

**Report of the Regional Workshop on Application of**  
**the FAO Pesticide Registration Toolkit**  
**29 May-3 June 2017**  
**Beijing, China**

**Summary**

The Regional Workshop on the Application of the FAO Pesticide Registration Toolkit was convened from 29 May - 3 June 2017 in Beijing, China in collaboration with the Institute for the Control of Agrochemicals of the Ministry of Agriculture (ICAMA). More than forty participants (40) from Cambodia, China, Indonesia, Laos, and Philippines, as well as Regional Office for Asia and the Pacific, participated in the workshop.

The Food and Agriculture Organization of the United Nations (FAO) developed a Pesticide Registration Toolkit to support pesticide regulators in countries with limited resources to go through the process of evaluating pesticide registration dossiers. It can be used as a training and reference tool for pesticide registration authorities in order to provide assistance for decision making. The Toolkit can also be considered as a decision support system for registration authorities in developing countries. This workshop aimed at enhancing pesticide regulatory management capacity in Asian countries, sharing data and experience and expanding knowledge on pesticide registration.

During the workshop, the three facilitators introduced the structure and contents of the Pesticide Registration Toolkit and helped the participants get familiar with the Toolkit. The presentations, given by the facilitators, demonstrated to the participants how to use the Toolkit to find data, establish links to registration procedures, share national experiences on risk assessment, etc. The participants exercised with several examples by using the Toolkit at each section of the workshop. Finally, the participants provided their feedback based on their experiences. It was hoped that the training would enable registration authority of participating countries to improve the capacity of regulatory management through registration enhancement. Participants considered that the toolkit will enable countries especially for least capacity countries in regulatory management of pesticides to apply the analogy strategy by bridging assessment methods in pesticide registration process and make appropriate decision by consideration of feasibility of the local situation.

In addition, the Chinese experts shared with the other participating countries their knowledge and experience in regulating highly hazardous pesticides, and demonstrated Chinese methods and procedures for human health risk assessment and environmental risk assessment. China's operator risk assessment model (COP-Risk) and fate model for paddy field (TOP-RICE model) were also introduced to the participants.

At the end of the workshop, the participants provided their overall comments to the workshop. Most of the participants found that the Toolkit was very useful for them and were willing to share the Toolkit to their colleagues in the future. The participants from different countries also hoped that FAO could provide more training in the future.

## **Report**

### **1. Opening ceremony**

Dr. Piao Yongfan, Senior Plant Protection Officer of the Food and Agriculture Organization of the United Nations (FAO) and Executive Secretary of the Asia and Pacific Plant Protection Commission (APPPC), welcomed all participants on behalf of the FAO. He pointed out the importance of risk assessment and pesticide management on pesticide registration. The training workshop on the FAO Pesticide Registration Toolkit was a precious opportunity for Asia Pacific countries to share experience and upgrade skills and knowledge. Dr. Piao thanked the Institute for the Control of Agrochemicals of the Ministry of Agriculture (ICAMA) of the People's Republic of China for its strong support to APPPC. He also wished the training on the Toolkit a fruitful meeting to all participants.

Mr. Zhou Puguo, Director General of ICAMA welcomed representatives to the workshop. He appreciated the APPPC for selecting China as the host country to organize the workshop. He said that China was a major producer, user and exporter of pesticide. With the attention and help from FAO/APPPC and other international organizations , as well as the support and participation of Asian countries, China could constantly improve its pesticide registration management. Mr. Zhou believed that the workshop was a valuable opportunity for study and communication, he encouraged the participants to learn from each other and make efforts for the coordinated and consistent development of pesticide registration management in Asia and the Pacific region.

### **2. Introduction of participants and expectations**

Participants introduced themselves and explained their roles in countries pesticide registration process.

Participants shared their expectations about the Toolkit and the Workshop. The expectations of the Toolkit focused on exchanging of data from other countries, comparing risk and cost-benefit evaluations, mastering different evaluation models, making reasonable risk reduction decisions, harmonizing registration procedures, etc. The expectations of the Workshop focused on sharing data and experience, expanding knowledge on pesticide registration, catching up with new developments, etc.

### **3. Workshop introduction and objectives**

The Toolkit is a web-based decision support system for pesticide registrars, it will assist the registrars in the evaluation and registration of pesticide.

The main objective of the workshop focused on familiarizing the participants with the structure and contents of the Toolkit, learning how to find data, sharing national experiences on risk assessment.

### **4. Outcome of the survey on pesticide registration capacities**

On-line survey had been sent to all participants for 2 weeks in advance of the workshop. The outcome of the survey was explained in detail to the participants. All the participating countries have their own pesticide registration authorities.

