Report of the Regional Workshop on Practical Aspects of Pesticide Risk Assessment and Phasing out of Highly Hazardous Pesticides (HHPs) 19-22 May 2014 Nanjing, China



SUMMARY

The workshop took place in Nanjing, China from 19-22 May 2014 and was attended by 27 participants from 15 Asian countries. It was divided into four parts: Pesticide registration and risk assessment; phasing out of highly hazardous pesticides (HHP); cracking down on fake and substandard pesticides; new developments. The sessions focused on practical aspects such as checking the registration status in other countries, obtaining risk assessment information and justifications on regulatory actions, sharing lists of HHPs and alternatives, sharing reports on health and environmental incidences, as well as findings from monitoring for fake or substandard pesticides. To facilitate information exchange in Asia, an electronic working group on pesticide risk assessment was formed. It will establish a platform for exchange of information related to the subjects discussed. Countries were encouraged to take appropriate actions in reviewing 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 the pesticide industry and agricultural production more competitive and sustainable.

BACKGROUND AND PURPOSES

Over the past years, the FAO Regional Office for Asia and the Pacific has organized a number of regional workshops aimed at enhancing harmonization among countries' regulatory framework for the control of pesticides. This workshop on pesticide risk assessment and phasing out of highly hazardous pesticides was organized in the same context and aimed specifically on a number of practical aspects of pesticide management that the earlier workshops identified as areas for further attention.

Although countries are aware of internationally recommended procedures for the registration of pesticides, there often are impediments that prevent the application of full-fledged registration procedures. This is particularly the case for countries with limited human and financial resources.

This workshop aimed to provide an opportunity to exchange experience and to discuss risk assessment for pesticide registration and phasing out of highly hazardous pesticides. It explored the scope for closer collaboration among countries regarding these and other aspects of pesticide management.

More specifically, the purposes of the workshop were 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.

The workshop was jointly funded by regional project GCP/RAS/229/SWE on Pesticide Risk Reduction in SE Asia, the APPC Secretariat and the Institute for the Control of Agrochemicals (ICAMA) of the Ministry of Agriculture, and it was organized by FAO in conjunction with ICAMA and the Department of Agricultural of Jiangsu Province. It was held in Nanjing, Jiangsu, China from 19 to 22 May 2014, and was attended by 27 delegates from 15 Asian countries as well as by resource persons from FAO and the Swedish Chemicals Agency (KEML).

OPENING SESSION

Mr. Piao Yongfan, Senior FAO Plant Protection Officer and Secretary of the Asia-Pacific Plant Protection Commission (APPPC) opened the workshop by welcoming the participants and introducing the panel guests. He gave a brief history of APPPC's leadership role in building pesticide management capacities in Asia by harmonizing pesticide regulatory management and promoting regional cooperation and exchange of information. This workshop on practical aspects of risk assessment and phasing-out of highly hazardous pesticides follows previous

efforts. He thanked the Ministry of Agriculture in China through Mr. Chen Youquan and ICAMA for organizing this meeting together with the Jiangsu provincial Department of Agriculture. He hoped that the workshop would contribute to a further exchange of information and experiences among the participants and to advance pesticide risk reduction in the region.

Mr. Chen Youquan, Deputy Director General of the Department of Crop Production and Protection of the Ministry of Agriculture also welcomed the participants and recognized the efforts of FAO and APPPC in strengthening pesticide regulatory management which is highly targeted to the present situation and challenges of the future. In recent years, China has made important progress in phasing out HHPs and promoting low-residue and low-risk plant protection products.

Mr. Zhang Jianyong, DG of the Jiangsu Province Agricultural Commission, described the important position of Jiangsu Province as the second largest economy in China and a leader in protected agriculture and the production of pesticides. In recent years, efforts were made to strengthen the registration of pesticides, the supervision of the market, research on pesticide safety and environmental risks, and export services. The Asian family needs each other for economic and social development, and the management of HHPs is an opportunity to exchange experiences between the countries and for closer cooperation.

Mr. Sui Pengfei, DG of ICAMA, stressed the importance of pesticide risk assessment which may promote a science based regulatory management of pesticides. Increased efforts were made to supervise the pesticide market with the banning or phasing out of 33 HHPs and no new registration of HHPs. This has greatly improved the risk situation with only 1.8% of the registered pesticides being highly hazardous and 88% being low toxic pesticides. ICAMA actively promotes cooperation and harmonization of pesticide regulations for a safer agricultural production and ecological environment.

