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GUIDANCE FOR HARMONIZING PESTICIDE REGULATORY MANAGEMENT IN SOUTHEAST ASIA

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC
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FOREWORD

Since 1982, FAO has played an important role in assisting and supporting countries in Southeast Asia to regulate the use of agricultural pesticides and to implement the *International Code of Conduct on the Distribution and Use of Pesticides* within the region. An efficiently regulated and managed pesticide registration scheme is a pre-requisite for ensuring that pesticides used in a country are useful for controlling pests and would not cause adverse effects to humans and the environment. Such a scheme also enhances the development of the agricultural sector and strengthens agricultural trade nationally and globally.

While government procedures should take full account of local circumstances and needs, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate and affordable pesticide application and protective equipment, there is also a need to harmonize pesticide management within the region to apply similar requirements and quality standards. This would strengthen pesticide management in the individual countries and make the registration process more efficient and transparant.

To promote greater harmonization, FAO implemented the project titled *"Assisting countries in Southeast Asia towards achieving pesticide regulatory harmonization"* from 2009 to 2011 under its technical cooperation programme (TCP). The project provided the necessary technical inputs to achieve regulatory harmonization as well as training to increase the capacities of the regulatory agencies. In particular, it produced a set of guidelines to support the countries in their efforts to harmonize their registration systems. These guidelines were formally adopted at the final meeting of the project management committee and recommeded for implementation by the member countries.

In this publication, the guidelines have been summarized and compliled so that they may serve as a reference manual to the countries in Southeast Asia in their efforts to strengthen and harmonize their pesticide management.

It is hoped that this guidance will not only facilitate the regional harmonization of pesticide regulatory processes, but that it will also foster greater cooperation and exchanges among the countries as well as contribution to food safety approaches.

Hiroyuki Konuma
Assistant Director-General and
FAO Regional Representative for Asia and the Pacific

Bangkok, April 2012

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LIST OF ACRONYMS

a.i.	active ingredient
ASEAN	Association of Southeast Asian Nations
BAMS	Bureau of Agricultural Material Standard
BPI	Bureau of Plant Industry
DA	Department of Agriculture
DAALI	Department of Agronomy and Agricultural Land Improvement
DAE	Department of Agricultural Extension
DAL	Department of Agricultural Legislation
DNA	Designated National Authority
DOA	Department of Agriculture
DOAE	Department of Agricultural Extension
DPP	Directorate of Plant Protection
ESCAP	Economic and Social Commission for Asia and the Pacific
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FAOSTAT	FAO Statistical Database
FDA	Food and Drug Administration
FFS	Farmer Field School
FPA	Fertilizer and Pesticide Authority
GAP	Good agricultural practices
GBQC	General Bureau of Quality Control
GDP	Gross Domestic Product
GNI	Gross National Income
GTZ	German Agency for Technical Cooperation; now: GIZ
IPM	Integrated Pest Management
MARDI	Malaysian Agricultural Research Development Institute
MAS	Myanmar Agricultural Service
MOA	Ministry of Agriculture
MOARD	Ministry of Agriculture and Rural Development
MoE	Ministry of Environment
MoH	Ministry of Health
MOPH	Ministry of Public Health
MRL	Maximum residue limits
NA	Not available
NGO	Non-governmental organization
NPC	National Project Coordinator
OC	Organochlorine (pesticides)
OECD	Organisation for Economic Co-operation and Development
OP	Organophosphate (pesticides)
OPR	Office of Pesticide Registrar
PANAP	Pesticide Action Network Asia and the Pacific
PIC	Prior Informed Consent (Rotterdam Convention)
PMC	Project Management Committee

POP	Persistent organic pollutants (Stockholm Convention)
PPC	Plant Protection Center
PPD	Plant Protection Department
PPI	Plant Protection Institute
PPPIO	Plant Protection and Phytosanitary Inspection Office
PPQS	Directorate of Plant Protection, Quarantine and Storage
PRG	Plant Growth Regulator
PRMD	Pesticide Registration and Management Division
RDA	Rural Development Administration
RMB	Research Management Bureau
SEA	Southeast Asian countries
TCP	Technical Cooperation Programme
TG	Technical grade
TOT	Training of Trainers
UNEP	United Nations Environmental Programme
USD	United States Dollar
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WTO	World Trade Organization