In Cambodia, there are more than ten full-time staff in the registration authority in charge of pesticide registration. All types of pesticides can be registered. One to ten new products with new

active ingredients apply for registration each year, and it takes one to three months to evaluate an application.

In China, there are more than ten full-time staff in the registration authority in charge of pesticide registration. All types of pesticides can be registered. Eleven to twenty-five new products with new active ingredients apply for registration each year, and it takes six to twelve months to evaluate an application.

In Indonesia, there are six to ten full-time staffs in the registration authority in charge of pesticide registration. All types of pesticides can be registered. Eleven to twenty-five new products with new active ingredients apply for registration each year, and it takes three to six months to evaluate an application.

In Lao PDR, there are more than ten full-time staff in the registration authority in charge of pesticide registration. All types of pesticides can be registered. Twenty-six to fifty new products with new active ingredients apply for registration each year, and it takes one week to one month to evaluate an application.

In Philippines, there are three full-time staff in the registration authority in charge of pesticide registration. Only agricultural pesticides can be registered. One to ten new products with new active ingredients apply for registration each year, and it takes more than twelve months to evaluate an application.

## **5. Toolkit**

### **5.1 Introduction to the FAO Pesticide Registration Toolkit**

The objectives of the Toolkit were highlighted as making existing information relevant for the pesticide registrars available “at their fingertips” and provided guidance on key registration procedures and methods in an interactive manner. It furthermore provides assistance for decision making and can also be used as a training and capacity building tool for the pesticide registration authority. The Toolkit can be considered as a decision support system for registration authorities in developing countries. However, it was stressed that the Toolkit is not an automated system for evaluation of specific pesticide, it supports and facilitates decision making by registrars as well as provides an advice for different steps of registration process from the submission to the decision making. In addition, the Toolkit provides access to data requirements and testing guidelines for the evaluation of a specific type of pesticide for particular use, and evaluation methods for the various aspects of the pesticide registration dossier.

### **5.2 Decision making module**

The decision making module was explained in detail. This tool describes different types of elements to be taken into account to decide whether a pesticide can be registered. It was stressed that this tool does not provide international criteria for the registration of pesticides, but considers different aspects of decision making. These decisions are guided by national pesticide legislation, other national legislation and policy on environment, health and trade/economic development, as well as national human health and environmental protection goals. In principle, both risks and value should be acceptable before a pesticide would be accepted of the registration. If the risk to human health or environment is considered unacceptable a pesticide should not be registered, even if it may have high value. It was highlighted that a pesticide which is not efficacious, does not bring (potential) economic benefits to the user, or cannot be used in a suitable manner, should not be registered, irrespective of whether its risk is acceptable.

During the exercise participants were invited to do a card game. Participants reviewed the information provided on the card and made a registration decision.

### **5.3 Principles of health and environmental assessment for pesticide registration, as used in the Toolkit**

A presentation on principles of health and environmental assessment was made to the participants. Based on the definition of pesticide registration from the *International Code of Conduct on Pesticide Management*, it should be demonstrated that the pesticide product does not pose an unacceptable risk to human or animal health and environment under the conditions of use in the country or region.

Definitions of hazard and risk were explained. It was noted that hazard assessment is based on intrinsic properties of a pesticide, irrespective of exposure rate, yet the risk assessment is based both on the properties of the pesticide and on the level and probability of exposure. Evaluation of adverse effects on human health and environment can be hazard-based or risk-based.

The advantages and disadvantages of tiered (stepwise) risk assessment was demonstrated to the participants. The advantage is that applicants only provide data needed for expected risk assessment tier, and as a result less data are required for less hazardous pesticides. However, a disadvantage is the necessity to define data requirements depending on the level of risk. It was explained that tiered risk assessment from the worst case situation to more realistic cases. If the risk in the worst case condition is acceptable, it doesn't have to do further assessment.

### **5.4 Data requirements module**

The data requirement module was presented to the participants. It was noted that data requirements are provided as defined in the FAO/WHO *Guidelines on data requirements for the registration of pesticides (2013)*. It was highlighted that data requirements are not the same for every type of pesticide, but will depend on the pesticide group, the pesticide type, the intended use, and the type of registration. This tool has a search function of data requirements or a list to browse all studies. In addition the list of data requirements can be printed or saved on the computer. After the presentation, participants were invited to explore the tool and practice finding data requirements and testing guidelines.

