



Food and Agriculture
Organization of the
United Nations

Report of the APPPC Training Workshop on Pesticide Quality Control

25 -28 June 2018, Beijing, China

Executive Summary

Pesticide quality control is one of the most important requirements for the registration and market inspection. Various efforts from countries were made to establish a series of national standards for quality of pesticide products to reduce potential risks to human, animal health and the environment.

In order to improve the country capacity in pesticide quality control as well as enhance regional collaboration in risk reduction, Asia and Pacific Plant Protection Commission (APPPC) decided to organize a regional training workshop on pesticide quality management as one of action plan of APPPC Standing Committee on Pesticide Management, and it was adopted by the 30th Session of APPPC on November 2017. The workshop was convened from 25-28 June 2018, in Beijing, which was jointly sponsored by APPPC and China. The Institute of Control of Agrochemicals, Ministry of Agriculture and Rural Affairs (ICAMARA) facilitated a number of specific sessions with extensive inputs from Chinese experts of pesticide regulatory management. The workshop was supported by Chinese technical assistance programme-pesticide regulatory management for neighboring countries along the “Belt & Road” by providing funding support to several participants and sharing training contexts with other participants who attended the regional workshop. As a result more than 20 participants from Bangladesh, Cambodia, China, Laos, Myanmar, Pakistan, Philippines, Sri Lanka, Thailand and Viet Nam participated in the workshop. During the workshop 9 experts from China kindly shared their experiences and technical knowledge in various sections with participating countries.

The workshop, addressed broad knowledge and operational skills associated with pesticide quality control and regulatory management in line with the code of conduct, which would help participants to improve the capacity in pesticide quality control and regulatory management as well. The training included FAO/WHO specifications for pesticides, risk reduction and phasing out HHPs, import and export management, quality control context, storage stability test, physical/chemical properties detection, etc. Batch analysis of pesticide technical concentrates highlighted important value in quantitative detection of impurity, which is the determination for the content of the active constituent and each impurity present at a concentration of 0.1% or more using specific methods as well as content of relevant impurities. Meanwhile, the lab exercise enabled participants an operational experience in the process of lab analysis at a GLP lab, which has been fully equipped with comprehensive procedures and been certified by OECD. Participants shared lessons and experience in pesticide quality control and pesticide management through country report on status in the areas.

Collaboration in quality control in the region

The workshop provided an opportunity to exchange the updated status of pesticide quality control and market inspection in participating countries. It enabled the participants to better understand progressive developments, existing gaps and constraints. It was observed that there is a lack of specified inspection regulations for pesticide quality control in some countries and some regulations are not updated timely. The country capacities in management of quality control are dynamic. Data requirements and market inspection are diverse from country to country. Meanwhile the workshop discussed a way forward toward to potential action plan of collaboration in quality control through collaboration, resources and information sharing, which will enhance their ability of pesticide quality control and market inspection management schemes to make them more effective, efficient and transparent. It is hoped that enhancement of capacity in detection may contribute to the improvement of quality control in participating countries in the region.

The workshop built up a potential collaborative regional network on communication and collaboration in regulatory management especially in terms of pesticide quality control, import/export management, and sharing risk analysis and registration dossier, etc. as well the phasing out HHPs.



Report

1. Opening ceremony

Dr. Yongfan Piao, Senior Plant Protection Officer of FAO and Executive Secretary of APPPC welcomed all participants on behalf of FAO. He introduced the Chinese counterparts who attended the opening session of the workshop on behalf of the Ministry of Agriculture and Rural Affairs (MARA), and participants from countries were invited to make a brief self-introduction. Dr. Piao highlighted the importance of pesticide quality control in the context of pesticide regulatory management in line with the Code of Conduct on Pesticide Management. He stressed that the training workshop on pesticide quality control was an opportunity for Asia and Pacific countries and countries especially along the “Belt & Road” to share experiences with Chinese counterparts and jointly build up capacity of pesticide registration and evaluation. Dr. Piao thanked the MARA and ICAMA of China, for the kind support and strong commitment to APPPC of FAO for continual supports and wished the participants a fruitful meeting.