1. INTRODUCTION

Pesticides are applied widely in the Southeast Asia, not only to ensure food security and feed a growing population, but also to protect human health against vector-borne diseases. There is now a greater awareness among the countries in the region that pesticides can also have adverse effects if not applied properly, or if poor quality or highly hazardous products are used. Since 1982, FAO has played an important role in assisting and supporting the countries in Southeast Asia to have pesticide legislation in place to regulate the use of these products. From 1988 until 1992, the FAO initiatives were supported through a trust fund provided by the Government of Japan for the implementation of the *International Code of Conduct on the Distribution and Use of Pesticides* (hereinafter referred to as the Code of Conduct) within Asia and the Pacific region. Nevertheless, many countries have experienced serious problems in the enforcement of their legal provisions. The political and economical developments during the 1990s created a wide range of private sector activities in the field of pesticides. Pesticides started to be produced or formulated in various Southeast Asian countries and they became an increasingly important economic trade factor. While most products were imported from Europe, Japan and the USA, more and more came from neighbouring countries such as the People's Republic of China and India.

Such a situation requires effective national pesticide management capacities. An efficiently regulated and managed pesticide registration scheme is a pre-requisite for ensuring that pesticides used in the country are useful for controlling pests and would not cause adverse effects to humans and the environment. Such a scheme would also enhance the development of the agricultural sector and would strengthen the sale of agricultural products nationally and globally.

Harmonized pesticide registration in the region would play a crucial role in supporting this development. It would allow for the application of similar requirements and quality standards, e.g. on pesticide residues and precautionary measures. Since many of the countries face similar problems, greater coordination and more information exchange among pesticide authorities would help overcome these challenges. However, insufficient trained manpower and quality control facilities are serious impediments in some countries.

In recent years, some efforts were undertaken to harmonize pesticide registration in the region. For example, there exists an *Expert Working Group on the Harmonization of Maximum Residue Limits (MRLs)* among ASEAN countries, but progress on this initiative has been rather slow due to a number of reasons, inclucing a lack of trained personnel.

In January 2002, FAO, in collaboration with the Department of Agriculture in Thailand, the German Agency for Technical Cooperation (GTZ) and the Asia and Pacific Crop Care Association, sponsored a workshop on pesticide regulatory harmonization for Southeast Asian countries. The aim of the workshop was to assess the desire and need for harmonizing pesticide regulations among the participating countries. The delegates from Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam and Singapore made presentations describing their regulatory process. While there were obvious similarities among the countries, considerable differences were also apparent. Disparities were noted in the times necessary for registration, types of registration classifications, definitions and registration terms for commodity and proprietary pesticides, length of time for protection of proprietary data, labelling requirements and the lists of banned pesticides. It also became apparent that some countries were already more advanced in pesticide registration and control matters, and they possessed good laboratory facilities for pesticide quality and residue control. Others, however, had only limited resources, facilities, know-how and experience.

It was also noted that a regulatory framework for biopesticides was absent in most countries while the Philippines had already done extensive work in this area. Other problem areas included poor user attitude, lack of awareness of pesticide risks, residues in food, pesticide poisonings and usage inconsistent with

label recommendations. A number of countries had priority problems that they hoped harmonization would address. Illegal transborder movement of unregistered and highly toxic pesticides was a particular concern of Cambodia and Malaysia, while other countries, e.g. Indonesia, expressed the hope that harmonization would lead to better trade in agricultural products.

The regulators from the seven Southeast Asian countries saw the move towards a more harmonized system as very positive and expressed their support for the initiative. All countries recognized the need for improved information exchange to advance the harmonization process. It was also noted that better education and training was needed to build capacity in the regulatory systems; particularly, training in risk assessment and analytical methodologies was required.

