and Stockholm Conventions and the Montreal Protocol

Purpose:

Regional lists of banned/restricted pesticides have been produced for previous workshops (2005, 2012); as a new element, information has been added for this workshop about pesticides listed in the Conventions that have not been banned, but are not registered and thus are *de-facto* prohibited.

			Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
PIC	2, 4, 5-T and its salts and esters		2	1	2	1	2	1	1	1	1	1	2	2	1	1	1
PIC	Alachlor		1	3	4	4	4	4	4	1	1	1	2	2	1	4	1
PIC	Aldicarb		1	1	3	3	1	2	2	1	1	2	2	2	2	2	2
POP, PIC	Aldrin		1	1	1	3	1	1	1	1	1	1	1	2	1	1	1
PIC	Binapacryl		1	1	2	1	2	2	1	1	1	1	2	1	2	1	2
PIC	Captafol		1	1	2	1	3	1	1	1	1	1	na	1	2	2	1
POP, PIC	Chlordane		1	1	2	3	1	1	1	1	1	1	1	2	1	1	1
POP	Chlordecone		2	1	2	3	2	1	2	2	1	2	2	2	2	1	2
PIC	Chlordimeform		1	1	1	1	2	2	1	1	1	1	2	1	2	1	2
PIC	Chlorobenzilate		1	1	2	1	1	2	1	1	1	1	2	1	2	na	2
POP, PIC	DDT		1	1	1	3	3	1	1	1	1	1	1	1	1	1	1
POP, PIC	Dieldrin		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
PIC	Dinoseb and its salts and esters		2	1	2	3	2	2	1	1	1	1	2	2	2	1	2
PIC	Dinitro-ortho-cresol (DNOC) and its salts		2	1	2	1	2	2	2	1	1	2	2	2	2	na	2
PIC	EDB		2	1	1	3	1	2	1	1	1	1	2	2	2	1	2
POP, PIC	Endosulfan		1	1	3	3	1	1	1	1	1	1	1	1	1	1	1
POP	Endrin		1	1	1	3	1	1	1	2	1	1	1	1	1	1	1
PIC	Ethylene dichloride		1	1	2	3	3	2	2	1	1	2	2	1	2	1	2
PIC	Ethylene oxide		2	1	2	3	2	2	1	1	1	1	2	2	1	1	2
PIC	Fluoroacetamide		1	1	1	1	2	2	1	2	1	1	2	2	2	na	2
POP, PIC	HCH/BHC (mixed isomers)		1	1	1	3	1	1	2	1	1	2	1	2	1	1	1
POP	α-HCH		1	1	1	2	2	1	2	1	1	2	2	1		1	2
POP	β-HCH		1	1	1	2	2	1	2	1	1	2	2	1		1	2
POP, PIC	Heptachlor		1	1	2	3	1	1	1	1	1	1	1	1	1	1	1
POP, PIC	Hexachlorobenzene HCB		1	1	2	3	2	1	2	2	1	2	2	1	2	1	1
POP, PIC	Lindane (gamma-HCH)		1	1	1	3	1	1	1	1	1	1	1	2	1	1	1
PIC	Mercury compound (Hg)		2	1	2	1	3	1	1	1	1	1	1	1	1	na	1
PIC	Mercuric Fungicides		1	1	2	1	2	1	2	1	1	2	1	2	1	na	2
Montreal	Methyl Bromide		3	3	3	1	3	3	1	3	1	1	1	3	3	4	2
POP	Mirex		1	1	1	3	2	1	2	2	1	2	1	2	2	1	2
PIC	Monocrotophos		1	1	1	3	3	1	1	3	1	1	1	1	3	1	1
PIC	Parathion		1	1	1	3	2	1	2	2	1	2	1	1	1	1	1
POP	Pentachlorobenzene (PeCB)		2	1	2	2	1	1	2	2	1	2	2	2	1	na	2
PIC	Pentachlorophenol/PCP and its salts and esters		2	1	1	3	1	1	2	1	1	2	2	2	1	1	1
POP, PIC	Toxophene		1	1	1	3	1	1	1	2	1	1	1	1	2	na	1
Total = 35	Banned =	1	25	33	16	11	14	23	21	25	35	22	16	17	17	24	18
	Never registered =	2	9		15	3	14	10	13	8		13	18	17	14	2	17
	Registered, restricted use =	3	1	2	3	20	6	1		2				1	2		
	Registered, regular use =	4	0	0	1	1	1	1	1							2	
	?/na												1		2	7	

Summary of pesticides listed in the Stockholm and Rotterdam Conventions and the Montreal Protocol that have been banned in Asian countries

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam	Total
PIC	2, 4, 5-T and its salts and esters																10
PIC	Alachlor																6
PIC	Aldicarb																5
POP, PIC	Aldrin																13
PIC	Binapacryl																9
PIC	Captafol										na						10
POP, PIC	Chlordane																12
POP	Chlordecone																4
PIC	Chlordimeform																10
PIC	Chlorobenzilate														na		9
POP, PIC	DDT																13
POP, PIC	Dieldrin																15
PIC	Dinoseb and its salts and esters																6
PIC	Dinitro-ortho-cresol (DNOC) and its salts														na		4
PIC	EDB																8
POP, PIC	Endosulfan																13
POP	Endrin																13
PIC	Ethylene dichloride																6
PIC	Ethylene oxide																7
PIC	Fluoroacetamide														na		7
POP, PIC	HCH/BHC (mixed isomers)																11
POP	α -HCH																8
POP	β -HCH																8
POP, PIC	Heptachlor																13
POP, PIC	Hexachlorobenzene HCB																7
POP, PIC	Lindane (gamma-HCH)																13
PIC	Mercury compound (Hg)														na		11
PIC	Mercuric Fungicides														na		8
Montreal	Methyl Bromide																5
POP	Mirex																7
PIC	Monocrotophos																11
PIC	Parathion																10
POP	Pentachlorobenzene (PeCB)														na		5
PIC	Pentachlorophenol/PCP and its salts and esters																9
POP, PIC	Toxophene														na		11
	Total	25	33	16	11	14	23	21	25	35	22	16	17	17	24	18	

 = banned na = no answer

Observations

- There is no detectable pattern for the banning of Convention pesticides

Registration status in Asian countries of the pesticides listed in the Stockholm and Rotterdam Conventions and the Montreal Protocol