Following the welcome speeches, Mr. Harry van der Wulp, Senior Policy Officer from FAO Headquarters, Rome, gave an introduction to the workshop. After a recent series of workshops on normative aspects of pesticide management, this workshop has been organized to address practical aspects, recognizing the limited human and financial resources for implementation of the regulatory framework for the control of pesticides in many developing countries. Comprehensive risk assessment procedures are followed in the EU and US. Several Asian countries also have well developed procedures. A main purpose of the workshop is to explore how countries with limited resources can make use of risk assessment information available from more advanced countries. Further the workshop aims to explore the scope and mechanisms for collaboration among the Asian countries in the phasing out of HHPs and other aspects of pesticide management.

The opening session ended with the election of Mr. Gu Baogen, DDG of ICAMA as chairperson of the workshop sessions. This was followed by a group photo and a round of introductions by each workshop participant.

SESSION I. PESTICIDE REGISTRATION AND RISK ASSESSMENT

<u>Summary of questionnaire findings – Gerd Walter-Echols, consultant</u>

A questionnaire survey was conducted among all participating countries before the workshop. The results showed a great diversity of approaches to pesticide registration and banning of HHPs. However, whether formally banned or not, most HHPs identified by international conventions are either not permitted or restricted in almost all survey countries, indicating a high degree of harmonization. Most surveyed countries conduct risk assessment as part of the registration procedure, but in most cases it only concerns partial risk assessment based on toxicology data. Risk information from international sources, primarily from international organizations, are considered. Authorities generally consult the FAO/WHO Pesticide Specifications as well as the international conventions regarding pesticides; the registration status of a pesticide in the EU or USA is checked to a lesser extent. When renewing a registration, most countries take new risk information into account. 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, almost all surveyed countries either banned or restricted some pesticides because of health or environmental risk concerns.

<u>Introduction to health and environmental risk assessment – Lilian Törnqvist and Jenny</u> Rönngren, KEML

A brief introduction to the principles and elements of risk assessment of pesticides was given, as well as some current issues under international discussion. Hazard assessments as well as basic concepts of risk assessments using exposure models were presented. The established reference values e.g. ADI, AOEL, ARfD and NOEC values found in different reports on active substances, such as EFSA conclusion reports, are recommended to be used globally. The presented exposure models used in EU are based on measured data from different countries/regions in Europe and US were used to build up common databases. The estimations of exposure in other regions should however be adapted to local circumstances of use.

Risk assessment in China - Mr. Tao Changjiang, Director of Health Division, ICAMA

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.

<u>Access to information from the pesticide registration process in the EU – Lilian Törnqvist and</u> Jenny Rönngren, KEML

The Swedish Chemicals Agency has produced a guidance document on how to access and interpret registration information from the EU. This guidance document was introduced and its use was demonstrated on some examples. The easiest way to get registration information is to use the pesticide data base on the web-site of DG SANCO. The best way to find information on GHS classification of chemicals is to search in the classification data base made available by ECHA.

Pesticide registration information from US-EPA – Harry van der Wulp, FAO

A document was made available to the participants that provides 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 Chemical Search or the National Pesticide Information Retrieval system (NPIRS). There is no list of banned products. The websites can be used to find risk assessment reports, MRLs information and copies of approved labels. A live demonstration was given on how to navigate in the different webpages. US-EPA acknowledges that it can be difficult to find information at their website and all participants were encouraged to contact US-EPA if they need assistance. Contact details are provided in the guidance document.

How to access registration data from China – Gu Baogen

The website http://www.chinapesticide.gov.cn/index.html has a Chinese and English part. The different categories of information that are available in the Chinese version were explained and demonstrated. An English part of the website does not yet cover all Chinese pages, but it includes a search engine that allows to look up the registration status of individual products in China.

How to access registration data from Japan – Yoshiyuki Takagishi

The website http://www.acis.famic.go.jp/searchF/vtllm000.html is only available in Japanese. It was developed by the Food and Agriculture Materials Inspection Center (FAMIC) and makes it is 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) publishes 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. A list of registered active ingredients in English was made available.

