

Report of the Workshop on the FAO Pesticide Registration Toolkit

1-5 June 2015, Hanoi, Viet Nam

**Workshop on the FAO Pesticide Registration Toolkit
1-5 June 2015, Hanoi, Viet Nam**



Summary

The workshop on the FAO Pesticide Registration Toolkit was convened from 1 to 5 June 2015 in Hanoi, Viet Nam. Twenty-seven (27) experts from Malaysia, Myanmar, Nepal, Thailand and Viet Nam as well as FAO Headquarters and Regional Office for Asia and Pacific participated in the workshop.

FAO started developing a Pesticide Registration Toolkit to support pesticide regulators in countries with limited resources to go through the process of evaluating pesticide registration dossiers. The Toolkit will give guidance on which evaluations need to be done, how a registration authority – in the most straightforward way – can still produce meaningful results, and where relevant information can be found for registration by analogy as well as based on comprehensive evaluation.

During the workshop the FAO experts presented the Toolkit and help participants in using its tools. Participants exercised on each tool of Toolkit and provided their feedback based on their experiences.. At the end of the workshop, participants provided their overall comments. and recommendations which will be incorporated during further development of the Toolkit.

1. Opening

Dr Nguyen Xuan Hong, Director General of the Plant Protection Department (PPD), Ministry of Agriculture and Rural Development (MARD), welcomed the delegates from Malaysia, Myanmar, Nepal, Thailand and Viet Nam to the workshop. He expressed his appreciation to the FAO Regional Office for Asia and the Pacific (FAO RAP) as well as to the Asia and Pacific Plant Protection Commission (APPPC) for selecting Viet Nam as a hosting country and support in organizing this capacity building workshop. He noted that according to the recent estimate of FAO, farmers will have to produce 70% more food by 2050. However, agricultural intensification is facing many problems, especially with increasing use of pesticides. Pesticide registration is the first and important stage when a regulatory authority can influence the national pesticide market. Various regional projects have been conducted with the technical and financial support from FAO and other donor organizations in order to harmonize registration of both chemical- and bio-pesticides in South East Asia. Furthermore, FAO has designed a Pesticide Registration Toolkit to support pesticide regulation in countries with limited resources. Dr Nguyen Xuan Hong wished all participants a productive and successful workshop and a nice stay in Hanoi city.

Dr Yongfan Piao, Senior Plant Protection Officer of FAO and Executive Secretary of APPPC welcomed all participants on behalf of FAO. He noted that International Code of Conduct on Pesticide Management is widely recognized. Strengthening of use of the Code through harmonization of pesticide management, and in particular registration, is very important. A regional TCP project and other activities, such as a workshop in Nepal in January 2015 on the revised Code of Conduct, have been carried out. FAO, in collaboration with WHO, has developed many guidelines on pesticide management, and one of the significant new efforts is the Pesticide Registration Toolkit. He highlighted that five countries from the region were selected to participate in this pilot workshop and practice on new Toolkit and provide inputs for its further improvement. Dr Piao also thanked Dr Nguyen Xuan Hong, for his strong support to APPPC and wished a fruitful meeting to all participants.

2. Introduction, objectives, expectations, getting to know each other

2.1 Roles in pesticide registration

Participants introduced themselves and explained their roles in countries pesticide registration process. Thus, experts reviewing efficacy data that are routinely required to be submitted to support products that control pests of public health significance, toxicologists and ecotoxicologists who review potential for a substance to result in adverse effects to an organism after long-term exposure and carrying out residue studies on toxicity, solubility of pesticide residues, experts testing pesticides and biopesticide to determine the adverse effects, if any, of a chemical, compound, or effluent pre-market licensing of pesticides on the basis of data demonstrating no unreasonable adverse health or environmental effects when applied according to approved label directions, officers who developing requirements on safer use of pesticide in the country, issuing import permit for pesticide, heads of pesticide registration committees, regulating authorities are attended to the workshop. In total twenty-seven specialists from Malaysia, Myanmar, Nepal, Thailand and Viet Nam as well as expert from FAO were presented.

2.2 Resources for registration

Participants shared the information on number of staff involved in pesticide registration in their country.

Thus, in Malaysia 14 full time specialist, 15 administrative staff and 10 laboratory staff are involved in pesticide registration. The pesticide registration board is inter-ministerial and consists of 14 members. In Myanmar pesticide registration authority consists of nine persons, while the registration board consists of 10 members from various ministries. In Nepal 13 staff are involved in pesticide registration, for about 25% of their time. The registration board consists of 16 members and is inter-ministerial. In these three countries all pesticides are registered by one registration authority,

In Thailand the registration authority consists of 25 technical specialists, 15 laboratory staff and nine administrative staff, it only plant protection products, while other pesticides are authorized by the Ministry of Public Health. The registration board for plant protection products consists of 25 members, all from the Department of Agriculture. In Viet Nam 4 full time specialists and 3 administrative staff are conducting pesticide registration. In addition, a pesticide laboratory provides expertise on residues and pesticide quality. The authority only registers plant protection products. The registration board consists of 9 persons, all from the Ministry of Agriculture and Rural development.