A second workshop on pesticide regulatory harmonization was held in Kuala Lumpur in August 2003. It was attended by delegates from nine Southeast Asian countries, FAO, the pesticide industry and the Pesticide Action Network. The Lao People's Democratic Republic and Myanmar, now attending this meeting, confirmed similar difficulties and problems as identified by the other countries at the first workshop. At this workshop, the scope and approach of strengthening pesticide management among Southeast Asian countries was discussed. The guiding principle was that the countries wanted to support and strengthen each other as the problems encountered were not confined to individual countries, but were regional problems. Hence, they could only be solved through harmonized approaches, active information exchange and direct collaboration among the pesticide registration authorities. It was understood that countries with more advanced facilities, experiences and registration schemes would assist those countries with lesser capacities and fewer facilities.

Taking into account the advance of globalization, it would be important for the countries in the region to harmonize their pesticide regulatory process in order to stay competitive in the international marketplace. With regulatory harmonization, countries in the region would be able to work together more closely, share their resources, lower the costs of the pesticides regulatory process, improve trade and provide better protection of the population and the environment against poor quality and highly hazardous pesticides.

For the same reasons, the harmonization of pesticide registration was also actively pursued elsewhere in the world, notably:

- the Organisation for Economic Co-operation and Development (OECD) Pesticide Forum;
- the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticide;
- the European Union; and
- the Permanent Interstate Committee for Drought Control in the Sahel (CILSS) among African countries.

The *International Code of Conduct on the Distribution and Use of Pesticides* provides the foundation for the harmonization of pesticide regulations in Southeast Asia. Greater cooperation through information exchange and pesticide harmonization is strongly encouraged by the Code. Harmonization would also be crucial for the implementation of a number of international conventions related to pesticides. These include the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Chemicals and Pesticides in International Trade*, the *Stockholm Convention on Persistent Organic Pollutants* and the *Basel Convention on the Transboundary Movement of Hazardous Wastes*.

To achieve greater harmonization of pesticide regulations, the government representatives of eight Asian countries, namely Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Thailand and Vietnam, expressed the need for assistance from FAO. Without such an intervention, it was thought that the countries would find it very difficult to achieve this objective. It was hoped that the assistance would provide the necessary technical inputs and the impetus to work together more closely.

In response to this request, FAO agreed in 2009 to implement a project under its technical cooperation programme (TCP) to assist the countries in Southeast Asia towards achieving greater pesticide regulatory harmonization. The implementation of the project took place in 2010 and 2011.

Project objectives

The main objective of the project was to assist Southeast Asian countries towards achieving harmonization in the pesticide regulatory process in line with the provisions of the Code of Conduct. This was to be achieved through

(1) Reviewing existing regulatory processes and related activities on pesticides in Southeast Asian countries and providing recommendations for a practical and sustainable modality to assist the countries to harmonize pesticide registration.

(2) Preparation of guidelines on:

- harmonization of pesticide registration requirements including the format for minimum data requirement and the modality for a sustainable process;
- harmonization of pesticide registration requirements for biopesticides including the format for minimum data requirement and the modality for a sustainable process;
- harmonization of pesticide labelling requirements;
- harmonization of bio-efficacy testing; and
- harmonization of monitoring and surveillance of pesticide residues in agriculture products.

(3) Strengthening the existing network for information exchange among pesticide regulatory authorities in Southeast Asia.

(4) Training and upgrading the capabilities of pesticide regulatory officers in the fields of:

- pesticide data registration evaluation and risk assessment;
- pesticide residue analysis; and
- pesticide formulation analysis.

(5) Capacity building to sustain and develop further the activities initiated under this project to achieve harmonization of pesticide regulations among the countries in the region.

Project outputs

(1) A set of guidelines and the modality for the harmonization of pesticide registration among Southeast Asian countries.

(2) A set of guidelines and the modality for the harmonization of registration requirements for biopesticide.

(3) A set of guidelines and the modality for the harmonization of pesticide labelling.

(4) A set of guidelines and the modality for the harmonization of monitoring pesticide residues in agriculture products.

(5) Updated guidelines for the preparation of bio-efficacy test protocols with review of existing FAO bio-efficacy test protocols and formulation of ten new ones.

(6) A system for information exchange on pesticide matters among participating countries using the internet.

(7) Ten pesticide regulatory personnel trained in pesticide residue analysis.

(8) Ten pesticide regulatory personnel trained in pesticide formulation analysis.