How to access registration data from Malaysia - Madam Atika Abdul Kadir Jailani

A brief description of their pesticide legislation and the responsibilities of the pesticide board was presented. Various rules and regulations regulate the implementation of the Pesticide Act. The "Highly Toxic Pesticides Regulations" of 1996 regulate the management of HHPs. The introduction was followed by a demonstration of the information that is available on the website of Department of Agriculture. 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 that provides pesticide

recommendations for different crops, pests for farmers and extension agents. SISMARP in only Bahasa Malaysia language.

How to access registration data from Thailand - Ms. Panida Chaiyanboon

Thailand has some information related to pesticide registration available on-line but it is only in Thailanguage. 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 Thailanguage) are the Hazardous Substance Act and registration application forms. The Royal Thail Government Gazette website www.ratchakitcha.soc.go.th publishes the government notifications.

During the final discussion of the presentations it was pointed out that the quality of automatic website translation engines has greatly improved in recent years and allows users a general understanding of the content of foreign language webpages.

<u>Discussion: To what extent can countries make use of registration information from reference countries?</u>

The workshop participants were divided into three groups that discussed the following questions:

1. What information from reference countries would be useful to you in conducting risk assessment as part of the registration process?

The group responses included: registration status; lists of banned and restricted products; efficacy data; residue data, MRLs and PHIs; eco-toxicological data; target crops and pests; pesticide use patterns; use precautions; and recommendations from international bodies

2. Which of this information would need adjustment because of the specific situation in your country?

The group responses included: efficacy data, residue data; dietary data; use patterns: toxicity of formulated products; use precautions; label information, MRL, PHI; exposure, occupational risk and application technique.

3. What do you need to do to make such adjustments?

The group responses included: requesting efficacy and residue data from the manufacturer, local studies, dietary-, use- and food consumption data; cooperation between countries within the Region.

In summary it was concluded that risk assessment is important, but it is not necessary for all countries to conduct full risk assessment as much of the information is available can be shared and adapted.

Conclusion

Several presentations highlighted importance of risk assessment to justify regulatory decisions, particularly with regard to highly hazardous chemicals. However, since most countries do not have the expertise and resources to carry out comprehensive risk assessments, they can make use of the internationally available information. For particular pesticides under review,

registration authorities can check whether they are registered in other countries and they can access review reports and regulatory justifications to help them with their own decision making.

SESSION II. PHASING OUT OF HHPs

FAO Policy on HHP – Harry van der Wulp, FAO

In 2006, the FAO Council mandated FAO to step-up its work on risk reduction, including a progressive ban on HHP. In follow-up, the FAO/WHO Joint Meeting on Pesticide Management formulated criteria for HHPs and is preparing guidelines on phasing out HHPs. The revised Code of Conduct now also contains a definition of HHPs, 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 Joint Meeting has listed a number of identification criteria for HHPs, which include certain Hazard classes/categoriesof the WHO or GHS classification or listing by the Stockholm and Rotterdam Conventions or the Montreal Protocal.

To phase out HHPs in their territories, countries can do the following: (1) Identify HHPs that are registered and in use; (2) assess whether their availability is really necessary and whether there are alternatives; (3) Where possible, take regulatory action to phase out the products concerned or otherwise take risk mitigation actions; (4) Provide guidance about alternatives where needed; and (5) establish, strengthen and maintain a monitoring and reporting system. Suggested areas for collaboration are: (1) Share data from monitoring and reporting systems; (2) Share information on examples of successful phasing out of HHPs and viable alternatives; (3) Share information on related regulatory and policy actions.

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.

<u>Summary of questionnaire findings – Gerd Walter-Echols, consultant</u>

The questionnaire results showed that most of the participating countries agreed with most of the criteria for identifying HHPs such as high acute toxicity under WHO Class I and pesticides listed by Conventions. There was a slightly lower level of acceptance of other categories. Consequently, the information sources that were most often used to identify HHPs where international conventions and the WHO Classification of Pesticides by Hazard. National data bases of other countries were consulted to a lesser degree. Only half of the surveyed countries had compiled lists of HHPs. A preliminary analysis of the country lists of registered pesticides showed that all countries have registered active ingredients that appear in the Convention lists or fall under the WHO Class I Hazard classification. All countries would review the registration when a new pesticide is listed in one of the Conventions. For listings under the Stockholm Convention, most countries would stop import and production and encourage the producer to withdraw the product. They would then cancel the registration after a phasing out period which may last from 6 months to two years. While there is already a high level of agreement on the phasing out steps, four countries prefer to recall a product for disposal, while six countries would allow a phasing out period.