Mr. Ouyang Shachen, the representative of International Cooperation Department of the MARA warmly welcomed delegates from the countries along the Belt and Road. In order to facilitate enhanced international cooperation, communication and connection across the Belt and Road Region, the MARA of China has been positively exploring the long-term mechanism of cooperation among countries as well as development of partnerships with various counterparts for collaboration in the development. China has hosted pesticide management techniques training programmes for several times in collaboration with the APPPC, FAO. The "Implementing Plan for China-FAO South-South Cooperation Trust Fund (2nd phase)" includes a “Pesticide Programme” and the major objective of which aims at promote capacity of countries in pesticide risk reduction through the coordination on pesticide registration, management policies and regulations across the Asia Pacific Region, which may contribute to the food security in the region. He wished all participants from overseas could gain knowledge and enhance friendship.

Mr. Li Jianwei, Director of Pesticide Division, Plant Production Department of the MARA welcomed all participants from member countries of APPPC. He briefed participants with four measures taken by China with purpose of strengthening the pesticide management: (1) increase of the requirements for pesticide registration; (2) restriction of highly hazardous pesticide for registration, application and retails, only limited number of retailers authorized may retail the high risk and toxic pesticides; (3) reduction of the chemical pesticides applied at the field to avoid the contamination to the environments, and encouraged to use alternative methods for pest management; (4) strengthening the market inspection and quality detection. China wish to help other countries to improve pesticide detection infrastructure as well as capacity development in pesticide risk analysis through technical assistance, sharing lessons and experience in establishment of the mechanisms and procedures of registration and review.

Mr. Zhou Puguo, Director General of the ICAMA welcomed representatives to the workshop. He expressed his appreciation to APPPC for selecting China as a host country and support in organizing this workshop. China is a big country in terms of the scale of its farming sector and the production, use and export of pesticide products. With the assistance from FAO/APPPC and other international organizations and the participation of countries in Asia and the Pacific region, China could constantly improve its pesticide quality control management and establish the guidelines and MRLs to support food safety, as the chair country of CCPR. He said China had paid more

attention to the innovation, green, and safety, and the pesticide quality control technology is increasing obviously. He believed this workshop was a valuable opportunity for study and exchange; and he hoped that, with the guidance from FAO/APPPC, member countries could learn from each other, reinforce each other, and make efforts for the coordinated and consistent development of pesticide quality control management in Asia and the Pacific region.



2. Pesticide quality control

2.1 FAO/WHO specifications for technical grade active ingredients

Professor Chen Tiechun gave an introduction on FAO/WHO specifications for pesticides. A pesticide specification includes criteria for properties in some or all of the following categories: description of the product, active ingredient identity and content, relevant impurities, physical properties, and storage stability. Test methods should be straightforward, robust, widely accepted, and well validated. Well-trained technicians and a properly equipped laboratory are required for reliable results. FAO and WHO specifications are international points of reference for quality of agricultural pesticides (FAO) and public health pesticides (WHO). Technical grade pesticides are relatively pure active ingredients, used to prepare formulations. TC is technical material and TK is technical concentrate. TC is usually ≥ 900 g/kg active ingredient, with solvent(s) removed during synthesis and no solvent added subsequently. TK contains < 900 g/kg active ingredient and may contain solvents or diluents. TC specification has only a lower limit for active ingredient content; TK specification has upper and lower limits; Increasing the purity of a TC does not increase its hazard significantly and may rather decrease it; higher content of active ingredient in TK may increase hazard. Information to support specification for technical grade active ingredient include active ingredient identity, manufacturing route, materials and conditions, 5-batch analytical data and manufacturing limits, methods of analysis, physico-chemical characteristics of pure and technical grade active ingredient, guidelines including sub-methods for determination of physico-chemical characteristics, and full toxicology and eco-toxicology data package.

2.2 FAO/WHO specifications for formulated pesticides

Prof. Li Guoping introduced the manual on development and use of FAO and WHO specifications for pesticides which is considered as a bible for development FAO/WHO pesticide specifications.