(9) Thirty pesticide regulatory personnel trained in pesticide registration data evaluation and risk assessment, as well as pesticide residues monitoring and surveillance.

Guidance document

This guidance document summarized and compliled the guidelines initiated by the project consultants. The original documents were edited for consistency and to improve readability. Care was taken not the change the original meanings expressed by the authors. In some cases, repetitions were deleted, and the annexes to the guidelines for biopesticide registration were reorganized to group together similar sets of recommended data requirements.

2. SUMMARY AND ANALYSIS

2.1. Summary and analysis of registration requirements

2.1.1. Introduction and background

Agricultural developments in Southeast Asia have resulted in significant increases in the trade volume and sales of pesticides. There are many pesticide companies that promote their products and encourage farmers to use repeated applications to protect their crops against insect pests and diseases. Often, farmers mix different products in an effort to increase their effectiveness. The widespread use of highly toxic products coupled with a lack of protective measures frequently results in poisonings and environmental damage. Smuggling and dumping of unregistered pesticides have been reported from some countries. Such developments warrant effective pesticide management capacities at the national level and a registration scheme to control the products used in the country. In order to protect their population and the environment, national authorities may have to ban or severely restrict the use of certain pesticides. Such action may also be required to meet international obligations under various treaties such as the Rotterdam, Stockholm and Basel Conventions and the Montreal Protocol.

After reviewing the current status of pesticide registration in the member countries and holding in-depth discussions with pesticide regulating authorities in Thailand, Philippines, Vietnam, Malaysia and Lao PDR, a consultant developed guidelines for harmonizing pesticide registration among Southeast Asian countries. The purpose of these guidelines was to facilitate the harmonization of pesticide management among Southeast Asian countries, so that pesticides data accepted in one country can be considered for registration of the same product in another country without compromising human health and environmental safety standards.

The draft guidelines were circulated to all member countries and to Crop Life. Their comments were appropriately considered and incorporated and the final guidelines were discussed and adopted at the Third PMC Meeting at Kula Lumpur (see Attachment 1).

2.1.2. Summary of country status

Each country has its own pesticide regulations and procedures. While there are many similarities between the various registration systems, there are also differences in types of registration, validity periods and data protection. Furthermore, there is a wide range in the capacity of pesticide regulators and enforcement personnel to implement these regulations.

Cambodia

- Most of the pesticides are imported from Vietnam, Thailand and China. Some pesticides enter the country illegally and bear labels in foreign languages (such as Thai or Vietnamese)
- Sub-decree No. 69 to control pesticides includes registration, labelling, licensing of imports, exports, manufacturers, retailers, re-packers, importers, and advertisement. It also regulates the import of pesticides for research purposes.
- There are four types of registrations under the Sub-decree No. 69, namely provisional, conditional, full and experimental use. However, only provisional, full and experimental use registrations are currently being implemented.
- DAL has the responsibility to register pesticides with the technical assistance from the Department of Plant Protection of the General Directorate of Agriculture (GDA) which

evaluates the data for registration. Samples submitted at the time of registration are sent to GDA for laboratory and field testing.

- However, no analysis of the formulation is presently done due to the unavailability of analytical facilities and staff. The MAFF and the inspectors have the power to impose administrative punishments such as asking for rectification, giving warnings and seizing products.
- Cambodia is signatory to the Basel and Stockholm Conventions as well as the Montreal Protocol. The Ministry of Environment is the focal point for the Basel and Stockholm Convention. The country has not yet signed the Rotterdam Convention, for which the MAFF would be the focal point.
- Data protection period: 3 years

Lao PDR

- In Lao PDR, the Ministry of Sciences and Technology and the Ministry of Natural Resources and Environment are involved in chemical control.
- Under the Regulation on the control of pesticides in Lao PDR, No. 2860/MAF, the Minister of MAF has approved on 11 June 2010 the registration of 97 products: 21 herbicides, 40 insecticides, 22 fungicides, 11 plant growth regulators and 3 rodenticides; 55 pesticides are banned
- In 2004, Lao PDR became a contracting party to the Stockholm Convention and in 2010 it became a party to the Rotterdam and Basel Conventions. However, the implementation of the latter two conventions is not yet clear between the ministries.
- Data protection period: 2 years