2.3 Needs in terms of technical support

Participants shared the information on their needs. It was highlighted the lack of technical expertise in toxicology and chemistry. Human resource problems were identified as a common constraint for all participating countries. Some countries stressed their need for technical and analytical laboratories

3. Introduction to the Pesticide Registration Toolkit

History of the development of Pesticide Registration Toolkit (hereafter the Toolkit) was presented. It was highlighted that FAO is continuously developing different tools for pesticide management, but that countries requested FAO to develop guidance for pesticide registration that would be available more easily (e.g. though the internet). This concern was raised because existing published guidelines were not well used and registrars were not fully aware of them, or the guidelines were not sufficiently user-friendly and interactive. In response to this concern, FAO presented a first concept of the Pesticide Registration Toolkit at the FAO/WHO Joint Meeting on Pesticide Management (JMPM), which subsequently endorsed its development. In 2011-2012 a “mock-up” version of a web-based Toolkit was developed and later in 2013, FAO obtained the funding for the development of a fool-fledged Toolkit. Real development of the Toolkit started in 2014 under the coordination of FAO. The FAO HQ coordination unit invites experts on specific topics to provide advice on the type of information and guidance that should be included in the Toolkit.

It was explained that the objective of this workshop was to review of the drafted Toolkit modules and allowing the registrars and experts present to provide their comments and feedback.

The objectives of the toolkit were highlighted as making existing information relevant for the pesticide registrars available “at their fingertips” and provide 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, yet 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.

The Toolkit supports links to the pesticide-specific information, such as through registration databases where all information on specific pesticide can be found, restricted pesticides, specifications of the pesticide, hazard classifications, maximum residue limits and labels, if they are available.

It was explained that the development of Toolkit is ongoing and testing website (www.envistaweb.com/pret) is designed to be used during and after the workshop. Subsequently the Toolkit will move to the FAO website. The workshop aimed to allow early testing of the structure and content of the Toolkit by pesticide registration staff. Participants were informed that the Toolkit will be reviewed on a regular basis, and improvements will be made, especially with the input and feedback from pesticide registrars.

In response to the question whether this Toolkit will focus on chemical pesticides only, it was answered that currently the main focus is on chemical and biochemical pesticides, since many guidelines were developed specifically for this group of products. As new information and materials become available the Toolkit will widen its focus, guidance on microbial pesticides, for instance, will be included in the Toolkit after in 2015.

4. Registration approaches

The Registration Approaches Tool of the Toolkit was presented and explained to the participants. The objectives of the tool were defined as providing explanation of different pesticide registration approaches and guidance for selection of the most appropriate approach. The pesticide registration approach was defined as “*the strategy that registration authority applies to evaluate and authorize a pesticide*”. The approaches range from basic to comprehensive.

It was noted that registration approach may range from basic to comprehensive, depending on resources available. The approaches will differ in the evaluation methodology that can be applied, the complexity of evaluation of the pesticide and amount of data required to conduct the evaluation. Thus, for example, the resources may vary from minimal to ample, evaluation methodology from bridging all aspects, to bridging some aspects, to a full local evaluation. In regard to complexity it can vary from low to high, and the data requirements from few to many. It was noted that this tool provides a number of approaches and allows choosing the one which better fit specific country situation.

Two types of registration approaches were laid out, so far, in the Toolkit: *registration by analogy* and *registration based on complete evaluation*.

Registration by analogy is a basic registration approach which assumes limited comparison between a pesticide product submitted for authorization in a resource-limited country and a similar product registered in one or more reference countries. The advantages of this method are that less resources are required and it is less complex. However, this method is more uncertain. It was discussed that the registration by analogy is applied by many registration authorities around the world, but was never formalized.

Complete evaluation is a classic approach of pesticide registration which defines evaluation of all aspects of the pesticide registration dossier. It requires a broad range of local expertise as well as sufficient financial resources. Using this registration approach, different aspects can be evaluated at the different levels of the complexity.

Rationalization of the “complete evaluation” can be done by *bridging* when assessment conducted in one country is interpreted for the situation in another country. Another way is extrapolation of data from other countries e.g. residue and efficacy trials.

Participants discussed that in their countries the size of pesticide dossier (or amount of documents required) varies, from a few pages to the big binders, depending on the product which has to be authorized.

It was concluded that FAO strongly recommends that registration authorities work towards increasingly comprehensive evaluation of pesticide.

For the exercise, participants were divided into five groups to have a discussion on pesticide registration approaches. The objective was to explore how the pesticide registration approach applied in their countries compares to the approaches and options presented in Toolkit. The participants were invited to answer to number of questions.

Thus, with regard to the *current pesticide registration approach in the countries*, Myanmar and Nepal apply registration by analogy; Malaysia and Viet Nam apply both registrations by analogy and based on complete evaluation. And only Thailand has enough resources to apply registration based on complete evaluation.

The reasons why the specific approach was chosen were different. Thus, in Malaysia registration based on complete evaluation is applied for new active ingredients if there is no FAO/WHO specification. In Nepal and Myanmar registration by analogy is chosen because all pesticides are imported and due to a lack of resources.

In case of a new active ingredient or pesticide product for the country, all aspects will generally be evaluated.