Professor Li gave an introduction on the structure and aims of specifications for formulated products; data requirements for developing specifications for formulated products; the new formulations and new test methods. The material shall consist of a homogeneous mixture of technical happyfos, complying with the requirements of FAO specification 999/TC (December 2007), together with carriers and any other necessary formulates. It shall be in the form of granules for application after disintegration and dispersion in water. The product shall be dry, free-flowing and free from visible extraneous matter and hard lumps.

2.3 Pesticide risk reduction and phasing out highly hazardous pesticides

In order to promote the development of pesticide risk reduction, Dr Lin Ronghua introduced ICAMARA had set a department named Re-evaluation Division (RED) in charge of drawing up the policies and regulations for the registered pesticide and phasing out highly hazardous pesticides in China. Here, Dr Lin introduced the background about pesticide risk reduction including the situation of experiences from other countries and industries, the relevant law and regulations and so on. Furthermore, what China did before and after the RED establishment was shown. Finally what plan and challenge for registered pesticide management of China in future were discussed. The pesticide life cycle management system was established in China, which encompassed pesticide registration, manufacture, marketing, application and re-evaluation. MARA is in charge of pesticide registration management. ICAMARA was responsible for the detailed technical evaluation for pesticide registration.

In terms of the data requirement for pesticide registration, the applicant should submit those chemistry, toxicity, efficacy, residue and environmental effect data and other relevant information. The data should be generated by these laboratories certificated by MARA or is mutually accepted by GLP data. The pesticide registration application goes through data completeness check, technical evaluation, pesticide registration committee review, public comments to confirm the quality, effectiveness and safety of pesticide product and then approved by the MARA. The risk assessment methodology is applied within the pesticide registration evaluation gradually in recent years. Total of 38,315 pesticide products were registered in China till now, which related to 661 active ingredients. There are 2,232 pesticide manufacturers, which including 2,127 of domestic manufacturers and 105 of overseas manufacturers.

2.4 Pesticide import and export management in China

Dr Wu Houbin introduced the pesticide import and export management in China. The Chinese government pays great attention to the management of pesticides, especially the management of imported and exported pesticides. Chinese regulatory enforcement for import and export control of pesticide relies on three Laws, three Regulations, two international Treaties, three Measures and two mediums. Three Laws are Customs Law; Foreign Trade Law; Law on Import and Export Commodity Inspection. Three Regulations are Regulation on the Administration of the Import and Export of Goods, Regulations for the Implementation of the Law on Import and Export Commodity Inspection, Regulation on Pesticide Administration. Two international Treaties are Rotterdam Convention and Stockholm Convention; Three Measures include Measures on the Management of Pesticide registration, Measures on the Management of the Pesticide Production License, Measures on the Management of the Pesticide Business License. Two mediums are Pesticide import and export registration management release notice (PRN) and certificate for exported pesticide information (ICAMARA certificate). Under severe regulatory conditions, the quality of pesticides exported from China is safe and can be used with confidence.

As an important producer and exporter of chemicals, especially of pesticides, the Chinese government has always paid much attention to the Rotterdam Convention. Institute for the Control of Agrochemicals, Ministry of Agriculture and Rural Affairs (ICAMARA), responsible for implementing Rotterdam Convention on pesticide. According to the requirements of the Convention to send out notifications of final regulatory actions and export notice, attend Chemical Review Committee meetings and conference of parties meeting, respond to import decisions and export notice. Pesticide import and export management is an important means of implementing the Rotterdam Convention. In order to strengthen the management of pesticide import and export, the Chinese government has actively carried out international cooperation in the field of pesticides. Including cooperation of international organizations and bilateral cooperation. For example, ICAMARA established a long-term partnership with international organizations, such as FAO, WHO and OECD, established cooperative relations with the United States, UK, Canada, Brazil, Argentina, Thailand, Viet Nam, Turkey, Ukraine, Cambodia, Japan and other countries.