Malaysia

- Presently, there are several laws for the control of pesticides. The Pesticides Act 1974 is the main law and the most comprehensive act which controls various aspects of pesticides. To implement the Act, the Pesticides Board was established. It is comprised of members from relevant government agencies. For the implementation of the various sections of the Act, appropriate rules and regulations were formulated. Presently there are seven main sets of rules and regulations which have been gazetted and are being implemented, namely on registration, labelling, importation for research and educational purposes, licensing of sale and storage, pest control operation, regulations for highly toxic pesticides and advertising.
- The Pesticides Control Division of the Department of Agriculture was entrusted with the task of providing the secretariat to the Board for the implementation of the Act.
- Malaysia is actively implementing and participating in international agreements related to the sound management of chemicals and pesticides, namely the FAO Code of Conduct, Rotterdam Convention, Stockholm Convention, Montreal Protocol, Basel Convention, SAICM and Chemical Weapon Convention.
- Post-registration monitoring includes review of registration, taking market samples, monitoring residues in crops and the environment as well as monitoring of poisoning cases.
- Non-regulatory activities include education and training of farmers on the safe and effective use of pesticides, recycling of used pesticide containers, establishing a Vegetable Farm Certification Scheme (SALM) to promote Good Agricultural Practices (GAP) which includes the judicious use of pesticide, a Organic Farm Certification Scheme (SOM) and the promotion of IPM.
- Data protection period: 10 years

Myanmar

- The Pesticide Law was enacted in 1990 in line with the FAO Code of Conduct and in 1991, the Ministry of Agriculture and Irrigation prescribed the procedures relating to the pesticide law. A Pesticide Registration Board (PRB) was formed with the Managing Director of the Myanmar Agriculture Service (MAS) as Chairman and the Head of the Plant Protection Division as the secretary.
- There are four types of registration such as experimental, provisional, full, amended registration and Special Use Permit and they are needed for import and export purposes. Until March 2010, 1266 registration certificates have been granted.
- Analysis for quality control is carried out by pesticide analysts who are either graduate in BSc, MSc (Chemistry) or Agricultural Chemistry. There is a need for capacity building of analysts due to limited number of trained persons available at present.
- Myanmar is signatory to International Conventions and Agreements, such as Rotterdam, Stockholm and Basel conventions, the WTO/SPS agreement and RENPAP.
- So far, 19 pesticides have been banned and 7 pesticides are categorized as restricted pesticides.
- In addition, both local consumption and export commodities are being analyzed for pesticide residues.
- Data protection period: 10 years

Philippines

- Pursuant to Section 1 of Presidential Decree No. 1144 promulgated on May 1977, the Fertilizer and Pesticide Authority (FPA) was created with the mandate to regulate import, manufacture and use of pesticide in the country. The FPA, thereafter, promulgated and adopted the Rules and Regulations, No. 1 series 1977 to govern the importation, manufacture, formulation, repacking, distribution, sale, storage, and use of pesticides in the interest of improving agricultural production, protecting public health and enhancing environmental quality. According to the FPA Rules and Regulations, all chemical pesticides and biorational products have to be registered and their handlers licensed by the FPA. Presently, the Ministry of Health has been given the responsibility for the control of household pesticides.
- FPA's Pesticide Regulatory Policies and Implementing Guidelines (Green book) (Revised 2001) prescribe the procedure for the registration of chemical pesticides, policy guidelines on biorational pesticides, licensing, certification and accreditation of pesticide handlers, product stewardship and responsible care, post-registration activities, and penalties for violations. Standards are set by FPA on quality and suitability of the active ingredients and of the formulated products, bio-efficacy, and safety to handlers, safety to consumers and users, safety to the environment, handling, packaging, labelling and disposal. For the purposes of registration, pesticides are grouped based on their nature and use pattern as follows:
  i. Chemical pesticides for agriculture, home garden, turf use and other chemical pesticides used alone or in combination with others in formulations; and
  ii. Biorational pesticides, i.e. biochemical pest control agents including semio chemicals (pheromones, kairomones, allomones, hormones, natural plant regulators (auxins), enzymes), microbial pest control agents, namely bacteria, fungi, protozoa and viruses-based products. There have been no recent amendments to the rules and regulation, however, an updating of the Green Book is expected soon.
- The power and functions of the FPA is vested in and exercised by a Board of Directors.
- Data protection period: 8 years