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
PIC	2, 4, 5-T and its salts and esters															
PIC	Alachlor															
PIC	Aldicarb															
POP, PIC	Aldrin															
PIC	Binapacryl															
PIC	Captafol															
POP, PIC	Chlordane															
POP	Chlordecone															
PIC	Chlordimeform															
PIC	Chlorobenzilate															
POP, PIC	DDT															
POP, PIC	Dieldrin															
PIC	Dinoseb and its salts and esters															
PIC	Dinitro-ortho-cresol (DNOC) and its salts															
PIC	EDB															
POP, PIC	Endosulfan															
POP	Endrin															
PIC	Ethylene dichloride															
PIC	Ethylene oxide															
PIC	Fluoroacetamide															
POP, PIC	HCH/BHC (mixed isomers)															
POP	α -HCH															
POP	β -HCH															
POP, PIC	Heptachlor															
POP, PIC	Hexachlorobenzene HCB															
POP, PIC	Lindane (gamma-HCH)															
PIC	Mercury compound (Hg)															
PIC	Mercuric Fungicides															
Montreal	Methyl Bromide															
POP	Mirex															
PIC	Monocrotophos															
PIC	Parathion															
POP	Pentachlorobenzene (PeCB)															
PIC	Pentachlorophenol/PCP and its salts and esters															
POP, PIC	Toxophene															

■ = banned or not registered

■ = restricted registration

□ = registered

Observations

- Most of the Convention pesticides are not registered (i.e. prohibited) in most Asian countries.
- Only six pesticides are registered in 2 or more countries: Alachlor and Methyl Bromide are each registered (regular or restricted use) in 8 or more countries; Monocrotophos is registered for restricted use in 4 countries; Aldicarb, DDT and Ethylene dichloride are registered for restricted use in 2 countries each.

2. If the list of registered products is available on-line, please provide the web address/URL for the website

Background

Sharing registration information among the Asian countries promotes transparency and harmonisation of pesticide regulatory management.

Survey responses

China P.R.:	www.chinapesticide.gov.cn
India:	www.cibrc.nic.in
Japan:	http://www.acis.famic.go.jp/searchF/vtllm000.html (in Japanese)
Malaysia:	http://www.doa.gov.my/web/guest/senarai-racun-makhluk-perosak-berdaftar

Observations

- Only four countries make their lists of registered pesticides available on line;
- India has downloadable lists of registered and banned products;
- China has a search engine to obtain registration information on specific products;
- Some information is only available in the national language.

Conclusions

- On-line access to country pesticide registration information is very limited in the region.
- The workshop data sets on registered active ingredients, banned or restricted pesticides may be used for sharing pesticide registration information among the countries.

3. Multiple registered formulations

Background

The registration of identical or similar products under different brand names confuses pesticide users and discourages informed decision making.

Survey responses

As an example, roughly how many formulated products are registered in your country that contain:		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
1. Cypermethrin	Min = 1 Max = 615	177	~300	615	17	6	8	18	106	6	50	63	133	1	70	36
2. Abamectin	Min = 0 Max = 1 402	18		1 402	8	0	2	4	41		30	1	43	12	204	99

Observations

- More than 100 different pesticide products containing Cypermethrin are registered in Bangladesh, China, Cambodia, Pakistan and Malaysia;
- More than 100 different pesticides products containing Abamectin are registered in China and Thailand.

Conclusions

- The examples of Cypermethrin and Abamectin demonstrate that there are high numbers of different formulated products that are likely to confuse customers and distort informed decision making in the selection of products; farmers get product information mostly from advertisement or salespersons.

4. At what level do you assess risk of pesticides to human health and the environment?

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

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Is risk assessment part of the registration procedure?	Yes = 13 No = 2	Y	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y
If yes, do you conduct a partial or full risk assessment (tick below)																
Do you conduct a full risk assessment during registration evaluation that includes the assessment of exposure data?	Yes = 7 No = 7	N	Y	Y	Y	N	Y		Y	N	N	N	N	Y	N	Y
Do you conduct a partial risk assessment or hazard assessment during registration evaluation based on toxicology data?	Yes = 10 No = 4	Y	Y	Y	Y	Y	N		Y	N	Y	Y	Y	N	N	Y
Do you accept (as a replacement of your own assessment), the hazard/risk assessments published by international organizations/conventions?	Yes = 11 No = 3	Y	Y	N	Y	N	N		Y	Y	Y	Y	Y	Y	Y	Y
Do you accept (as a replacement of your own assessments), the risk assessment conducted by other national registration authorities?	Yes = 6 No = 8	Y	Y	N	Y	N	N		Y	N	N	Y	N	N	N	Y
Total	Yes =	4	5	3	5	2	2		5	1	3	4	3	3	2	5
	No =	1	0	2	0	3	3	1	0	4	2	1	2	2	3	0
If yes, give name(s) of country/ies: Bangladesh: China, Japan, USA, India, Rep. of Korea, Thailand, European Union DPR Korea: EU, China, Russia Malaysia: OECD, EU countries Mongolia: FAO, Codex Viet Nam: EC (SANCO), US(EPA)																
Y = Yes; N = No																

Observations

- Risk assessment is part of the registration procedure in 87 percent of the counties. It is not part of the registration procedure in Lao PDR and Mongolia;
- Half the countries make full risk assessments that includes the assessment of exposure data;
- More countries conduct a partial risk assessment than a full risk assessment;
- Eleven countries accept the hazard/risk assessments published by international organizations/conventions, 6 countries accept hazard/risk assessments conducted by other registration authorities;
- Countries most often consulted are the EU (4), US/OECD (3) and China (2).

Conclusions

- Countries with enough national resources conduct their own risk assessment, while countries with limited resources rely more on published risk assessments.

5. When deciding whether or not to register a pesticide, do you check any of the following international resources?

Background

Various international information recourses on pesticide characteristics and risks are available to assist registration authorities in their registration decision

Survey responses

When deciding whether or not to register a pesticide, do you check any of the following international resources?		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
INCHEM FAO/WHO Pesticide Data Sheets	A = 8, R = 5, S = 2, N = 0	S	R	A	A	S	R	A	A	A	A	R	A	R	R	A
Rotterdam Convention	A = 9, R = 4, S = 2, N =	R	R	A	A	R	A	S	A	A	S	R	A	A	A	A
Stockholm Convention	A = 8, R = 4, S = 3, N =	R	R	A	A	R	A	S	A	A	S	R	A	S	A	A
European Union registration status	A = 2, R = 5, S = 5, N/- = 3	S	S	R	S	S	R	N	A	A	N	-	S	R	R	R
USA registration status	A = 3, R = 4, S = 5, N = 3	S	S	R	N	S	R	N	A	A	N	S	S	A	R	R
Total	Always			3	3		2	1	5	5	1		3	2	2	3
	Regularly	2	3	2		2	3					3		2	3	2
	Sometimes	3	2		1	3		2			2	1	2	1		
	Never				1			2			2	1				
Registration status of other countries or sources that are being used: (give name)																
DPR Korea: China																
India: Case to case basis																
Japan: Australia, Canada, etc.																
Lao PDR: Thailand, Viet Nam, Cambodia, China, Malaysia																
Malaysia: Australia, Japan, OECD countries																
Mongolia: For the registration, CAS number, chemical formula, scientific name and field and laboratory experiments are considered.																
Thailand: the pesticide decided to be registered must be registered in the countries which are the sources of a.i. or formulated products																
Nepal: India																
Are there any countries of which you would like to check the registration status of products, but you do not because the information is not easily available on line? If yes, which countries?:																
Bangladesh: China, India, Indonesia, Thailand, Malaysia, Japan, Sri Lanka, Rep. of Korea, Pakistan																
Cambodia: China and other ASEAN nations																
India: Japan, DPR Korea																
Lao PDR: China																
Thailand: For registration, the applicant must provide the certificate of registration in the countries which are the source of the products																
Malaysia: ASEAN countries																
Nepal: China																
Pakistan: India																
Viet Nam: China, South East Asia countries, Japan																
A = Always; R = Regularly; S = Sometimes; N = Never																

Observations

- The WHO/FAO pesticide information and convention lists are the most often checked international resources;
- The registration status in other countries is checked by most countries; besides the EU and USA registration status, countries also check Australia, Canada, China, Japan and neighbouring countries.