Pesticide industry in China is developed remarkably with rapid progress. There are more than 2,100 manufacturers in the country. More than 600 active ingredients and 38,000 products registered in China. In 2017, outputs of pesticide in China reached 1,388 thousand tons (A.I.). In 2016, usage of pesticide in agriculture sector in China reached 292.5 thousand tons (A.I.). In 2017, the export volume for pesticide reached 1,467 thousand tons (formulation); export value for pesticide reached 6,760 million USD. In term of Export value, TC accounted for 56.3%, 3,806 million USD; formulation accounted for 43.7%, 2,954 million USD; insecticide accounted for 28.2%, 1,905 million USD; fungicide 15.3%, 1,034 million USD; herbicide 54.4%, 3,679 million USD; in 2017, import volume for pesticide reached 407 thousand tons (formulation); import value for pesticide reached 411 million USD. Imported pesticides are mainly fungicides. In term of import value, fungicide account for 43.7%, insecticide account for 30.2%, herbicide account for 23.9%.

2.5 Chemistry data requirements and evaluation of pesticide registration

In the presentation, Dr. Wu Jinlong introduced the general chemistry data requirements for the registration of TC/TK and formulation of pesticides, meanwhile demonstrating the differences between chemical pesticides and bio-pesticides. Then, he also gave a summary of key elements on evaluations of chemistry data. Finally, he briefly introduced major changes on chemistry data requirements update in the new Regulations on the Management of Pesticides. The system of evaluation for quality of pesticide is composed of three parts: data requirements, product standards, and test guidelines. The review of chemistry data could answer the following five questions-what the product is; how the product were manufactured or formulated; what the basic characteristics of the product are; what the stability of the product is; what the parameters of the product to determine product quality;

The role of product standards is a group of parameters to determine product quality during market supervision, and used for product quality control by its producers. China has established a four-level system of pesticide product quality standards including national standards, industrial standards and group standards, enterprise standards, which are harmonized with FAO/WHO specifications. The role of test guidelines is to harmonize test methods. Test guidelines are produced in line with relevant guidelines of Collaborative International Pesticides Analytical Council (CIPAC), EU and the US. China developed 59 guidelines related to product chemistry tests. These are including: 38 Guidelines on the determination of physico-chemical properties of pesticides, such as thermal stability, explosibility, etc.; Guidelines on validation of analytical methods for agrochemicals; Test guidelines on batch analysis of TC for pesticide registration;

Guidelines for storage stability testing of pesticides at ambient temperature; 19 Guidelines on the determination of physical properties (control items), such as suspensibility, persistent foaming, etc.

2.6 Pesticide quality control management of FAO and China

In the presentation, Dr. Zhang Hongjun introduced pesticide quality control management of FAO/WHO and China as well as the international cooperation and development. Quality control of pesticide refers to the inspection of pesticide products imported, manufactured and/or available in the market to check whether they meet the desired requirements including and packaging and specifications as well as to identify for non-conformities and take the necessary corrective actions. FAO/WHO and CIPAC try to harmonize these national standards and facilitate international pesticide trade. FAO/WHO has jointly established the FAO/WHO pesticide specifications providing the reference for quality control throughout the world. During the 19th Communist Party of China (CPC) Central Committee, Xi Jinping, General Secretary of the Communist Party of China (CPC) Central Committee, has urged developing a modernized economy to push the country's economic development to a new level. The government will establish the strict fined rules for illegal products. Regulation on Pesticide Administration (RPA) issued by the State Council in 1997, and revised in 2001, 2003, 2017. China has established a four- level system of pesticide product quality standards including national standards, industry standards, group standards and enterprise standards. MARA carries out pesticides market surveillance every year, and the number of sampling is more than 5,000 each year in china. At present, the qualified rate of the sampled pesticides product reaches over 80%.

2.7 Storage stability test of pesticide products

Prof. Liu Fengmao, China Agricultural University, presented the storage stability test of pesticide products. Storage stability is the reference for quality and risk management of pesticides, the evaluation document is essential material for national or international registration. Prof. Liu introduced the test methods of accelerated storage stability test, real time storage stability, low temperature stability and freeze-thaw stability in China. He also introduced comparison with the international guidelines, as well, the factors affecting the storage stability was discussed and the improving methods were recommended.