Phasing out of HHPs in China - Ms Zhang Wei, ICAMA

When phasing out a 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).

<u>Phasing out of HHPs in China – Industry Experience-Xia Feng, China Crop Protection</u> Industry Association (CCPIA)

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% of the production. Over the last 50 years, the major formulation types changed from solid to liquid and 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 – 3 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, 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 and 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.

Phasing out of HHPs in Thailand - Ms. Panida Chaiyanboon

The criteria used for identifying HHP, the division of responsibility among various committees of the Department of Agriculture and the phasing out process were presented. In Thailand, there are presently 29 pesticides registered for restricted use, 2 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 to one of the 8 regional offices of the DAO within 15 days, which will then destroyed then by incinerator.

Phasing out of HHPs in Malaysia - Madam Atika Abdul Kadir Jailani

Following a decision by the Pesticide Board, the Minister will issue a directive to for ban. This directive is communicated to the producers and users, and a grace period of normally 6 months in granted to sell off the product. Resistance from the industry may result in delaying the decision, during which period the Pesticide section has to collect information on economic impact, effectiveness and availability of alternative products is collected and relayed to the producers. It would be better if these facts and figures were already available at the time when the ban is announced, and if all stakeholders are involved during the process.

Phasing out of HHPs in Nepa l- Mr. Dilli Ram Sharma

The organization of pesticide management in Nepal and the pesticide use situation in the country were described, including the attitudes and practices by farmers. Some unregistered HHPs are brought into the country from India. Methyl bromide was collected and disposed. Recently, endosulfan has been banned, and 15 pesticides will be banned soon.

Discussion

The workshop participants were asked to make a priority list of the issues that came up when pesticides were phased out and then discuss steps to overcome the problems.

Issues	Solution
Lack of unified criteria for HHPs	Recommend regional priority list for phasing out
	 Inform producers and users on status of HHPs
Lack of documented poisoning cases	Strengthen monitoring system
or environmental problems;	 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	 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
No specific procedure for phasing	 develop procedures and regulations
out	 review registration validity
	• first restrict use in some crops, then ban
Resistance and pressure from	 Conduct stakeholder meetings
stakeholder	 Communicate legal framework or procedure
	 Involve other ministries
	• Multifactorial problems need multifactorial solutions

Lack of disposal facilities	•	Allow a phasing out period or make manufacturer or
		importer responsible

Conclusion

To phase out HHPs, countries should first review registered products and identify those that meet the critieria of HHPs; -assess whether their availability is really necessary and whether there are alternatives; take regulatory action to phase out the products concerned and provide guidance about alternative where needed; consider what risk mitigation action can be applied if the product cannot be phased out; and finally establish, strengthen and maintain a monitoring and reporting systems for health and environmental impacts of pesticides. 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 from countries that have phased out HHPs showed that there were initial complaints, but no negative effects to agriculture or the agrochemical industry were observed. On the contrary, in China the phasing out of HHPs has challenged the pesticide industry to strengthen their product and formulation development efforts and make structural adjustments. This has placed China products in a much better position on the global market and made the industry and agricultural production more sustainable.

SESSION III. FAKE AND SUBSTANDARD PESTICIDES

<u>Summary of questionnaire findings – Gerd Walter-Echols, consultant</u>

The questionnaire results showed that almost all countries check the quality of pesticides at registration or import/manufacture. Fewer check the quality of products sold in pesticide shops, and only 3 countries regularly check the quality in the field. The number of actual analyses carried out in 2013 showed that only 5 countries have sufficient analytical capacities to carry out systematic and routine quality control checks. Thailand and Vietnam predominantly analyzed registration and import samples, while Pakistan and India predominantly analyzed shop and field data. Only China has a monitoring programme that checked both registration and field data.