### **5.5 Assessment methods module**

The assessment methods module was introduced to the participants. The tool provides methods for the evaluation of the various aspects of the pesticide registration dossier. The levels of complexity of assessment methods are different from relatively simple to complex. Assessment methods were chosen based on pesticide group, main topic and sub-topic. It was noted that the Toolkit currently focused on chemical pesticides. It was also highlighted that the assessment methods couldn't be chosen automatically, the technical staff had to choose the suitable assessment model based on the properties of pesticide, their working experience and knowledge. After the presentation, participants were invited to practice the assessment methods module.

### **5.6 Risk mitigation module**

A presentation on risk mitigation module was made to the participants. The objective of this tool is to list of various measures for mitigation of human health risks and environmental risks. It will help to ensure that the risk of pesticide is acceptable for local condition of use. It was highlighted that measure should have been demonstrated, or is likely, to be effective under local conditions as well as being practical for the pesticide user, and preferably not compromise pesticide product efficacy. Therefore, expected reduction of risk should outweigh the cost of the measure.

It was concluded that whenever a risk mitigation measure is required or recommended as a part of registration, it should be assessed whether the measure can be realistically implemented under the proposed condition of use.

### **5.7 Registration strategies module**

The tool was used to help applicant to select the most appropriate strategy. Registration by analogy and complete evaluation are the two main registration strategies in the Toolkit. If there is a similar product, then analogy approach could be a better choice. The FAO recommends that registration authorities work towards increasingly comprehensive evaluation of a pesticide.

### **5.8 Information sources module**

The information sources menu was explained in detail. The Toolkit provides some important links to search and compare specific information of pesticide. First, registration elsewhere shows the information of pesticide which has been registered on the same or a similar crop in different country. Second, the pesticides have been banned or severely restricted that can be checked by Rotterdam and Stockholm Convention. Third, scientific or technical reviews of the pesticide can be checked. Fourth, the Toolkit provides some important links to do hazard classification. Fifth, the direction for use and other information on label of pesticide can be checked by Approved Labels section. Sixth, the maximum residue limits (MRL) section provides some international and national sources such as codex alimentarius, global MRL database, etc. Seventh, pesticide properties and specification also can be found from the relevant database. In addition, internationally harmonized terms and definitions can be found in the glossary.

## **6. Highly hazardous pesticides**

### **6.1 Highly hazardous pesticides – risk reduction process**

A presentation on highly hazardous pesticides (HHPs) was made to the participants. Highly hazardous pesticides (HHPs) have been paid a special attention in the worldwide because it's high acute human toxicity, chronic human toxicity, severe environmental hazards etc. FAO/WHO issued specific guidelines on HHPs (2016) to help countries including criteria for identification and steps of the risk reduction process for HHPs.

### **6.2 China's experience in regulating highly hazardous pesticides**

China has published a series of policy such as food safety law to prohibit applying the extremely toxic and highly toxic pesticides on vegetable, fruit, tea, etc. The procedures and methods were established and risk assessments for several HHPs were carried out. The phytotoxicity, resistance and pesticide residue of 137 active ingredients have been reported, while its effects on human, animal and environment also have been clear. Regulatory measures including banning, cancelling, withdrawing was taken on HHPs. Chinese government has banned about 19 highly toxic organophosphorous pesticides. The pesticides were in the list of Stockholm, Rotterdam and Montreal Convention were also banned by the government.

### **6.3 Highly hazardous pesticides – identification**

There are eight criteria to identify if a pesticide is an HHP based on the World Health Organization (WHO), the globally harmonized system (GHS) and relevant binding international agreements or conventions. Criteria 1: WHO class Ia and Ib; Criteria 2, 3 and 4: GHS category 1A and 1B for carcinogenicity, mutagenicity and reproductive (CMR); Criteria 5: Stockholm Convention; Criteria 6: Rotterdam Convention; Criteria 7: Montreal Convention; Criteria 8: high incidence of adverse effects; and other HHP criteria.

## **7 Human health risk assessment**

### **7.1 Evaluation of human health effects – hazard and risk assessment**

A presentation on occupational hazard and risk assessment was made to the participants. It was highlighted that hazard assessment is based on intrinsic properties of the pesticide and irrespective of exposure rate. Risk assessment is based on the properties of the pesticide and the level and probability of exposure. Therefore, the evaluation of adverse effects on human health can be hazard-based or risk-based.

The outcome of the hazard assessment is based on international hazard classifications: i. WHO recommended classification of pesticide by hazard, ii. GHS, iii. FAO/WHO joint meeting on Pesticide Management- Highly Hazardous Pesticides.