2.8 Batch analysis of pesticide technical grade

Dr. Cao Lidong from Institute of Plant Protection, Chinese Academy of Agricultural Sciences gave an introduction of batch analysis. Batch analysis of pesticide technical concentrates is the determination for the content of the active constituent and each impurity present at a concentration of 0.1% or more using specific methods as well as content of relevant impurities (present at any level). The sum of the quantitative level of active constituent and impurities are often referred to as the mass balance. Because of the analytical error associated with each analytical procedure, the mass balance should be in the range 98-102%. Results of the analysis should be provided for at least five commercial-scale production batches of the active constituent. The most challenging work for batch analysis is the qualitative determination of impurities. The sources of impurities mainly include starting materials, reaction intermediates, and by-products from side reactions. The side reactions are mainly degradation, isomerization, hydrolysis, oxidation, over substitution, and rearrangement reactions. The determination of impurities is important: (1) Preliminary test to determine the number of impurities; (2) Deduce the tentative chemical structure based on mass spectrum and synthetic route; (3) Confirm the structure of

impurity through the chromatographic and mass comparison with authentic impurity standard which is obtained by custom synthesis or commercial available standard; (4) For impurity standard difficult to obtain, preparative chromatography can be used to isolate and purify the impurity for qualitative determination. In addition to frequently used analytical methods such as HPLC, GC, LC-MS, and GC-MS, new analytical technologies, which refer to technologies that are not frequently used in batch analysis, include MALDI-TOF-MS, ELSD, ion chromatography, X-ray and so on were also briefly introduced. Validation of an analytical method is to demonstrate that the procedure, when correctly applied, produces results that are fit for purpose. Finally, validation parameters including selectivity (specificity), linearity, range, accuracy, precision, limit of detection and quantitation were introduced.

2.9 Physical and chemical properties detection in technical and formulation

Dr. Li Hongxia from Nutrichem Laboratory Co., Ltd. gave an introduction of physical and chemical properties detection in technical and formulation. Detection of physical-chemical parameters is used for determination of chemical and physical properties of pesticide technical and formulation. Data on pesticide physical-chemical parameters, which is a basement to review statistically the safety of pesticide manufacturing, formulating packaging, storage and transportation, marketing and use, are also submitted for the application pesticide registration. Terms of the main requirements of physical-chemical parameters in different countries was described. Varieties pesticide formulations and their different physical status, some defections of physical-chemical parameters were also described. Various items related international methods for pesticide physical-chemical parameters were compared. Some problems about physical-chemical parameters were raised and some countermeasures were discussed.

3. Lab visit and breakout group exercise in testing physical and chemical property

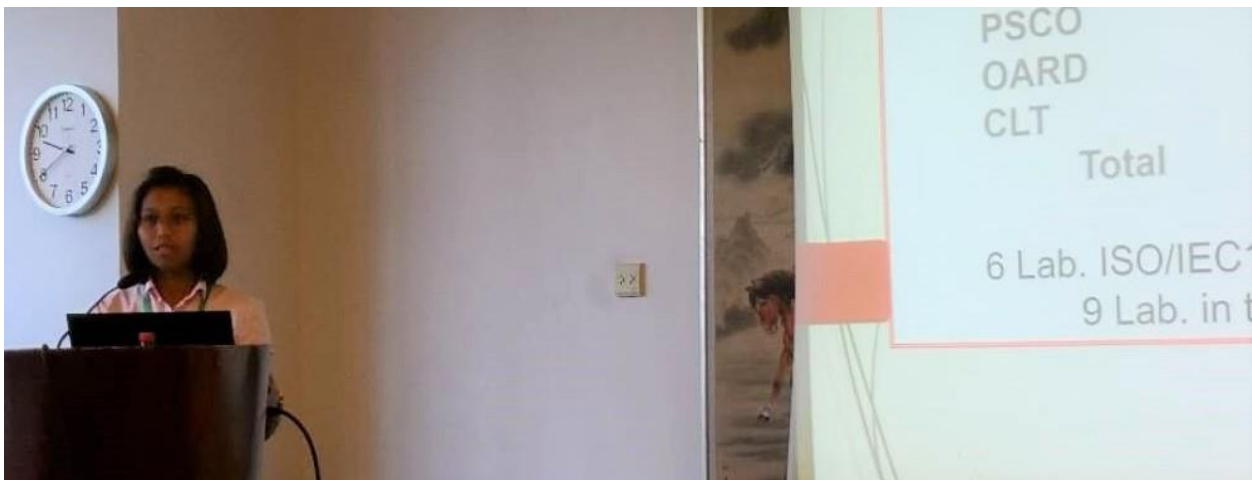
Nutrichem is an R&D-centric company based in China, which specializes in the development of crop protection products. Nutriechem GLP Laboratory, Nutrichem, is the first GLP laboratory that passed through authentication of OECD. GLP reports from the lab are recognized by US EPA.