Conclusions

- International resources are an important tool for registration authorities to find specific information when reviewing pesticides for registration.

6. Registration Renewal

Background

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

Survey responses

At the end of the registration period, what actions are taken?		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Simple administrative renewal after payment of a fee without review of new data	Yes = 5 No = 9	Y	N		N	N	N	N	N	N	Y	N	Y	Y^	N	Y
Assessment of whether new risk information should be considered, followed by partial review if needed	Yes = 10 No = 5	N	Y	Y	Y	N	Y	N	Y	Y	N	Y	Y	Y^	Y	N
Full technical review of the updated application dossier for the renewal of the registration (re-registration)	Yes = 5 No = 10	N	Y	Y	Y	N	N	N	N	Y	N	N	N	N	Y	N
Total	Yes =	1	2	2	2	0	1	0	1	2	1	1	2	2	2	1
	No =	2	1		1	3	2	3	2	1	2	2	1	1	1	2
* India: Validity period of a pesticide of registration is not defined. ^ Sri Lanka: no review after 3 years; partial review after 6 years																
Y = Yes; N = No																

Observations

- Two-third of the responding countries consider new risk data at the end of the registration period;
- Five countries (33%) conduct a full technical review when renewing a registration (re-registration);
- Five countries renew the registration without a technical review of new data;
- Some countries reported multiple renewal procedures.

Conclusions

- Some countries may not have the personnel capacity to review and re-assess pesticide registration dossiers and therefore renew a pesticide registration mostly as an administrative procedure.

7. Review

Background

A review of the pesticide registration dossiers can be conducted at different levels of intensity and scrutiny from simple checks to complex assessments.

Survey responses

Does partial or full review include:		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
– Checking whether the pesticide has been added to international treaties	Yes = 13 No = 2	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
– Checking for changes in the registration status in other countries	Yes = 10 No = 5	N	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	N	Y
– Review against national data on efficacy and incident reports	Yes = 9 No = 6	N	N	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	N
– New full risk assessment based on updated toxicology dossier data	Yes = 5 No = 9	N	N	Y	Y	N	N	N	Y	N		Y	N	N	Y	N
Total	Yes =	1	1	4	4		1	2	4	3	2	4	3	3	3	2
	No =	3	3			4	3	2		1	1		1	1	1	2
* India: Validity period of a pesticide of registration is not defined.																
Other:																
Cambodia: Analytical check on quality																
Japan: Completeness of the data package should be checked, referring to the up-to-date data requirement. Any additional data will be reviewed to decide if re-evaluation is needed.																
Sri Lanka: Partial review is conducted after 6 years of registration																
Y = Yes; N = No																

Observations

- In most cases, a review of the registration dossier includes checking with international treaties and the registration status in other countries;
- A majority of countries reported that they review against national data on efficacy and incidence reports even though such reports may be difficult to generate.

Conclusions

- Some countries may not have the personnel capacity to conduct the reviews, particularly some countries with high numbers of formulation registrations.

8. Monitoring and Review

Background

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. 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

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Do you have specific regulations or guidelines for monitoring the health and environmental impact of field use of high risk pesticides?	Yes = 8 No = 7	N	N	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	Y	N
Do you have a specific active surveillance programme to monitor the health and environmental impact of field use of high risk pesticides?	Yes = 4 No = 10	N	N	Y	N	Y	Y	N	Y	N	N	N	N	N		N
Do your regulations or guidelines have a provision to cancel an existing registration on the basis of new information regarding its hazards?	Yes = 14 No = 1	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Total	Yes =	1	1	3	2	3	3		3	2	1	2	1	1	2	1
	No =	2	2		1			3		1	2	1	2	2		2
Japan: Note: There is no specific definition of high risk pesticides in Japan. The Ministry of the Environment monitors the concentrations of substances including pesticides in public water and ground water for which Environmental Quality Standard for human health are established (or are likely to be established) under the Basic Environment Law. Furthermore, MOE yearly monitors the concentrations of those pesticides in river of which the predicted environmental concentrations in water are close to the maximum acceptable level to protect aquatic animals and plants (i.e. Pretilachlor).																
Y = Yes; N = No																

Observations

- About half the responding countries have guidelines for monitoring the health and environmental impacts of high risk pesticides, but only four countries have active surveillance programmes;
- All but one country have a provision to cancel an existing registration on the basis of new information regarding its hazards.

Conclusions

- Most countries do not monitor the health and environmental impacts of high risk pesticides.

9. Actions taken over the past five years on previously registered pesticides

Background

The changes in the past five years should show the progress and focus of the management and phasing out of highly hazardous pesticides.

Survey responses

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
How many previous registrations have been cancelled/withdrawn over the past 5 years because of environmental or health concerns?	Max: 28 Min: 0		2	16 + 12#	6	2	0	0	2	*	22	2	3	8	2	5
How many previously full registrations have been restricted over the past 5 years because of environmental or health concerns?	Max: 29 Min: 0			9	6	–	0	0	5	~10	–	1	–	1	29	–
Separate lists with changes				x	x	x			x						x	x
China:	In addition to the 16 cancellations, the registration and manufacture of 12 other pesticides was suspended															
India:	Endosulfan and Lindane															
Japan:	Note: There is no record of cancellation of pesticide registration by the Japanese Government due to environmental or health concerns over the past 5 years. However, there are some cases where registrants voluntarily withdrew registrations of uses for certain pesticides/crops in case the estimated dietary intakes would likely to exceed ADIs or registrants decided not to submit necessary data to address health or environmental concerns.															
*Mongolia:	There is no clear years to cancel and withdraw															
Thailand:	EPN, Dicrotophos															

Observations

- Twelve countries reported changes in the registration status of certain products over the past five years for reasons related to health or environmental consideration;
- Most changes were reported from China, Myanmar and Thailand;
- In total, there were 82 actions that lead to a cancellation/withdrawal/suspension, and 61 actions that lead to a restriction in the use of a pesticide;

Conclusions

- As the focus of regulatory management is shifting from controlling the quality of products to assessing their human and environmental risks, existing registrations are cancelled, withdrawn, suspended or phased out, or the use is restricted to certain crops or qualified personnel.