Most countries have 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 alerts from neighbouring countries. Regarding the severity of the problem, most countries regarded fake or substandard pesticides as a minor problem. Major problems were reported about counterfeit pesticides from 1 country; about substandard pesticides from 2 countries; about fake pesticides with no active ingredient from 1 country; and about illegal pesticides without registration from 4 countries. About half the countries reported not to have sufficient data about or another category.

Quality control and implementation in China - Zhang Wenjun, ICAMA

The presentation described the relevant laws and regulations, particularly for the control of import and export. The "One Implementation Practice" refers to the joint issuance of import and export certificates by 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 8 are accredited by OECD countries, 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 added to a black list.

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 1157 chemicals which make up 98% 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. It was demonstrated, how 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. ICAMA agreed to make a one page handout for countries on how to check relevant information on their website or through other means.

Quality control and implementation in Malaysia -Madam Atika Abdul Kadir Jailani

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 exceeds the allowable concentration of 13%; Endosulfan which has been banned; pesticides with foreign language labels or pesticides without a registration number.

Quality control and implementation in Thailand - Ms. Panida Chaiyanboon

The responsibility for quality control lies with the MOA. In 2013, 646 samples were collected at points of entry, 176 at production sites, and 820 at pesticide shops or the market. 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.

Quality control and implementation in Japan - Yoshiyuki Takagishi

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 carry out the quality inspections at the manufacturing site and a 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.

Discussion

The members of the electronic working group presented the outcome of their discussions on the scope of a cooperative mechanism between the countries to share information on risk assessment, phasing out of HHP and to crack down on substandard and counterfeit products:

Name: Electronic Working Group on Pesticide Risk Reduction

Activity 1: Platform for Exchange of Information

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

Other activities will be discussed and decided by the working group before 1 July 2014. Each country should nominate an official and a technical contact point to Ms. Zhang with copy to Mr. Piao.

Conclusion

With regard to preventing the import and distribution of fake and substandard pesticides, the three 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. The working group may develop the appropriate formats for sharing experiences and information in some of these areas.

SESSION IV. UPDATES AND NEW DEVELOPMENTS

Chinese experience with removing trade names from labels – Li Youshun, ICAMA

In China in 2007, there were 2400 enterprises selling 622 active ingredients in 23,000 pesticide formulations and 16,000 trade names. This created confusion for farmer's decision making and many trade names were similar to each other. Many cheap product formulations encouraged farmers to use pesticides repeatedly. Consequently, in 2007, six new regulations were issued, including regulations for label text and design. They included 1024 approved abbreviations for

common names, and mixture names were limited to 5 Chinese characters. The company may add its company logo or trademark to identify the specific brand of pesticide active ingredient. These actions reduced the number of pesticide names from about 15,000 to 1700. Presently, there are about 2500 product names. The guiding principles behind these new regulations were the consumers' right to know and to avoid repeated use of pesticides. All companies are considered equal before the law and thus trade names are also treated equal. The change in label regulations lead to an increase in quality and compliance of pesticide labels, and made the pesticide market more competitive. Companies had 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 product brand should be decided by the market and not by Government authorizations. The type of pesticide is indicated by a colour band, and the toxicity classification is prominently indicated on the label. It is based on the formulation, however, highly toxic active ingredients are also indicated. The introduction of the GHS system is under consideration, but not considered urgent.

Revision of the Code of Conduct – Harry van der Wulp, FAO

A new revised version was approved in 2013 and is named "Code of Conduct on Pesticide Management". It has been adopted by both FAO and WHO and thus creates a unified code for all pesticides used in agriculture and public health. It considers pesticide management as part of chemical management as well as sustainable agricultural development. The main changes in the new version are: inclusion of public health pesticides and integrated vector management (IVM); updated definitions, e.g. a new and shorter definition of pesticides; more emphasis on health and the environment; and introduction of GHS for classification and labelling. For the first time, reference is made to children in line with the ILO Convention. Governments are also advised to facilitate the exchange of information. In support of the Code of Conduct, an extensive set of technical guidelines has been developed by the Joint Meeting on Pesticide Management, and a pesticide registration toolkit is under development.