The countries that conduct a complete evaluation shared their experience on how they rationalize the evaluations. Thus, Vietnam informed that new products have to go through the bio-efficacy trial in Viet Nam. Thailand informed that they do an extrapolation for the residue studies.

With regard to the constraints in the countries to use the registration approaches mentioned in Toolkit, all countries highlighted the lack of expertise to evaluate all pesticides, as well as insufficient facilities, financial resources, and technical knowhow. In addition, it was stressed that there is a language barrier for using extrapolation or bridging, as almost registration information is provide in national languages.

The discussion showed that participating countries are very diverse in terms of the registration approach chosen in their countries. Based on resources available countries use registration by analogy method and other countries use complete evaluation for pesticide registration. It was concluded that the approach should be chosen based on the realities and capacity of the country. Unanimously, participants agreed that additional information will be useful especially for the countries using analogy.

5. Registration process

The registration process tool was presented. that the pesticide registration process consists of many steps and actions, that are taken by both the applicant and the registration authority. Often the registration process is lengthy and complex. However, FAO recommends that registration process comprises at least four phases to ensure that application is handled effectively, evaluation is conducted in a standard way and decision is taken in transparent manner.

Each phase was described in detail. The first phase is *pre-application* which consists of two steps: pre-application meeting and issue of experimental permits. The second phase is *registration*, with 5 steps such as *submission of the dossier by the applicant*, for which it is important to clearly communicate what are the registration requirements. The next step in this phase is the *completeness check of the dossier*. It was highlighted that this step is more than just checking the data but includes the quality of the data; in many countries it is done by scientists. This step is followed by *dossier evaluation* which is the main step of the phase. The evaluation should be followed by a *registration decision*. It was stressed that at this step the registration authority has to confirm or reject the registration, considering all aspects (e.g. mitigation measure etc.). Once the decision is taken, the registration authority will have to inform all concerned parties. The registration *publication* may include the summary of evaluation.

Once two phases described above are passed, the *post registration* phase will start from *archiving*. The archiving needs to be done very carefully in order to be able to provide decision supporting documents, if any conflict situations occur. If the country is a Party to Rotterdam Convention and a pesticide was banned or severely restricted, a *notification to the Rotterdam Convention* should be sent. Another important step is *monitoring and evaluation*. It is important to have data on how a pesticide performs in the field and obtain feedback on use, problems and adverse effect of the pesticide. In cases when, after the registration of a pesticide, the registrant requests to introduce some changes, the registration authority have to review *extensions and changes*. This can lead to changes in application rates, crop, target pest, etc. Sometimes, when an applicant does not agree with the decision, he/she may appeal.

The last phase of the registration process is *review*. Review may be *periodic and unscheduled review*. This is the time when registration authority will reconsider the dossier and decide to issue or not a re-registration or extension. This may occur when new information becomes

available, e.g. that the pesticides is more dangerous to the environment than it was during the first registration. Review will result in *re-registration or cancellation*.

All these steps are quite universal but the level of details and effort for individual steps may be different. Furthermore, it was noted that increasingly, regulatory authorities will use dedicated administrative software to manage the registration process and that this software will vary from country to country.

During the exercise, participants reviewed how the registration process followed in their countries compared to the process presented in the Toolkit. In addition, participants were invited to provide the list of steps in their registration process which are not included in the Toolkit schema and identify which steps are not part of the registration process.

The results of the exercise showed that in Viet Nam registration process is similar to the one presented in Toolkit with some differences in the order of each step (e.g. experiment permit will be issued after the dossier evaluation and in case of extensions and changes). Thailand and Nepal follow to all steps in the Toolkit schema. Participants from Myanmar informed that there is no pre-application meeting in their registration process. It also was noted that the publication of the registration decision is only done on paper. Due to limited resources, monitoring after the registration of a pesticide is not done regularly. Finally, Malaysia informed that the registration process includes all steps from the Toolkit. However, a pre-application meeting is not mandatory and usually the registration of pesticide is valid for 5 years after which the company has to go through the registration process again. Therefore, not later than six months before the end of registration, the company has to provide a new application.

In conclusion, all participants agreed that that the registration process in their country depends on their capacity.

6. Data requirements

The objective of this specific tool of the Toolkit was presented. It was highlighted that this tool will be used during identification the data that are required for registration of pesticide and also provide information about associated testing guidelines. It was noted that data requirements are provided as defined in the FAO/WHO *Guidelines on data requirements for the registration of pesticides (2013)* and that this module is interactive version of these guidelines. The purpose of using this tool is checking whether all necessary data been obtained from the applicant, checking whether requested data waivers may be justified, whether internationally accepted testing methods have been used, as well as helping to define national data requirements for registration of a pesticide, if these do not exist or need to be updated.

It was highlighted that data requirements are not the same for every type of pesticide, but will depend on the pesticide group (e.g. a chemical or microbial product), the pesticide type (e.g. an insecticide, herbicide or rodenticide), the intended use (e.g. on field crops intended for human consumption, for public health, or in forestry), and the type of registration (e.g. a new product with a new active ingredient for the country, or an extension of an existing registration). These four parameters to identify data requirements are used for each pesticide.