Products that have been cancelled/withdrawn/suspended are specified below:

		China	DPR Korea	India	Malaysia	Thailand	Viet Nam
Alachlor	PIC						
Aldicarb	PIC						
Aluminum phosphide	FM						
Asomate							
Cadusafos	1B						
Calcium phosphide							
Carbofuran	1B						
Chlorpyrifos methyl							
Chlorsulfuron							
Coumaphos	1B						
Dichrotophos	1B						
Edifenphos	1B						
Endosulfan	PIC/POP						
EPN	1A						
Ethametsulfuron							
Ethoprophos	1A						
Fenamiphos	1B						
Fenobucarb							
Fenthion							
Fonofos	O						
Isocarbophos							
Isophenphos-methyl							
Lindane	PIC/POP						
Magnesium phosphide	FM						
Methidathion	1B						
Methomyl	1B						
Methyl bromide	Montreal						
Metsulfuron-methyl							
Omethoate	1B						
Paraquat AS							
Phorate	1A						
Phosfolan-methyl							
Phosphamidon	1A						
Pyridaphenthion							
Sulfotep	1A						
Terbufos	1A						
Triazophos	1B						
Tributyl tin compounds							
Urbacide							
Zink phosphide	1B						

WHO Classes: 1A, 1B, O = obsolete; FM = fumigant

POP = Stockholm Convention

PIC = Rotterdam Convention

Observations

- Only four pesticides (Carbofuran, Endosulfan, Ethoprophos and Methomyl) had been withdrawn in more than one country; all other regulatory actions were only in a country;
- Eighteen (45%) pesticides belonged to WHO Classes I or obsolete;
- Five (13%) pesticides were listed by international Conventions.

II. PHASING OUT OF HHPs

1. Phasing out of Highly Hazardous Pesticides (HHP)

Background

To reduce pesticide related risks, the phasing out of HHP is one of the strategies. However, there is no universally acceptable definition of HHP.

Survey responses

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Do you have a specific list of pesticides that have been identified as HHP in your country?	Yes = 8 No = 7	N	Y	Y	Y	N	N	N	Y	N	Y	Y	Y	N	Y	N
Which of the following types of pesticides do you consider as HHPs in your country?																
Pesticide active ingredients with a high acute toxicity (WHO Class 1A and 1B)	Yes/10 = 14 No = 0	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y
Pesticide formulations with a high acute toxicity (WHO Class 1A and 1B)	Yes = 12 No = 2	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	N	Y	N	Y
Pesticide active ingredients that are highly carcinogenic (GHS Category 1A and 1B)	Yes = 11 No = 3	Y	N	Y	N	Y		Y	Y	Y	Y	Y	N	Y	Y	Y
Pesticide active ingredients that are highly mutagenic (GHS Category 1A and 1B)	Yes = 11 No = 3	Y	N	Y	N	Y		Y	Y	Y	Y	Y	N	Y	Y	Y
Pesticide active ingredients with a high reproductive toxicity (GHS Category 1A and 1B)	Yes = 11 No = 3	Y	N	Y	N	Y		Y	Y	Y	Y	Y	N	Y	Y	Y
Pesticide active ingredients that are highly hazardous to the environment (GHS category 1A and 1B)	Yes = 11 No = 3	Y	N	Y	N	Y		Y	Y	Y	Y	Y	N	Y	Y	Y
Pesticide active ingredients listed under the Stockholm Convention	Yes = 13 No =	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	
Pesticide active ingredients listed under the Rotterdam Convention	Yes = 13 No = 1	Y	Y	Y	Y	Y		Y	Y	Y	N	Y	Y	Y	Y	Y
Pesticide active ingredients listed under the Montreal Protocol	Yes = 13 No = 1	Y	Y	Y	Y	Y		Y	Y	Y	N	Y	Y	Y	Y	Y
Pesticides that disrupt the endocrine system	Yes = 9 No = 3	Y		Y	Y	Y		N	Y	Y	N		N	Y	Y	Y
Pesticides that are highly toxic when inhaled	Yes = 10 No = 3	Y		Y	Y	Y		N	Y	Y	N	Y	N	Y	Y	Y
Pesticides that under prevailing conditions of use in your country have shown a high incidence of severe or irreversible adverse effects on human health or the environment	Yes = 10 No = 2	Y	Y	Y	Y	Y		N	Y	Y			N	Y	Y	Y
Total	Yes =	12	6	12	8	12		9	12	12	7	10	4	12	11	11
	No =		4		4			3			4		8		1	
Japan: (Note: Japan has no specific definition for HHPs. Among 4 328 formulations registered in Japan, 426 products are classified as poisonous substances or deleterious substances under Poisonous and Deleterious Substances Control Act (As of 31 March 2014), to which special requirements apply concerning storage, transport and sale. Japan prohibits the sale and use of active ingredients listed under the Stockholm Convention.)																
Y = Yes; N = No																

Observations

- About half the countries have specific lists that identify highly hazardous pesticides;
- There is a high degree of agreement about the definition of highly hazardous pesticides;
- There is an overall agreement to include WHO Class I pesticides and those listed in the Conventions;
- Not all countries include carcinogenic, mutagenic, reproductive, environmentally hazardous endocrine disrupters, high inhalation toxicity or those that show a high incidence of adverse effects.

Conclusions

- There are different groups of highly hazardous pesticides which may be given different priorities for phasing out.

2. Information Sources

Background

Widely accepted information sources would help registration authorities to identify HHP in their own country

Survey responses

Which information sources do you use to identify highly hazardous pesticides?		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Rotterdam Convention	R = 12, S = 2, N =	R	R	R	R	R		S	R	R	S	R	R	R	R	R
Stockholm Convention	R = 11, S = 3, N =	R	R	R	R	R		S	R	R	S	R	R	S	R	R
Montreal Protocol	R = 9, S = 4, N = 1	R	R	S	R	S		S	R	R	N	R	R	S	R	R
European Union pesticides database	R = 5, S = 6, N = 2	S	S	R	R	S		N	R	R	N		S	S	S	R
US/EPA pesticides database	R = 4, S = 5, N = 3	S	R		N	S		N	R	R	N		S	S	S	R
Pesticide database of another country*	R = 2, S = 6, N = 4	N			S	S		S	R	S	N	S	N	N	S	R
PAN list of highly hazardous pesticides	R = 3, S = 3, N = 2	S				S		S	R				N	N	R	R
FAO/WHO pesticide reference materials	R = 9, S = 5, N =	S	R	R	S	S		R	R	S	R	R	R	S	R	R
IARC list of carcinogenic compounds	R = 5, S = 3, N = 2	S			S	S		N	R		R		N	R	R	R
National monitoring data	R = 7, S = 2, N = 3	S			R	S		R	R	R	N	R	N	N	R	R
Total	Regularly =	3	5	4	5	2		2	10	6	2	5	4	2	7	10
	Sometimes =	6	1	1	3	8		5		2	2	1	2	5	3	
	Never =	1						3			5		4	3		
*Other countries DPR Korea: China Lao PDR: Thailand, Viet Nam Mongolia: Russia Nepal: India Viet Nam: China, South East Asia countries																
R = Regularly; S = Sometimes; N = Never																

Observations

- The pesticide conventions and the FAO/WHO pesticide information are the most widely used sources of information;
- Registration information from other countries is less used to identify HHP;
- In half the countries, national monitoring data are regularly consulted to identify HHP.