### **7.2 Human health risk assessment in China**

The human health risk assessment in China was made to the participants. The basic principles of health risk assessment, hazard assessment, dietary risk assessment, operator risk assessment, and residential risk assessment on public health pesticide were described in details. ICAMA has built the China operator risk assessment model (COP-Risk) and residential risk assessment model on indoor use mosquito coil, vaporizing mat and liquid vaporizer (CML) for health risk assessment. The principles, methods and modules of health risk assessment were also presented.

## **8. Environmental risk assessment in China**

A presentation on environmental risk assessments in China was provided. The environmental risk assessments focus on aquatic ecosystems, birds, silkworm, honeybee, silkworm and groundwater. A new model named TOP-RICE model from ICAMA was introduced in detail. The TOP-RICE model is one of the high-tiered rice paddy models using assessment groundwater in south China. A case study of Flubendiamide was shown how to run TOP-RICE model and finish risk assessment using environmental fate and ecotoxicology data.

## **9. Case study**

### **9.1 Case study 1 – Registration by analogy – using a prepared “registration dossier”**

Participants were asked to compare a pesticide product in local situation and in reference country using Information Sources, then made a final decision follow analogy approach. A case study was given in the handout. The reference product’s label was examined from the Approved Label of Information Sources. Then participants looked over the information and filled in table using toolkit. There were six main parts in this table including basic information (country, applicant, and pesticide product) use, human health risks and environmental risks. Participants gave a sub conclusion at each part, made an overall conclusion finally. Compared product in local and reference country, the overall conclusions was that the registration by analogy was not sufficient. The products still required additional information such as risk mitigation.

Participants reviewed how to use analogy approach on registration through the exercise. The participants from Philippines and Cambodia expressed that registration by analogy was very useful for the pesticide products with limited resources. In conclusion, all participants agreed that the registration by analogy could save time and enhance efficiency on registration.

### **9.2 Case study 2 – Comprehensive human health review – using a prepared “registration dossier”**

Participants were asked to do a more comprehensive evaluation of a given product, which focused on the impact on occupational health. First, participants used the Hazard Identification and Characterization sub-topic in the Assessment Methods Tool to conduct a hazard assessment of the

product. Second, participants were invited to do a bridging evaluation, participants reviewed the reference risk assessment of the active ingredient of the product done by EFSA, and compared the operator risk assessment in the EFSA review with the use of this product in proposed uses given in the dossier. Third, participants were asked to do a local occupational risk assessment using China operator risk assessment module (COP-Risk).

### **9.3 Case study 3 – Partial environmental assessment**

Participants were invited to do an environmental evaluation of a product on the aquatic life. Participants installed the TOP-RICE model software followed instructor. Then environmental data was searched from the Toolkit. After data and factors were filled in the TOP-RICE model, participants ran the model. Then, a series of risk values were outputted after computation of the model. The participants became familiar with installation of the model, model factors, running model and output export of the model.

### **10. Feedback on the Toolkit**

The workshop participants conducted an evaluation of the Toolkit using a digital evaluation form. It was highlighted that the evaluation was aimed to improve the Toolkit, setup training and determine follow-up action. Most of the participants found that the Toolkit was very useful for them and would like to share the Toolkit with their colleagues. But some participants felt English version was quite difficult for them. Participants from different countries hoped that FAO and WHO could provide more training in the future.

### **11. Closure of the workshop**

Mr. Yan Duanxiang, Deputy Director of the Institute for the ICAMA of the People's Republic of China, gave a closing statement to the workshop. He expressed that China is a big country in pesticide production, use and export. The technical people of ICAMA had reviewed the pesticide products data referring to the guidelines from developed countries. However, the new regulation on the management of pesticide has been implemented on 1 June, 2017. The new version of regulation required more registration information compared the old one. The new regulation on the management of pesticide improves technical level of reviewer and independence research and development ability of enterprise in order to build a safe and green pesticide market. Moreover, China exports amount of pesticide to the Asian countries each year. But many illegal companies produce and sell counterfeit pesticide result in market disorder and economic losses of regular enterprises. Hence, China government is cracking down on illegal trade and reinforcing South-South Cooperation for building a friendly and formal pesticide market. He promised that China would like to assist exporter countries to verify the exporter pesticide products by providing corresponding ICAMA certificates. Finally, he appealed to Lao PDR, Philippines, Cambodia and Indonesia to cooperate with each other to keep the pesticide trade market healthy and orderly.