Participants were divided into four groups; each group conducted testing experiments respectively. Nutriechem GLP Laboratory staff provided technical guidance to participants with operational procedures and essential requirements of the group tests. The experiments included quantitative analysis of AI by using HPLC-CIPAC method and some physical and chemical characteristic: viscosity, melting point, bulk density test and optical rotation. After the experiments, each group presented and discussed by the group facilitator respectively. The practical exercises made participants had first-hand experience in operation of HPLC-CIPAC in the GLP lab for sensitizing stepwise process of various tests, which might be part of potential process for lab detection associated with quality management in their countries.



4. Country report on update status of pesticide quality control and regulatory management

Participants from Bangladesh, Cambodia, Laos, Myanmar, Pakistan, Philippines, Sri Lanka, Thailand and Viet Nam presented country report on the pesticide regulatory management and quality control. The country report presented invaluable information and experience on pesticide quality control, registration and regulations, etc. Active interactions and discussions between reporters and participants identified strengths and weakness of respective countries, and it provided essential basis for potential collaboration among countries.



5. Closure of the workshop

Dr. Piao Yongfan highlighted the importance of pesticide quality control in line with the implementation of code of conduct on pesticide management, and stressed values of sharing experience in pesticide regulatory management among countries in Asia-Pacific region. This training workshop provided valuable and important knowledge on pesticide regulations, detecting technologies, quality control management. It enabled participants to have better understanding of context of pesticide quality control, improvement of capacity in detection, quality control and pesticide registration. He stated that FAO/APPPC would seek more resources to support Asian countries to make sustainable progress in enhancement of capacity in pesticide quality control and pesticide regulatory management. He encouraged participants to take necessary follow up actions on close collaboration among countries either at bilateral or multilateral levels to share the experts, experiences and information concerned for promotion of harmonization on pesticide quality management, registration and regulatory management. He also reminded the delegates from Philippines and China to start proactive discussion on next action plan of the APPPC Standing Committee on Pesticide Management, which would be implemented next year with focus on the subject of pesticide residues detection. He, again, thanked the Chinese government, and ICAMARA for their valuable supports toward this workshop.

Timetable

Date	Time	Details
Sunday 24 June	Whole day	Arrival and registration in Beijing Airport
Monday 25 June	10:30- 11:30	Opening ceremony (addresses by APPPC, MARA, ICAMA)
	14:00- 17:00	FAO/WHO specifications for technical grade active ingredients— Prof. Chen Tiechun FAO/WHO specifications for formulated pesticides----- Prof. Li Guoping Pesticide risk reduction and phasing out highly hazardous pesticides-- Dr Lin Ronghua
Tuesday 26 June	09:00- 12:00	Pesticide import and export management in China---- Dr Wu Houbin Chemistry data requirements and evaluation of pesticide registration--- Dr Wu Jinlong Pesticide quality control management---- Dr Zhang Hongjun
	14:00- 17:00	Storage stability test of pesticide products---- Prof. Liu Fengmao Batch analysis of pesticide technical grade ---- Dr Cao Lidong Physical and chemical properties detection in technical and formulation-- Dr Li Hongxia
Wednesday 27 June	09:00- 17:00	Lab tour and pesticide group test in physical and chemical property--- NutriChem Lab Company in Beijing
Thursday 28 June	10:00- 17:00	Country report on pesticide regulatory management and quality control Closing of workshop

Lists of Participants

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