3. Status of HHP registration in your country

Background

A first step toward phasing out HHP is to identify these products among the registered pesticides and to restrict their use.

Survey responses

Total number of registered pesticides considered as HHP in your country (as per the first box of this section)		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Regular Registration	Max: 989 Min: 1			535	35	–		1	95		35	989	10		–	
Restricted Registration	Max: 535 Min: 1			535	30	–		2				109		1	29	
Number of HHP in country lists	Max: 65 Min: 2				65				5		35		10		2	

Observations

- Only about half the countries have identified pesticides that are considered as HHP;
- There is little regional harmonization in the management of HHP and actions are sketchy;
- Only few countries have restricted the use of HHP;
- Five countries have provided their lists of HHP which contain a total of 104 pesticides
 - Carbofuran is mentioned on 4 of the 5 lists
 - Acephate and Monocrotophos are listed three times
 - 13 pesticides are listed twice

Conclusions

- More action is required to identify HHP among the registered pesticides;
- Restricting the use of HHP may be applied as the first step toward phasing out these products.

Analysis of the data set on registered active ingredients against pesticides that may be considered as HHP

The lists of registered pesticides given by the countries were checked against the pesticides listed by international conventions, the *WHO Recommended Classification of Pesticides by Hazard* and the *PAN List of HHPs*. The following results are only a rough indication since the WHO and PAN lists do not cover all pesticides registered in Asia and only consider the hazard of the active ingredient and not that of the actual formulation.

Number of products in the regional database	Total	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Total registered a.i.	1 172	144	155	581	220	249	502	79	282	76	241	107	255	110	206	359
CONVENTIONS																
POP	4	0	0	1	4	1	0	0	0	0	1	1	0	0	0	0
PIC	17	1	1	6	16	9	2	1	6	2	9	4	2	3	3	3
Montreal	1	1	0	1	0	1	1	1	1	0	1	0	1	0	1	0
All Conventions	22	2	1	8	20	11	3	2	7	2	11	5	3	3	4	3
% of total	2%	1%	1%	1%	9%	4%	1%	3%	2%	3%	5%	5%	1%	3%	2%	1%
WHO CLASSIFICATION																
Obsolete ¹	30	0	0	3	19	2	7	0	1	0	1	0	0	1	0	0
WHO Class Ia ¹	15	1	0	7	4	4	4	1	5	1	6	1	2	0	0	5
WHO Class Ib ¹	32	7	1	18	11	14	12	2	14	1	15	5	11	7	7	8
Total	77	8	1	28	34	20	23	3	20	2	22	6	13	8	7	13
% of total	7%	6%	1%	5%	15%	8%	5%	4%	7%	3%	9%	6%	5%	7%	3%	4%
PAN LIST OF HHPs																
Chronic toxic a.i. ²	188	51	43	136	72	86	108	26	82	28	84	41	96	40	74	92
% of total	16%	35%	28%	23%	33%	35%	22%	33%	29%	37%	35%	38%	38%	36%	36%	26%
Environmentally toxic a.i. ²	159	54	39	119	51	74	88	26	82	20	76	38	87	39	59	88
% of total	14%	38%	25%	20%	23%	30%	18%	33%	29%	26%	32%	36%	34%	35%	29%	25%
EU LIST OF HHPs																
not approved	281	50	38	148	99	76	141	24	77	9	86	34	74	33	58	100
% of total	24%	35%	25%	25%	45%	31%	28%	30%	27%	12%	36%	32%	29%	30%	28%	28%
WHO + Conventions + EU not approved	302	54	39	159	105	85	150	27	86	12	93	38	79	37	62	106
% of total	26%	38%	25%	27%	48%	34%	30%	34%	30%	16%	39%	36%	31%	34%	30%	30%

¹ based on the *WHO Recommended Classification of Pesticides by Hazard*, 2009

² based on the PAN List of HHP, November 2013

Observations

- The majority of registered pesticides do not fall into the HHP category; however, all countries have some registered pesticides that might be considered highly hazardous;
- Some countries have succeeded in eliminating all highly hazardous pesticides that fall under the WHO Class Ia or are considered obsolete products;
- Pesticides that might have a high chronic toxicity or are environmentally highly toxic make up a significant number of registered pesticides

Conclusions

- Depending on the definition used to identify HHP (as given in the questionnaire responses above), all countries have registered pesticides that could be considered highly hazardous and should be phased out in the future.

4. Regulatory Actions

Background

The regulatory management of HHPs may involve national guidelines and regulations

Survey responses

After a pesticide registered in your country has been added to an international treaty or has been identified as highly hazardous, which of the following actions have been taken?		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Review registration to decide whether to restrict, phase-out or cancel the registration	Yes = 15	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Encourage registrant to voluntarily withdraw the product from the market	Yes = 10 No = 4	Y	Y	Y		Y	Y	Y	N	N	N	Y	Y	N	Y	Y
Stop issuance of importation or production licenses	Yes = 12 No = 3	Y	Y	Y	Y	Y	N	Y	N	Y	Y	N	Y	Y	Y	Y
Cancel the pesticide registration after a phasing-out period	Yes = 11 No = 2	Y		Y		Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y
Immediately cancel the pesticide registration	Yes = 6 No = 7	N	Y			N	N	Y	N	Y	Y	Y	Y	N	N	N
Let the registration expire at the end of the registration period	Yes = 2 No = 10	Y				N	Y	N	N	N	N	N	N	N	N	N
No special action is taken	Yes = 1 No = 9					N	N	Y	N	N		N	N	N	N	N
Total	Yes =	5	4	4	2	4	3	6	2	3	4	4	5	3	4	4
	No =	1				3	4	1	5	4	2	3	2	4	3	3
Other:																
India: Immediately registration is cancelled if desired by law/administration																
Malaysia: Mitigation measures to reduce impact																
Mongolia: Before the registration all pesticides to be involved in the list accurately evaluated and If it found HHP-s it will be directly removed from list.																
Y = Yes; N = No																

Observations

- All countries reported to review the registration of a product added to an international treaty or identified as highly hazardous;
- Other actions taken are (in order of priority):
 - stop issuance of importation or production licenses (12 countries);
 - cancel registration after phasing-out period (11 countries);
 - encourage registrant to voluntarily withdraw product (10 countries).
- Fewer countries consider immediate cancellation or no action as appropriate responses.