The FAO consultants expressed their appreciation to the host country and all the participants. Dr. Piao Yongfan stressed that the Toolkit training provided valuable and important knowledge on registration. He hoped participants share the approaches and experience from the training in order to improve pesticide registration level. In addition, the comments and suggestions of the Toolkit were welcome to contact with FAO. He also thanked Mr. Yan, Ms. Duan, Dr. Joost Vlaming, Mr. Gero Vaagt and staff from ICAMA for their valuable support.

**Timetable**

**Programme**

| <b>Topic</b>   | <b>Facilitators/Remarks</b>                |
|--|--|
| <i>Start of workshop: 09:00</i>  |  |
| <i>Lunch 12:00-13:30</i>   |  |
| <i>End of workshop: 17:00</i>  |  |
| <i>Registration: 08:00-09:00, 29 May, 2017 at Vanda Grand Hall at 2<sup>nd</sup> floor of Landmark Hotel</i>   |  |
| <i>Meeting room: Vanda Grand Hall</i>  |  |
| <i>Tea Break time: 10:30am, 15:30pm, everyday</i>  |  |
| <i>Welcome dinner: 18:00-20:30pm, 29 May, 2017 at Vanda Grand Hall at 2<sup>nd</sup> floor of Landmark Hotel</i>   |  |
| <b><i>Day 1</i></b>  |  |
| <b><i>Morning</i></b>  |  |
| Opening of the workshop  | ICAMA, FAO                                 |
| Introduction of participants and expectations  | FAO – Round table                          |
| Workshop introduction and objectives   | FAO – Presentation                         |
| Outcome of the survey on pesticide registration capacities<br>[On-line survey will be sent to all participants about 2 weeks in advance of the workshop] | FAO – Discussion                           |
| Introduction to the FAO Pesticide Registration Toolkit   | FAO – Presentation                         |
| <b><i>Afternoon</i></b>  |  |
| Feedback on participants' expectations   | FAO  |
| Toolkit – Decision Making module   | FAO – Presentation, card game, discussion  |
| Principles of health and environmental assessment for pesticide registration, as used in the Toolkit   | FAO – Presentation                         |
| <b><i>Day 2</i></b>  |  |
| <b><i>Morning</i></b>  |  |
| Toolkit – Data Requirements module   | FAO – Presentation, group work, discussion |
| Toolkit – Assessment Methods module  | FAO – Presentation, group work             |
| <b><i>Afternoon</i></b>  |  |
| Toolkit – Assessment Methods module  | FAO – Discussion                           |
| Toolkit – Mitigation Measures module   | FAO – Presentation, group work, discussion |
| <b><i>Day 3</i></b>  |  |
| <b><i>Morning</i></b>  |  |
| Highly Hazardous Pesticides – risk reduction process   | FAO – Presentation, discussion             |
| China's experience in regulating highly hazardous pesticides   | ICAMA – Presentation, discussion           |
| Highly Hazardous Pesticides – Identification   | FAO – Presentation, group work, discussion |
| <b><i>Afternoon</i></b>  |  |



| <b>Topic</b>   | <b>Facilitators/Remarks</b>                |
|--|--|
| Toolkit – Registration Strategies module   | FAO – Presentation, group work, discussion |
| <b>Day 4</b>   |  |
| <b>Morning</b>   |  |
| Toolkit – Information Sources module   | FAO – Presentation, group work, discussion |
| <b>Afternoon</b>   |  |
| Introduction to case studies   | FAO – Presentation                         |
| Case study 1 – Registration by analogy – using a prepared “registration dossier”           | Group work                                 |
| Case study 1 – Feedback  | Discussion                                 |
| <b>Day 5</b>   |  |
| <b>Morning</b>   |  |
| Evaluation of human health effects – hazard and risk assessment                            | FAO – Presentation, questions              |
| ICAMA – Human health risk assessment in China – selected procedures and models             | ICAMA – Presentation, questions            |
| Case study 2 – Comprehensive human health review – using a prepared “registration dossier” | Group work                                 |
| <b>Afternoon</b>   |  |
| Case study 2 – Continued   | Group work                                 |
| Case study 2 – Feedback  | Discussion                                 |
| <b>Day 6</b>   |  |
| <b>Morning</b>   |  |
| ICAMA – Environmental risk assessment in China – selected procedures and models            | ICAMA – Presentation, questions            |
| Case study 3 – Partial environmental assessment  | Group work                                 |
| Case study 3 – Feedback  | Discussion                                 |
| Feedback on the Toolkit and next steps   | On-line survey                             |
| <b>Afternoon</b>   |  |
| Results of the on-line survey, recommendations and next steps                              | Discussion                                 |
| Closure of the Workshop (15:00)  | ICAMA, FAO                                 |

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Activities during the Regional Workshop on Application of  
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