For each data requirement, a summary is provided which includes objectives of the study, circumstances under which the study is required, test organism, test substance, typical endpoints of the study and internationally accepted testing guidelines, with direct links. 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.

It was asked what data are required for registration by analogy. In response, it was explained that currently this tool can be applied for complete evaluation. Subsequently, a new box will provide data requirements also for registration by analogy.

Participants asked a number of questions about the listed intended uses, e.g. the differences between greenhouse food use and indoor food use was questioned. It was recommended to have the definitions in the website either through adding them to the glossary or providing links to the relevant documents.

After the presentation, participants were invited to explore the tool and practice finding data requirements and testing guidelines.

Participants compared the requirements of their countries with the list from the Toolkit. The results of the exercise showed that all countries have similar lists of requirements with some differences. Thus, in Malaysia the registration authority requires toxicology data for the formulations in addition, it is required to provide data on purity. In Thailand, the registration authority does not ask for residue definitions.

During discussion, participants from Nepal indicated that it is important to have waiting period data in the list of the requirements as farmers may harvest immediately after the application of pesticides. Therefore, Nepalese experts suggested linking these requirements to the residue requirements.

In addition, participants from Malaysia informed that in their registration process pre-harvest intervals (PHI), and the acceptable daily intake (ADI) are required and recommended to include these in the residue requirements.

It was concluded that requirements will vary from country to country. and registration process will also differ in real practice depending on local conditions and cases (e.g. In Malaysia, sometime additional test are required if in preliminary data consist a reason for concern. In addition participants noticed that sometimes terminology for the same tests is different from country to country.

Principles of health and environmental assessment 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. It was emphasized that an important factor are the local circumstances of use; for example, farmers are instructed to use personal protective equipment, but its availability can be different in different countries.

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. For the registration of pesticides, risk assessment is generally more important, hazard assessment can be conducted too.

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 progressively more realistic cases. If in the worst case condition (i.e. worst exposure and worst toxicity) the risk is acceptable, it is not needed to carry out further assessment.

Participants however, noted that in some cases the existence of the unacceptable risk is not a reason for rejection of the pesticide. Scientific criteria can be different from the political decision what is acceptable for the environment or human health.

In response to the question whether industry submitted data are reliable or not it was noted that there are many ways to check information (e.g. ask the laboratory which made an assessment or use international databases i.e. on carcinogenicity, toxicity etc.)

In response to the question whether effects on human health in some countries (even with less amount of pesticide use) bigger only due to the lack of knowledge it was explained that less effect on human health can only be achieved through the regular and strict monitoring, enhancement of knowledge, proper application and handling.

In conclusion the workshop, participants discussed advantages and disadvantages of local assessment and bridging. It was explained that in principle, the risk assessment of the locally proposed uses of the pesticide should be assessed. However there is a possibility for bridging (extrapolation) from an existing risk assessment conducted in another country or region to the situation under review.

7. Assessment methods

This tool provides methods for the evaluation of the various aspects of the pesticide registration dossier.

The level of complexity of assessment methods can vary from relatively simple to more complex, with less complex methods often also being less precise. Usually more complex methods are more locally specific.

The Toolkit allows to select assessment methods depending on pesticide group, main topic and subtopic. It was noted that currently the Toolkit focused on chemical pesticides.

Assessment methods are presented for different resource levels. For example, at medium level of resources, bridging of an existing residue assessment may be recommended rather than conducting a full local residue assessment. Each of the methods in the Toolkit will have a summary that describes the principles of the method and type of data needed, the actual description of the assessment as well as interpretation of the outcome. In addition the tool

provides a table summarizing the results of the assessment and external links, spreadsheet calculators, simulation models, etc.

8. Mitigation measures

The objective of this tool is to list of various measures for mitigation of human health risks and environmental risks. This 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 (e.g. farmers), and preferably not compromise pesticide product efficacy. Therefore, expected reduction of risk should outweigh the cost of the measure.

Furthermore, it should be possible to communicate the measure to the user in a relatively easy and effective manner and it should have a reasonable possibility of enforcement. Effective application of mitigation measures also depends on the literacy level of farmers/users.

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

9. Decision making

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. These are the priorities set with regard to the human or environment (e.g. protection of workers, biodiversity, ecosystems to protect, etc.)

It was highlighted that FAO recommends that regulators look at the alternatives of the existing pesticides (e.g. consider not to register a highly toxic pesticide if another pesticide is already registered with lower toxicity).

Participants discussed that in case different pesticides for the same use are existing in the market, the regulator should inform farmers about this.

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.

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.

Efficacy of a pesticide can be expressed either as “control” or “reduction” of a pest. Thus, sometimes pesticide applied in IPM system may provide only 70% efficacy, but within the overall IPM programme it is appropriate. Therefore, strictly requiring 90% efficacy for pesticides can stop development of IPM.

Another important outcome of the efficacy assessments is a Good Agricultural Practice table (GAP table). It was stressed that GAP recommendations should result in acceptable effectiveness, minimize phytotoxicity and adverse effect on rotational and adjacent crops.