5. Taking a HHP off the market

Background

The phasing out of HHP should follow procedures given in national guidelines and regulations.

Survey responses

When taking a HHP off the market, do you...		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Do you explore alternatives prior to prohibition?	Yes = 10 No = 4	N	N	Y	Y	Y	Y	Y	Y		N	Y	N	Y	Y	Y
Do you inform distributors and users prior to announcing the prohibition?	Yes = 13 No = 1	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
Do you generally allow a phasing out period?	Yes = 11 No = 4	N	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	Y	Y	Y
If you allow phasing out periods, do you have a standard period?	Yes = 8 No = 4	N	Y		N	Y		Y	Y		Y	Y	N	Y	Y	N
If yes, how long is that period (number of months)	Max = 24 Min = 3-6 n = 8		3-6			Y		12	6		12	24		24	24	
Total	Yes =	1	2	3	3	5	2	3	4	1	3	4	2	3	4	3
	No =	3	1		1		1	1		1	1		2	1		1
India: Depending upon the shelf life																
Y = Yes; N = No																

Observations

- Most countries inform the distributor and users prior to publicly announcing the prohibition;
- Two-third of the countries explore alternatives prior to prohibition;
- Two-third of the countries generally allow a phasing out period, but not all those countries have a standard period;
- The phasing out period varies widely from 3-6 months to 2 years.

Conclusions

- All countries have procedures for taking a product off the market.

6. Steps taken for taking a HHP off the market

Survey responses

Bangladesh: 1. Inform concern industry; 2. Stop production (Packing & Repacking) & ban on import of that product; 3. Withdraw from distributors; 4. Stop registration renewal.

Cambodia: Zinc phosphate 1. Stop issuance of importation or production; 2. Force the owners to recall those products from markets; 3. Inform all concerned institutions, dealers and users; 4. Doing transactional fine/cracking down.

China PR: 1. Explore alternatives prior to prohibition; 2. Inform distributors, users and the public prior to announcing the prohibition – Announcement from regulatory authorities; 3. Allow a phasing out period depending on the pesticides to be prohibited.

DPR Korea: Endosulfan 480 EC; 1. Assessment for the toxicity of product, social and economic impact, and alternatives, and review registration to decide which action to be taken; 2. Announcing the decision for restriction; 3. Stop issuance of importation licenses; 4. Investigation for the total stock and establishment of disposal measure.

India: Endosulfan 1. Various committees were constituted to review the product; 2. The product was banned in the state of Kerala; 3. The use of product was prohibited near water bodies; 4. Hon'ble Supreme Court of India (Apex court) has banned the product for use, manufacture and import in may 2011 till further order.

Japan: Endosulfan 1. The manufacturer of formulations containing Endosulfan had stopped the production and distribution of these products by 2009 in the light of discussion at the Stockholm Convention. Since the manufacturer did not seek the renewal of the registrations, registrations had expired for all of the formulations by 2010; 2. The Ministry of Agriculture, Forestry and Fisheries (MAFF) and local governments jointly made efforts to keep stakeholders (especially farmers) informed of possible phasing-out of Endosulfan in a few years; 3. Since November 2010, the manufacturer has voluntarily recalled the formulations containing Endosulfan through its own sales channel; 4. In December 2011, Japan established a nationwide system for manufacturers and the Japan Agricultural Cooperatives to jointly collect unused pesticides containing Endosulfan; 5. In April 2012, MAFF announced by its Ministerial Ordinance that it prohibits the sale and use of all the formulations containing Endosulfan in response to the decision by the Stockholm Convention to list this substance in Annex A of the Convention.

Lao PDR: 1. disseminate regulation; 2. educate.

Malaysia: Endosulfan; 1. Review (twice) by national authority; Issuance of circular to stakeholder; 3. Six month phase-out period; 4. Degazetted registration of product; 5. Enforcement by national authority.

Myanmar: 1. Notification issue; 2. information; 3. listing inventories; 4. recording the application area.

Thailand: Methamidophos; 1. Announcement of product prohibition; 2. Inform the registrant and users; 3. Allow phasing out period (15 days); 4. Collecting of products for destruction; 5. Monitor whether they are still in the market.

Nepal: Phorate; 1. Inform importers and distributors; 2. Publish the name of banned pesticide on government Gazette papers; 3. Stop registration and review; Let them provide phasing-out period for 2 years; 5. Monitor the banned pesticide whether it is in market or not.

Pakistan: Endosulfan 1. Agricultural Pesticides Technical Advisory Committee recommended to the Federal Govt. on 25.05.2012 to prohibit import of Endosulfan in technical grade & formulation under any brand name or generic name from 1st May 2012; 2. Allow the importers to use carryover stock before 30th October 2013; 3. SRO issued by the Federal Govt. on 1st November 2013 and ban its use in Pakistan.

Sri Lanka: Carbofuran; 1. Announce the ban; 2. No import permit issued; 3. Allow to phase out in the market within 24 months; 4. after 24 months cancel registration.

Viet Nam: Carbofuran 1. Identify of relevant information in the world and ourselves country; 2. Science Council of Ministry of Agriculture and Rural Development analys, assess information and propose; 3. Ministry of Agriculture and Rural Development declare off and give a point of time to apply; 4. Waiting for applying period; 5. Phase out form List of restricted pesticides.

Observations

- 14 countries provided examples;
- Examples were given for
 - Endosulfan (5 cases)
 - Carbofuran (2 cases)
 - Methamidophos, Phorate and Zink phosphate (each 1 case);
- The steps taken followed the following pattern
 1. Review product/explore alternatives (5)
 2. Announce decision and inform industry/public (10)
 3. Stop importation or production (7)
 4. Either recall the product for disposal (4) or allow stock to be used over a phasing-out period (6)
 5. Cancel registration/prohibit sales (5)
 6. Monitoring and enforcement (3)

7. Constraints related to phasing out HHPs

Please describe any specific issues you faced when phasing out HHPs?

Survey responses

Cambodia: It may be getting some complains from industries/dealers.

DPR Korea: 1. Farmer's complaint; For example, farmers are feeling considerable difficulty because of import prohibition of Monocrotophos, and requesting the import of the pesticide; 2. Difficulty in establishment of active measures for pest outbreaks; the application of new alternatives isn't easily realized because of various problems in technology, experience and finance.

India: Arranging the alternatives against the specific pest

Malaysia: Farmers complain on effectiveness and availability of alternative; prevalence of counterfeit products

Myanmar: Pest outbreaks; Complaints of importer, distributor impact on Socio-economic

Thailand: Some farmers complained for they thought that HHPs was useful for them and some farmers didn't know which pesticides could be replaced. The industry got pressure for they have to destroy the product which they invested. Normally there was no pest outbreak

Nepal: There is no evidence of pest outbreak due to banned pesticide

Sri Lanka: Farmer complains are a common place during phasing out

Viet Nam: Lack of science evidence/research; Industry pressure; Associations

Observations

- Complaints came mostly from industry/dealers and farmers who had to adjust their practices to the new situation;
- There was no mentioning of outbreaks or inadequate pest control as a result of phasing out HHPs.