Thailand

- Pesticides are regulated under the Hazardous Substance Act (No. 3) B.E. 2551 (2008).
- The Department of Agriculture is the responsible agency for regulating pesticides used for crop production.
- Regulation is made by registration, licensing and monitoring.
- The quality of pesticides and its residues in food crops are regularly monitored. Maximum residue limits (MRLs) for pesticides have been established since 2008. Pesticide poisonings are monitored and reported by the Department of Disease Control, Ministry of Public Health. On average there are 2 243 cases of pesticide poisoning reported annually, at the rate of 2.7-6.8 per 100 000 populations.
- Integrated pest management (IPM) has been widely implemented by rice, fruit, and vegetable growers.
- Thailand actively implements international conventions related to pesticides such as FAO Code of Conduct, Montreal Protocol, Rotterdam Convention and Stockholm Convention.
- Data protection period: 10 years

Vietnam

- Vietnam has promulgated a number of ordinances, decrees and regulations for management of pesticides.
- Vietnam has set up an Authority of Pesticide Registration with the Plant Protection Department under the Ministry of Agriculture and Rural Development (MARD).
- The MARD publishes annually the lists of pesticides permitted for use, pesticides restricted and pesticides banned. Presently, there are 886 active ingredient pesticides permitted for use, 15 are restricted and 29 are banned.
- Vietnam is a party to the Rotterdam, Basel and Stockholm Conventions as well as the Montreal Protocol.
- Data protection period: 5 years

Status of implementation of international conventions

- The Rotterdam, Basel and Stockholm Conventions provide a framework for the management of hazardous chemicals and wastes.
- Seven of the eight member countries are party to the Stockholm convention, six have ratified the Basel Convention, but only four have so far joined the Rotterdam Convention.
- Philippines, Thailand and Vietnam are the only countries that have joined all three conventions; Thailand has also constituted a national sub-committee for their effective implementation.
- Lao PDR and Myanmar have ratified the Stockholm Convention and taking action to ban POPs. However, Lao PDR has signed the Basel and Rotterdam Conventions in September 2010 and is in the process of ratifying them.
- Of the four countries that have ratified the Rotterdam convention, all have issued import responses for the 40 chemicals currently in Annex III; Malaysia and Thailand have notified the secretariat of final regulatory actions.
- The Rotterdam Convention provides mechanisms for information exchange on hazardous chemicals and pesticides, as well as the Prior Informed Consent (PIC) procedure for import and export of chemicals in Annex III of the Convention. The management of hazardous chemicals and pesticides requires particular attention by the regulatory authorities and the Rotterdam Convention complements the initiative of regional harmonization of the pesticide regulation.

Summary table of status of ratification and implementation

	Cambodia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam
Stockholm Convention	x	x	x		x	x	x	x
Basel Convention	x	x	signed	x		x	x	x
Rotterdam Convention			signed	x		x	x	x
– Import response to Annex IIII chemicals				40		25	39	26
– Notification of Final Regulatory Actions				3			54	

- Between 2000-2010 the Secretariat of the Convention has received about 800 notifications of national final regulatory actions (FRA) submitted by countries. The secretariat published summaries of these notifications in PIC Circulars every six months. The notifications cover about 220 chemicals (65 percent pesticide, 29 percent industry chemicals and 6 percent dual uses).
- Implementation of the FAO Code of Conduct is impressive in Malaysia and Thailand where the governments have taked steps to implement all aspects of the Code. However, in Lao PDR, Myanmar and Cambodia, only certain aspects Code are implemented due to inadequate resources and trained manpower.
- National Project Coordinators should play a catalytic role and pursue with the concerned authorities to initiate actions to hasten the process of ratifying the conventions which have not yet been done so far and draw up Action Plan for implementation of conventions which have been already ratified.
- However, support of the international agencies for infrastructure development and capacity building of the staff dealing with pesticide regulations and their enforcement especially for the countries like Lao PDR, Cambodia, Myanmar and Vietnam would be very essential to achieve faster pace in the implementation of the provisions of the Conventions relating to pesticides.