Participants discussed that sometimes a company may ask for the registration of one pesticide for four different crops, yet the assessment results show that it has an acceptable risk only for one crop. A registrar may register the pesticide for that one crop, alternatively it may not register such a pesticide if practice has shown that in local conditions farmers would not distinguish between crops and will apply the pesticide on the whole farm and probably at the highest doses.

In addition, participants discussed that control of inappropriate pesticide (tank) mixtures, if not authorized by the registration, should be the responsibility of extension officers when advising the farmers. Participants from Nepal informed that in order to discourage registration of highly hazardous pesticides (HHPs) the registration authority is demanding more data for registration, in contrast to bioproducts for which less data may be needed. Another way of promoting less toxic pesticide was shown by Malaysia where companies have to pay a higher registration fee for more hazardous pesticides.

With regards to the cost and benefits of pesticides, participants learnt that pesticides have two types of cost: private and public, the latter associated with residues, contaminated water etc. Often it is argued that pesticide private cost has to be less as farmers need to produce more products. However it may be that the pesticide is more hazardous and therefore the public cost can be very high. Therefore, it is important for the registration authority not being misled by low private costs.

During the exercise participants were invited to review a decision making tool.

Diverse results were obtained with regard to the human health assessment. Thus, Malaysia explained that even pesticide that did not show enough efficacy, could be registered in case if there is no alternative in country to be used for at least reduction of pest population or as a part of IPM.

In Nepal, human health impact is checked through the review of journals and international information. In Viet Nam, the registration decision usually is made based on acute toxicity and GHS classification. Thailand's decision making is based on WHO classification of acute toxicity, among others.

Participants also discussed environmental assessments. Thus, in Thailand the import and use of endosulfan was stopped due to environmental concern. In Viet Nam, if farmers inform that some product has an effect on fish, the registration board will revise the registration. However, none of the countries uses environmental models to evaluate environmental risk.

Relating to the sustainability assessment, Malaysia informed that the main focus is on effect on natural enemies, development of pest resistance, adverse effect etc. Therefore, companies are obliged to submit these data.

In regard to the cost-benefit assessment, in Malaysia it is required to provide data on yield as part of the experiment trials. In Nepal, usually farmers do not apply expensive pesticides. However, for registration purposes, a comparison of the yield is made.

Participants discussed that the export value of product can also be included in the cost- benefit assessment, if relevant.

As additional assessments for decision making, Malaysia, Myanmar and Thailand listed pesticide product specification review, quality control of pesticide, active ingredient against FAO/WHO specifications and any other additional analysis, if it was requested by the technical committee or registration board.

In conclusion, participants were informed that new data will be added for evaluation of microbial chemicals and botanical pesticides. It was stressed that registration authority has to decide what type of information will be required for registration of bioproducts depending on their capacity and knowledge. For example, many mineral oils are considered as a low risk products and may pass through a fast track registration process.

10. Information sources

The information sources menu was explained in detail. This part of the Toolkit provides links to pesticide specific information sources. In addition, this tool contains an address book of the National Registration Authorities (NRA) and their contact as well as contact lists of major organization, conventions. One of the most important elements is registration and reviews page of the tool. Several sections provide option for checking for registration elsewhere; for scientific reviews and approved labels. This tool also has a restrictions and bans page and hazard classifications, such as the globally harmonized system of classification and labelling of chemicals (GHS). Other international information sources are the Codex Alimentarius, the Global MRL (Maximum residue limits) database and various pesticide properties databases. In addition, internationally harmonized terms and definitions can be found in the glossary, with relevant parts of contextual background articles.

11. Introduction to case studies

Prior to the case studies, a presentation on human health effect hazard and risk assessment was provided.

Currently most appropriate hazard classification to be used in the Toolkit are *WHO recommended classification of pesticides by hazard, the Globally harmonized system of classification and labelling of chemicals, and FAO/WHO Joint Meeting on Pesticide Management – Highly Hazardous pesticides.*

Each international hazard classification system was explained in detail. Thus, *WHO recommended classification of pesticides by hazard & Guidelines to classification 2009* provides classification mainly based on acute oral and dermal toxicity. It was noted that WHO recommendation classification classifies individual pesticides (only active ingredient). This should be taken into account during the evaluation and registration process of the pesticide product.

The Globally harmonized system for the classification and labelling of chemicals (GHS) was developed for all chemicals, not just for pesticides. GHS is increasingly required for labelling of chemicals in international and domestic trade. In many countries GHS is replacing the WHO classification and other labelling guidelines for the purpose of harmonization. The GHS health classification is based on broad range of health aspects such as acute toxicity, skin

corrosion, serious eye damage etc. Meanwhile, for each health aspect there are classification criteria, hazard symbol, signal word and hazard statement. It was highlighted that the pesticide active ingredients are not individually classified by GHS and this has to be done by registrars.

With regard to the FAO/WHO JMPM it was noted that this system considers highly hazardous pesticides (HHPs). These include pesticides classified as WHO class 1a and 1b, or GHS categories 1A and 1B for carcinogenicity, mutagenicity and reproduction toxicity. In addition, pesticides which are covered by Stockholm Convention in its Annex "A" and Annex "B" and those meeting all criteria in paragraph 1 of Annex "D", or listed by the Rotterdam Convention in its Annex III or included in Montreal Protocol, or are pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse on human health or environment, are considered HHPs. It was stressed that the last criteria is country and use specific and directly depends on the capacity of the county, knowledge based and local circumstances.