Conclusions

- Complaints are normal but did not show reasons for not phasing out HHP.

III. FAKE AND SUBSTANDARD PESTICIDES

1. Quality Control

Background

In some countries, fake and substandard pesticides are found. Besides causing economic losses, some of these may also be hazardous to human health and the environment.

Survey responses

Quality control infrastructure and capacities		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Do you check the quality of pesticides at the time of registration application?	Yes = 12 S = 1 No = 2	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	S	Y	Y	Y	N
Do you monitor the quality of pesticides imported or manufactured in your country?	Yes = 12 S = 1 No = 2	Y	S	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y
Do you monitor the quality of pesticides sold in pesticide shops?	Yes = 10 S = 2 No = 3	Y	S	Y	Y	Y	N	Y	Y	N	Y	Y	Y	N	Y	S
Do you monitor the quality of pesticides applied in the field?	Yes = 3 S = 3 No = 9	Y	N	Y	S	Y	N	N	S	N	N	S	N	N	N	N
Total	Yes =	4	1	4	3	4	2	1	3	1	3	2	3	2	3	1
	S =		2		1				1			2				1
	No =		1				2	3		3	1		1	2	1	2
Y = Yes; S = Sometimes; N = No																

Observations

- The majority of countries monitor the quality of pesticides at registration, importation or manufacture;
- Two-third of the countries monitor the quality of pesticides in pesticide shops;
- Few countries monitor the quality of pesticides applied in the field.

Conclusions

- Almost all countries have quality control infrastructure and capacities.

2. Analytical Capacities

Background

To monitor for fake or substandard pesticides, countries need sufficient analytical capacities and programmes that monitor the quality of pesticides in shops or the field.

Survey responses

Number of samples actually analysed for quality in 2013	Total	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Samples submitted as part of the registration application	Max = 5 500 Min = 0	148	750	5 500	5	333	240	NA	200	12	600	0	540	–	2 107	–
Samples of pesticides imported or manufactured in your country	Max = 7 107 Min = 19	24			176		24	NA		–	200	19	–	200	822	7 107
Samples of pesticides collected in pesticide shops	Max = 8 217 Min = 19	226		4 909	67	1 709	–	NA	61	–	200	19	8 217*	–	820	495
Samples of pesticides collected in the field or brought to offices	Max = 240 Min = 0 n = 4	23	50		240		–	NA	60	–	x	0	–	–	–	–
Total	n = 14	x	x	x	x	x	x	NA	x	x	x	x	x	x	x	x
Japan: 16 technical grades (for contents of active ingredients and impurities) and 224 formulations (for physical and chemical properties)																
Pakistan: Punjab Province																

Observations

- Most countries analyse pesticide samples for quality;
- Most samples are submitted as part of the registration application;
- Six countries analyze >100 samples collected in pesticide shops or collected in the field;
- Four countries have a sizable shop/field monitoring programme with >1 000 samples.

Conclusions

- In the majority of the countries, current surveillance programs may be inadequate to detect fake or substandard pesticides.

3. Alerts

Background

Exchange of information and alerting responsible authorities may be an important factor in the fight against fake and substandard pesticides.

Survey responses

		Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Did you receive alerts about fake or substandard pesticides from information sources within your country?	Yes = 11 No = 3	Y	Y		Y	N	Y	N	Y	Y	(Y)	Y	Y	N	Y	Y
If yes, what were the sources: Bangladesh: Media, Police source, Individual information Cambodia: Through monitoring, some importers/dealers, some users DPR Korea: Final users, agricultural management organizations Malaysia: Stakeholder Mongolia: Some farmers tell that some pesticides used not shown efficient result even they are spraying in normal dose and condition. Myanmar: Plant protection Division of Department of Agriculture Nepal: Market information Pakistan: Provincial agricultural departments Thailand: Office of Agricultural Regulatory, DAO Viet Nam: Inspector, PPSD, media																
Did you receive alerts about fake or substandard pesticides from other countries or other external information sources?	Yes = 2 No = 11	N	N		N	N	Y	N		Y	N	N	N	N	N	N
If yes, what were the sources: Japan: A Rapid Alert System established by OECD Network of Experts on Illegal Trade of Pesticides Malaysia: stakeholder Mongolia: some pesticide importing companies																
If you do not receive alerts, do you think it would be useful to be alerted if neighbouring countries identify fake or substandard pesticides in their country?	Yes = 9 No = 4	Y	Y		Y	N		Y	Y	Y	N	Y	N	Y	N	Y
Have alerts helped in identifying substandard pesticides in your country?	Yes = 9 No = 4	Y	Y		Y	N		N	Y	Y	N	Y	Y	Y	N	Y
Total	Yes =	3	3		3		2	1	3	4	1	3	2	2	1	3
	No =	1	1		1	4		3			3	1	2	2	3	1
Y = Yes; N = No																
How do you follow-up to such alerts? Cambodia: Monitor at an entry check point; Inform to concerned competent authorities at border check point; Stop issuance of importation. DPR Korea: Collection of samples, analysis of the sample, survey and certification of the original source Malaysia: Enforcement action Mongolia: However, I never get this kind of alerts from neighbouring countries if I received alerts I will take urgent measures in order to be check and cancel of their use. Myanmar: Inspection Nepal: We collect the sample and analysis for quality maintain Viet Nam: Sampling and test-																

Observations

- Most countries have received alerts about fake or substandard pesticides from sources within their country; the information sources included all persons concerned about pesticides;
- Only two countries received alerts from sources outside the country;
- In the majority of cases, alerts had been helpful in identifying substandard pesticides within a country and initiating enforcement actions.

Conclusions

- More information exchange and regional cooperation may be helpful in fighting fake and substandard pesticides.

4. Problems over the past two years

Background

Even though it is difficult to assess illegal activities, the number of reported incidences may give an indication of the severity of the problem

Survey responses

Over the past two years, which of the following problems have been found in your country? How do you rate them?	Total	Bangladesh	Cambodia	China	DPR Korea	India	Japan	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Viet Nam
Counterfeit products (products that are packaged to look like another legally registered pesticide)	Major = 1 Minor = 10 ND = 3	2	2	2	2	2	ND	ND	2	1	2	2	ND	2	2	–
Substandard pesticides (products that contain less active ingredient than listed on the label)	Major = 2 Minor = 10 ND = 1	2	1	2	1	2	2	ND	2	*	2	2	2	2	2	1.2 %
Fake pesticides that contain no active ingredients	Major = 1 Minor = 8 ND = 5	2	2	2	2	2	ND	ND	2	ND	2	ND	ND	2	1	–
Fake pesticides that contain a different type of active ingredient than what is stated on the label	Major = 1 Minor = 6 ND = 7	ND	2	2	1	2	ND	ND	2	ND	2	2	ND	ND	ND	–
Illegal pesticides without registration	Major = 4 Minor = 8 ND = 2	2	2	2	ND	2	2	1	1	1	1	2	ND	2	2	2%
Total	Major =		1		2			1	1	2	1				1	
	Minor =	4	4	5	2	5	2		4		4	4	1	4	3	
	ND =	1			1		3	4		2		1	4	1	1	
Mongolia: We do not have possibility and sufficient facility to analyze active ingredient concentration regularly																
1 = Major; 2 = Minor; ND = No data																

Observations

- Most countries consider fake and substandard pesticides as a minor problem;
- The illegal sale of products without registration is considered a more severe problem.