<u>Update on the Reform of the Pesticide Registration System in Japan - Yoshiyuki Takagishi</u>

Since 2007, the pesticide registration system in Japan is undergoing a reform to incorporate new approaches and to promote greater participation in joint review and work sharing. The decision making is based on scientific data with a shift from hazard-based to risk-based assessments. Furthermore, Japan seeks a greater participation in international rule-making bodies such as Codex Alimentarius, OECD, etc. Risks should be communicated in a transparent manner to all stakeholders. The required number of supervised trials has been increased and certain trials from other countries are accepted. The registered uses are made for crops representing a 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. Ongoing programs are the development of crop groups; guidelines for livestock metabolism and animal transfer studies; evaluation of health effects of short-term intake of pesticides to enhance the protection of consumer health; evaluation of health risks to operators and bystanders; and procedures for joint reviews and work sharing.

Conclusion

The examples of innovative regulations in China and the revision of the Code of Conduct show the dynamic nature of pesticide management in order to adapt to the challenges of protecting human health and the environment while promoting sustainable agricultural and social development. Closer collaboration among countries within the Region would help implement the provision of the Code of Conduct, particularly for countries with limted resources.

SESSION V. CLOSING

The chairperson of the meeting, Mr. Gu Baogen, thanked the delegates for their active participation and thanked all speakers for their contributions. The workshop provided an occasion to learn about many new developments and showed opportunities for greater regional collaboration, exchange of information and deepening friendship.

Finally, Mr. Piao Yongfan, Senior FAO Plant Protection Officer and Secretary of the Asia-Pacific Plant Protection Commission (APPPC) summarized the findings and results of the workshop. All presentations demonstrated that great 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 with regard to regulatory actions, capacity development, information and knowledge sharing; and collaboration between importing and exporting countries on quality issue, fake products, etc. He regarded cooperation among countries as the continual driving force for achieving progress in strengthening regulatory management at both country and regional levels.

With these remarks he closed the indoor part of the workshop and specifically thanked KemI for their expert contributions and funding, as well as all other participants for their hard work

SESSION VI. FIELD TRIP

On 22 May, a field trip to locations in the vicinity of Nanjing was organized. The workshop participants visited the Gaozheng Agrochemical company that developed a solid formulation for Paraquat, and the Redsun Group factory that produces HCN, pyridine and pyrethroid based pesticides and exports about 60% of its production, including Paraquat, to more than 100 countries.

The workshop ended with a visit of the National Institute for Environmental Sciences (NIES) which collaborates with ICAMA as the environmental laboratory for pesticide registration. The institute was founded in 1978 and has more than 400 staff in six research centers. Pesticide risk assessment studies are carried out in the environmental chemistry laboratory, the environmental toxicology laboratory and a 3 ha field experimental site. Studies include fate studies, risk assessments, risk mitigations, environmental safety and alternatives to HHPs. For example, the institute investigated the risk of Imidacloprid on honeybees and Carbofuran on birds. The risk assessments are supported by a Pesticide Risk Assessment Exposure Simulation Shell (PRAESS), a computer model that can be used to simulate the fate of pesticides in different Chinese agricultural scenarios and to estimate potential residues in groundwater and different crops. Future focus will be on improving risk assessment technologies and to include pesticide adjuvants in the studies.

Annex 1

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Regional Workshop on Practical Aspects of Pesticide Risk Assessment and Phasing out of Highly Hazardous Pesticides (HHPs) 19-22 May 2014, Nanjing, China

Sunday	18 May 2014	
Preparatory meeting of organizing team		
Monday	19 May 2014	
08:30-09:00	Registration	
Opening and	welcome_Chair: YongfanPiao	
09:00-09:20	Welcome and opening	
	FAO, YongfanPiaoChinaElection of Chair	
09:20-09:30	Introduction to workshop, Harry van der Wulp, FAO	
	Logistics & housekeeping, ICAMA	
Risk assessm	ent in pesticide registration:	
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, Keml	
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, Keml	
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	
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Tuesday	20 May 2014
Phasing out Hig	ghly 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
	Phasing out HHPs: Experiences and lessons from Chinesepesticide 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 T	Tea break
	Explorative discussion on 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

Wednesday	21 May 2014
Preventing imp	port 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

Thursday 22 May 2014

8:00-16:00

Field visit

Red Sun industry

GoodAgro industry

Risk assessment lab, Environmental research Institute