Participants also were informed about various hazard-based decision criteria which are being used either to refuse or restrict the use of pesticide. It was noted that with respect to HHPs, the registration authority may use the International Code of Conduct (article 7.5). Examples of using restrictions depending on the hazard class of pesticide were demonstrated and explained to participants.

Participants also learnt that risk assessment can have different focus such as occupational risk, dietary risk and/or general population risk etc.

The occupational risk was considered in detail and includes operator risk assessment, and worker risk assessment. It was noted that operator risk assessment evaluates whether the pesticide does not pose an unacceptable risk to operators when handled and applied as authorized and under local conditions of use.

The method for determining an acceptable operator exposure level (AOEL) was discussed and predicting exposure for the operators as well as for the workers was demonstrated. The sources that can be used to obtain these data are included in the Toolkit. In the same manner, various sources are included in the Toolkit for calculation of predicted exposure. For initial risk assessment, estimating exposure using a model was recommended, noting that models may differ with respect to the exposure scenarios (e.g. protection factors by PPE, no PPE, dermal absorption and body weight).

In a similar manner, a consumer risk assessment can be done. It was explained that consumer exposure models take into account toxicological reference values. For chronic intake, the ADI (acceptable daily intake) is derived from chronic studies (such as carcinogenicity, reproduction toxicity etc.) and a safety factor. Sources of ADIs are the registration dossier or international sources such as Codex Alimentarius standards.

Predicted chronic dietary intake of the pesticide residue from all food (and water) sources can be calculated, ideally based on national food basket studies. However if such data is not available, the Global Environmental Monitoring System (GEMS) regional cluster diets can be used.

Furthermore, the principles of bridging risk assessments were explained. They include a comparison of the toxicology and exposure between two situations, leading to a conclusion whether the risk in the local situation is similar, lower or higher, than in the reference situation.

12. Case study 1 – Registration by analogy (using a prepared “registration dossier”)

During this practical exercise participants were asked to make a decision on registration of a pesticide using the registration by analogy approach, where a limited comparison is made between a pesticide product submitted for authorization in a resource-limited country and a similar product in one or more reference countries. The registration authority makes a decision to register a pesticide which has already been authorized for use in a reference country, if it judges its efficacy and risk are also likely to be acceptable in its own country. Participants were provided with guidance for completion of the exercise.

Unanimously, it was agreed that the exercise on registration by analogy and forms and tables used were very useful for the countries with limited resources.

13. Case study 2 – Complete review (using a prepared “registration dossier”)

Complete evaluation requires that a registration authority has access to a broad range of local expertise as well as sufficient financial resources.

In practice, in a comprehensive evaluation, certain aspects of the pesticide will be evaluated using more complex methods and/or using local data, while for other aspects methods requiring fewer resources will be used. What methods are chosen depends on priorities of the country, the type of pesticide being evaluated, and its intended use.

It was stressed that registration based on complete evaluation is the recommended approach in the Toolkit.

The participants were invited to review a case study concerning a more comprehensive evaluation of a pesticide. It was focused on the impact on human health.

14. Feedback on the Toolkit

Workshop participants conducted an evaluation of the Toolkit and the workshop through a digital evaluation form. It was highlighted that the evaluation was aimed to improve the Toolkit, the training setup and to determine follow-up action.

With regard to the usefulness of each tool in Toolkit, participants identified *Information Sources*, *Data Requirements*, *Registration by Analogy and Assessment Methods* as most useful and *Registration process* and *Registration approaches (full procedure)* as less useful. This was because the *Registration process* as well as the *Registration approaches (full procedure)* are well established in the countries.

Tools most likely to be used by registrars were the *Mitigation measures*, *Decision making* and *Registration approaches (full procedure)*.

With regard to the training, participating countries highlighted the need for national workshops as well as general regional training about the Toolkit. Participants also indicated the necessity of training on specific tools of the Toolkit such as *Registration process*, *Data requirements*, *Efficacy assessment*, *Hazard evaluation*, *Risk assessment with models*.

Problems with internet connections and the lack of training of staff were identified as two main factors that would prevent effective use of the Toolkit.

The quality of the presentations, exercises and handouts was highly appreciated.

All recommendations for the Toolkit were noted and FAO indicated they would be taken into account during further development of the tools. FAO also informed participants that it is planning to organize national workshops by including them into ongoing projects on pesticide management. At the same time countries were invited to prepare national capacity building plans (e.g. national committee/registration board, training for trainers etc.). The need for an e-learning tool was noted. One of the suggestions was to create a Frequently Asked Questions (FAQ) page. In addition a “Feedback” button will be available to facilitate the submission of comments and suggestions on each page of the Toolkit.