Conclusions

- There may be too little information to assess the problem of fake or substandard pesticides.

5. Most common pesticides found during 2013

Background

A list of the most commonly found fake and substandard pesticides in the various countries may give an indication of common problems in the region.

Survey responses

Product name	Country of origin on the label	Comments/Observations
Bangladesh Virtako 40 WDG Furadan 5 G Rovral 50 WP Nativo 75 WP Belt 24 WG Dursban 20 EC	Bangladesh	fake
DPR Korea Prometryn 50% WP Deltamethrin 25 EC Pyrazosulfuron ethyl 10% WP Butachlor 600 EC	China	Other A.I.; Simetryn Other A.I.; Cypermethrin Low contents of A.I.; 6.7% Other A.I.; Acetochlor
Japan Unregistered formulations containing Pyrethrins	Japan	A manufacturer intentionally sold organic fertilizer mixed with unregistered pyrethrins extracted from pyrethrum. Ministry of Agriculture, Forestry and Fisheries ordered it to stop manufacturing and selling these products and urged it to recall them which had been already on the market. No incident is reported from the use of these products.
Malaysia Paraquat Glyphosate Metomyl Endosulfan Fentin acetate Buprofezin	unknown unknown China Thailand China China	using Malaysia label using Malaysia label Chinese language Thai language Chinese language Chinese language
Mongolia: It is not possible to analyze every imported pesticide regularly. There are most common evidence that pesticides are not coming from the countries and manufacture's which are included in the list. Some pesticides are coming from countries which are not analyzed and evaluated in our country for registration using a brand names of the companies that are registered in list.		
Nepal: there was no evidence of fake pesticide among tested samples		
Sri Lanka Glyphosate Homai	India	Not known how they produce Illegally imported
Thailand Abamectrin Omethoate Dimethoate	— — —	a.i. below specification on the label

Conclusions

- These limited findings at country level do not reveal any broader inter-country patterns.

Regional workshop on Practical aspects of pesticide risk assessment and phasing out of highly hazardous pesticides Nanjing, China

WORKSHOP PROGRAMME

Sunday, 18 May 2014	
Preparatory meeting of organizing team	
Monday, 19 May 2014	
08:30–09:00	Registration
<i>Opening and welcome</i> Chair: Yongfan Piao	
09:00–09:20	Welcome and opening <ul style="list-style-type: none"> – FAO, Yongfan Piao – China. – Election of Chair
09:20–09:30	Introduction to workshop, Harry van der Wulp, FAO
	Logistics & housekeeping, ICAMA
<i>Risk assessment in pesticide registration:</i>	
09:30–10:00	Summary of questionnaire findings regarding pesticide registration, FAO
10:00–10:20	Coffee break
10:20–11:00	Brief introduction to health and environmental risk assessment, KemI
11:00–11:40	Risk assessment in China and how to access and interpret registration information from China, Mr. Tao Chuanjiang, Director of Health Division, ICAMA
11:40–12:40	Risk assessment in Europe and how to access and interpret registration information from the EU, KemI
12:40–14:00	Lunch break
14:00–14:30	How to access and interpret registration information from the US, FAO
14:30–15:30	How to access registration data from selected other countries, Japan, Malaysia and Thailand
15:30–15:50	Tea break
15:50–17:00	Discussion (in break out groups)
	To what extent can countries make use of registration information from reference countries? Introduction by FAO

Tuesday, 20 May 2014***Phasing out Highly Hazardous Pesticides (HHPs)***

- 08:30–09:00 FAO policy on HHPs, FAO
- 09:00–09:30 Summary of responses to questionnaire related to phasing out of HHPs, FAO
- 09:30–10:10 Phasing out HHPs in China, Mr Shan Weili, Director of Registration Division, ICAMA
- 10:10–10:30 Coffee break
- 10:30–11:00 Phasing out HHPs: Experiences and lessons from Chinese pesticide producers, Mrs Xia Feng, Deputy General Secretary, China Crop Protection Industry Association (CCPIA)
- 11:00–11:20 Phasing out HHPs in Thailand
- 11:20–11:40 Phasing out HHPs in Malaysia
- 11:40–12:00 Other country experiences
- 12:00–13:30 Lunch break
- 13:30–15:00 **Discussion** on phasing out HHPs (in break out groups)
- Brief introduction by FAO
 - Round 1: Identification of issues and constraints regarding the phasing out of HHPs (30 min)
 - Plenary presentations (15 min)
 - Round 2: Possible solutions and recommendations (30 min)
 - Plenary presentations (15 min)
- 15:00–15:30 Tea break
- 15:30–17:00 Explorative discussion on the scope for cooperative mechanisms on pesticide risk assessment (From information sharing to collaboration in review of new pesticides and currently used highly hazardous pesticides). – Introduction by FAO

Wednesday, 21 May 2014***Preventing import and distribution of fake and substandard pesticides***

- 08:30–09:00 Summary of questionnaire findings related to this subject, FAO
- 09:00–09:40 Chinese quality control/inspection scheme and implementation, Mr Zhang Wenjun, Director of International Cooperation Division, ICAMA
- Demo: How to check status of imported Chinese pesticides on line
- 09:40–10:30 Brief country reports from selected countries on this subject
- Malaysia, Thailand, Japan, others
- 10:30–10:50 Coffee break
- 10:50–11:20 Discussion on scope for a cooperative mechanism between trade countries to crack down on substandard and counterfeit products for instance through sharing quality control data among participating countries. Introduction FAO

Updates and new developments

11:20–12:00	The Chinese experience with removing trade names from pesticide labels, Mr Liu Shaoren, Director of Supervision and Regulation Division, ICAMA
12:00–14:00	Lunch break
14:00–14:40	The 2013 revision of the Code of Conduct on Pesticide Management, and the current set of technical guidelines, FAO
14:40–15:30	Other new developments of common interest
15:30–16:00	Tea break

Closing

16:00–17:00	Recap and closing
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Thursday, 22 May 2014

8:00–16:00	Field visit <ul style="list-style-type: none">– Red Sun industry– GoodAgro industry– Environmental Research Institute: risk assessment laboratory
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