14.1 Missing elements, difficulties, further needs, etc.

In the evaluation form participants also determined number of subjects that would be useful to include in the Toolkit. The list of missing elements identified as follows:

- Eco-toxicological assessments procedure
- Statistical methods for assessments of specification-determination of equivalence
- Protocols of internationally accepted methods for analysis of physico-chemical properties
- Analogy process of bio-control agents
- Registration of microbial and botanical pesticides
- Efficacy data requirements and more details on efficacy trials

In response to the request to include *data requirements for residues* and *pesticide poisoning symptoms* it was noted that these modules are prepared and will be uploaded into the Toolkit website shortly.

In addition it was recommended to develop a *quality analysis* module as it is very important to compare the quality of imported pesticide with the same pesticide in different country. In response, it was explained that FAO have developed a separate guideline on quality control so probably Toolkit will be explicitly refer to that guideline.

14.2 Follow up

Follow up actions were divided into short term and long term. Thus, in regard to the content to be added in the short term *efficacy assessment*, *environmental assessment* as well as *pollinators and natural enemies assessment* will be added shortly. Participants also were asked to take part in an evaluation survey in 3 months’ time to obtain feedback on the use of toolkit.

In addition participants will be informed as soon as possible on planning for country specific training by 2016.

FAO also will explore the possibility of producing hard copy training materials like it was done for the Rotterdam Convention and upload training materials used during the workshop. In addition a short explanation on the overall outline of the Toolkit could be uploaded to the website together with selected worked examples. However, it was stressed that the Toolkit only provides basic assistance for the pesticide registration authority and for more specific training each country will need to explore other resources.

It was concluded that all comments that were raised by the workshop, participants would be taken into account and incorporated into the Toolkit.

15. Closing workshop

The FAO consultants expressed their appreciation to the hosting country and all participants. Dr Piao stressed that this extensive training provided valuable and important knowledge on using the new Toolkit. However, he reminded participants that it is a decision making support tool which does not replace evaluation and decision making by national registrars. It was also noted that the APPPC region is the first where this Toolkit was tested and participants provided their valuable input to further improve the Toolkit. As it is pilot workshop, FAO could not invite all countries from the region, yet 4-5 participants from each selected country could collaborate during the exercises. He also thanked Mr. Harold van der Valk and Mr. Joost Vlaming, FAO consultants, as well as Mr. Harry van der Wulp, FAO Senior Policy Officer for their valuable support. Finally, he thanked the director of PPD for hosting the meeting.

Programme

Day 1

Introduction, objectives, expectations, getting to know each other

Questions:

- ❖ What are your roles in pesticide registration
- ❖ What are your resources for registration?
- ❖ What do you need in terms of technical support?
- Introduction to the Pesticide Registration Toolkit [presentation]
- Registration approaches [presentation, exercise, discussion]
- Registration process [presentation, exercise, discussion]

Day 2

- Data requirements [presentation, exercise, discussion]
- Assessment methods [presentation, exercise, discussion]
- Mitigation measures [presentation, exercise, discussion]

Day 3

- Decision making [*presentation, exercise, discussion*]
- Introduction to case studies [*presentation*]
- Case study 1 – Registration by analogy (using a prepared “registration dossier”)
[*exercise, presentations, discussion*]

Day 4

- Case study 2 – Complete review (using a prepared “registration dossier”)
[*exercise, presentations, discussion*]

Day 5 (½ day)

- Case study 2 – Complete review continued
- Feedback on the Toolkit [discussion]
- Missing elements, difficulties, further needs, etc.
- Follow up
- Closing of workshop

List of Participants

Malaysia

1. Ms Hartini binti Yusuf
Agricultural Officer
(Registration Unit)
Pesticide Control Division
Department of Agriculture, Jln Sultan Salahuddin
Kuala Lumpur 50632, Malaysia
Tel: 6011 11551121
Email: hartini@doa.gov.my; hartini_yusuf@yahoo.com

2. Mr. Baharuddin Basri
Toxicologist
(Toxicology/Ecotoxicology Unit)
Pesticide Control Division
Department of Agriculture, Jln Sultan Salahuddin
Kuala Lumpur 50632, Malaysia
Tel: +6019 2188491
Email: baharuddinb@doa.gov.my

3. Ms Rohaya binti Mat Nor
Agricultural Officer
(Bio-efficacy Unit)
Pesticide Control Division
Department of Agriculture, Jln Sultan Salahuddin
Kuala Lumpur 50632, Malaysia
Tel: 6019 3947668
Email: rohaya@doa.gov.my

4. Ms Nur Amina Joyce Abdullah
Formulation Chemist
(Formulation Unit)
Pesticide Control Division
Department of Agriculture, Jln Sultan Salahuddin
Kuala Lumpur 50632, Malaysia
Tel: 011 26226608
Email: amina@doa.gov.my; mayaumaew@yahoo.com

Myanmar

1. Ms. Seng Raw
Staff Officer
Department of Agriculture

Ministry of Agriculture and Irrigation

2. Ms. Aye Kyawt Kyawt Ei
Staff Officer
Department of Agriculture
Ministry of Agriculture and Irrigation

3. Ms. Pyone Pyone Aye
Junior Research Assistant
Department of Agricultural Research
Ministry of Agriculture and Irrigation

4. Ms. Nilar Myint
Research Technician
Department of Agricultural Research
Ministry of Agriculture and Irrigation

Nepal

1. Yubak Dhoj G. C., PhD
Director General
Department of Agriculture
Ministry of Agricultural Development
Government of Nepal
Harihar Bhawan, Lalitpur District
Nepal
Tel: ++ 977 (01) 5521323
Cell: ++ 977 98511 28 129, 9841 097 986
Fax: ++ 977(01) 5524093
Email: yubakgc@yahoo.com

2. Dr. Dilli Ram Sharma
Program Director/ Coordinator of National IPM Program
Plant Protection Directorate
Department of Agriculture
Ministry of Agriculture Development
Kathmandu, Nepal
Email: sharmadilli@yahoo.com

3. Mr. Kaman Singh Thapa
Pesticide Register
Pesticide Registration and Management Section
Plant Protection Directorate
Department of Agriculture
Ministry of Agriculture Development
Kathmandu, Nepal
Email: thapa.kamansingh@gmail.com

4. Mr Manoj Pokhrel
Plant Protection Officer

Report of the Workshop on the FAO Pesticide Registration Toolkit 1-5 June 2015, Hanoi,
Viet Nam

Pesticide Registration and Management Section
Plant Protection Directorate
Department of Agriculture
Ministry of Agriculture Development
Kathmandu, Nepal.
Email: manojpkrl@gmail.com

Thailand

1. Ms. Jintana Poomongkutchai
Senior Science Research Specialist
Agricultural Production Sciences Research and Development Division
Department of Agriculture (DOA)
Ministry of Agriculture and Cooperatives (MOAC)
50 Phaholyothin Road, Ladyao, Chatuchak, Bangkok 10900
Thailand
Tel: 02-579 3577 Fax: 02-940 6875
Email : kunjintana@yahoo.com

2. Ms. Wipada Plodkornburee
Senior Entomologist
Plant Protection Research and Development Office
Department of Agriculture (DOA)
Ministry of Agriculture and Cooperatives (MOAC)
50 Phaholyothin Road, Ladyao, Chatuchak, Bangkok 10900
Thailand
Tel : 02-579 5583 Fax: 02-940 5396
Email : pomag26@gmail.com

3. Ms. Utchalee Namvong
Senior Agricultural Research Scientist
Agricultural Regulatory Office
Department of Agriculture (DOA)
Ministry of Agriculture and Cooperatives (MOAC)
50 Phaholyothin Road, Ladyao, Chatuchak, Bangkok 10900
Thailand
Tel : 02-579 7986 Fax: 02-579 7990
Email : utt_utchalee@hotmail.com

Viet Nam

1. Mr. Huynh Tan Dat
Chief of Pesticide Management Division
Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: datht.bvtv@mard.gov.vn

2. Ms. Phan Thanh Hang
Vice chief of Pesticide Management Division

Report of the Workshop on the FAO Pesticide Registration Toolkit 1-5 June 2015, Hanoi, Viet Nam

Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: hangpt.bvtv@mard.gov.vn

3. Mr. Ngo Xuan Khu
Officer of Pesticide Management Division
Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: khunx.bvtv@mard.gov.vn

4. Ms. Luong Hai Yen
Officer of Pesticide Management Division
Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: yenlth.bvtv@mard.gov.vn

5. Mr. Nguyen Trung Tin
Officer of Pesticide Management Division
Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: tinnt.bvtv@mard.gov.vn

6. Ms. Tran Phuong Hoa
Officer of Pesticide Management Division
Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: hoattp.bvtv@mard.gov.vn

7. Ms. Bui Thanh Huong
Officer of Pesticide Management Division
Plant Protection Department
149 Ho Duc Di - Dongda – Hanoi
Vietnam
Email: huongbt.bvtv@mard.gov.vn

FAO

1. Mr. Harry van der Wulp
Senior Policy Officer
AGPM
Food and Agriculture Organization of the United Nations (FAO/UN)
Viale delle Terme di Caracalla, 00100, Rome, Italy
Email: Harry.vanderWulp@fao.org

Report of the Workshop on the FAO Pesticide Registration Toolkit 1-5 June 2015, Hanoi,
Viet Nam

2.Mr. Piao Yongfan
Senior Plant Protection Officer
Food and Agriculture Organization of the United Nations (FAO/UN)
39, Maliwan Mansion, Pra Atit Road, Banglumpoo
Bangkok 10200, Thailand
Tel: 66 2 697 4268
Email: Yongfan.Piao@fao.org

3. Mr. Artur Shamilov
Junior Professional Officer
Food and Agriculture Organization of the United Nations (FAO/UN)
39, Maliwan Mansion, Pra Atit Road, Banglumpoo
Bangkok 10200, Thailand
Tel: 66 2 697 4344
Email: Artur.Shamilov@fao.org

Consultants

1.Mr. Harold van der Valk
FalConsult
Vissersdijk 14
4251ED Werkendam
The Netherlands
+31 183 500410
Email: harold.vdvalk@gmail.com

2.Mr. Joost Vlaming
Envista Consultancy
Aalsmeerhof 27
6843 VV Arnhem
The Netherlands
+31 6 45434440
Email: joost@envista.nl