2.1.3. Project outputs

Guidelines on harmonization of pesticide registration

The guidelines describe the recommended process for the registration of chemical pesticides and list the data requirements for different types of registrations. These guidelines take into account various guidelines by FAO and the OECD for pesticide registration.

The general requirements are in line with the provisions of the Code of Conduct and international conventions. This includes the documentation of the registration process, establishing a pesticide board or technical committee for assisting in pesticide risk evaluation, establishing appropriate procedures for monitoring the quality of pesticides and accidental exposure to humans and the environment, as well as data protection requirements for proprietary and confidential business information.

The specific requirements provide guidance for a unified application process that includes registration requirements for different kinds of registration, minimum data requirements for each type of registration, a detailed process of technical evaluation, and requirements for re-registration or exempting pesticides from registration. It also provides the requirements for licensing import and export, manufacturing facilities, stockiest, distributors and retailers as well as pest control operators.

The following parameters are considered crucial for pesticide registration harmonization:

i. Registration process compliance with FAO Code of Conduct and international conventions,
ii. Designation of responsible authority and adequate facilities,
iii. Documentation of registration process,
iv. Establishing of Pesticide Board/Technical Committee,
v. Establishing of monitoring procedures for registration,
vi. Validity periods for different kind of registration,
vii. Period of data protection (proprietary and confidential business information),
viii. Unified application format for pesticide registration,
ix. Establishment of separate fee structure for each kind of registration,
x. Minimum data requirements for each kind of registration,
xi. Technical evaluation of data dossiers by competent experts,
xii. Risk Assessment and Efficacy evaluation,
xiii. Compliance with good laboratory practices (toxicity and residue data),
xiv. Issue of registration certificates with validity period,
xv. Establishing procedures for appeal,
xvi. Label claim/Extension of label claim,
xvii. Pesticide review and re-registration,
xviii. Licensing of manufacturing facilities, stockiest, distributors, retailers and premises.

Registration parameters which are desirable but not crucial for harmonization:

i. Conditional registration,
ii. Unconditional registration,
iii. Exemptions from pesticide registration requirements,
iv. Export registration requirements,
v. Licensing of pest control operators,
vi. Quality testing of pesticides.

Data requirements for registration of pesticides

The six annexes of the guidelines provide all the recommended data requirements for proprietary and supplementary registrations of the technical concentrate and the formulated product. They are given for chemical, biochemical (e.g. pheromones and growth regulators) and microbial pesticides (e.g. bacteria, fungi, viruses or protozoa). These annexes take into account data requirements recommended by FAO and OECD.

The six annexes were summarized in the tables below so that similarities and differences in the data requirements for the various categories could be easily seen. While there are clear patterns, some items may need further explanations.

The total numbers of data requirements in these tables for various types of pesticide registrations are given in the next table:

Number of required data for different types of registrations

	Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
Annex:	**2A**	**2B**	***2C***	**3A**	**3B**	**3C**	**4A**	**4B**	**4C**
	Proprietary registration		**Sup-plementary registration**	**Proprietary registration**		**Sup-plementary registration**	**Proprietary registration**		**Sup-plementary registration**
	Technical grade AI	**Formulated product**		**Technical concentrate of BPCA**	**Formulated product of BPCA**		**Active agent of MCPA**	**Formulated product of MCBP**	
Active ingrediant/agent	34	34 (0*)	0	25	25 (0*)	0	22	17	14
Formulated product	–	25	25	–	24	24	–	11	11
Toxicity	13	7	7	6	6	6	6	6	6
Bio-efficacy	–	12	12	–	12	12	–	12	12
Residue data	7	–	–	–	–	–	–	–	–
Environmental data	7	2	2	2	2	–	5	5	–
Label and packaging	12	20	20	12	20	20	15	18	18
	73	100	66	45	89	62	48	69	61

* reduced data requirement when the technical active ingredient is already registered

The following observations can be made:

- The number of required information ranges from 100 items for the proprietary registration of chemical formulations to 45 items for the proprietary registration of the technical concentrate of biochemical pesticides.
- The information required on the active ingredient is largely similar for chemical and biochemical pesticides, while a different set of information is required for microbial pesticides.
- When the technical grade active ingredient is already registered, its data can be used for the registration of the formulated product; however, when the technical grade is not registered, the registration data for the technical grade active ingredient is required along with the data for the formulated product.
- Data requirements for the proprietary and supplementary registrations of a formulated product are largely identical.
- Basic toxicity data are required for all types of pesticides; however, more long-term studies are required for the registration of the technical grade active ingredient of chemical pesticides.
- The same bio-efficacy data and pest information is required for the different types of formulated pesticides.
- Residue data are only required for the proprietary registration of the technical grade active ingredient of chemical pesticides.
- Environmental fate and toxicity studies are only required for the technical grade active ingredient of chemical pesticides and in some cases for microbial pesticides.
- Largely the same labelling and packaging information is required for all types of pesticides and registrations.

Summary and Comparison of Data Requirements for Registration of Pesticides

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	2A	2B	*2C*	*3A*	3B	3C	4A	4B	4C
S. No.	Data parameters	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration
		Technical grade AI	Formulated product		Technical concentrate of BPCA	Formulated product of BPCA		Active agent of MCPA	Formulated product of MCBP	
Active Agent										
A.1.	**Chemical identity/Identity of active agent (MCPA)**									
	1.1. Chemical abstract services number (if any)	Required	Not required*	Not required	Required	Not required	Not required	Required	Required	Required
	1.2. Common name (proposed or accepted by ISO and synonyms)	Required	Not required*	Not required	Required	Not required	Not required	Required	Required	Required
	1.3. Structural formula	Required	Not required*	Not required	Required	Not required	Not required			
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Required	Not required*	Not required	Required	Not required	Not required			
	1.5. Empirical formula and molecular weight	Required	Not required*	Not required	Required	Not required	Not required			
	1.6. Specification together with method of analysis of active ingredient	Required	Not required*	Not required	Required	Not required	Not required			
	1.7. Plant species (common/scientific name) from which the active ingredient extracted				Required	Not required	Not required			
	1.8. Scientific name							Required	Required	Required
	1.9. Synonyms							Required	Required	Required
	1.10. Taxonomical Position (Class/Order/Family/Sub-family)							Required	Required	Required
	1.11. Strain/serotype/biotype							Required	Required	Required
* Required only in those cases where technical grade is not registered but its formulation (readymade) is directly imported and is intended to be registered.										
A.2.	**Physical properties of pure active ingredient/Identification characteristics of MCPA**									
	2.1. Appearance (physical state, colour, odour)	Required	Not required*	Not required	Required	Not required	Not required			
	2.2. Melting/decomposition/boiling point	Required	Not required*	Not required	Required	Not required	Not required			
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 °C), but only when above 10-3 Pascal)	Required	Not required*	Not required	Required	Not required	Not required			
	2.4. Solubility in water and organic solvents (at a temperature preferably in the range of 20-25 °C)	Required	Not required*	Not required	Required	Not required	Not required			
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Required	Not required*	Not required	Required	Not required	Not required			

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	2A	2B	*2C*	*3A*	3B	3C	4A	4B	4C
S. No.	Data parameters	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration
		Technical grade AI	Formulated product		Technical concentrate of BPCA	Formulated product of BPCA		Active agent of MCPA	Formulated product of MCBP	
	2.6. Density (for liquids only)	Required	Not required*	Not required	Required	Not required	Not required			
	2.7. Hydrolysis rate under stated relevant conditions	Required	Not required*	Not required	Required	Not required	Not required			
	2.8. Photolysis under stated relevant conditions	Required	Not required*	Not required	Required	Not required	Not required			
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Required	Not required*	Not required	Required	Not required	Not required			
	2.10. Methods of analysis of physic chemical properties				Required	Not required	Not required			
	2.1. Morphological characteristics							Required	Required	Required
	2.2. Cultural characteristics							Required	Required	Required
	2.3. Biochemical properties							Required	Required	Required
	2.4. Serological identification (where appropriate)							Required	Required	Required
	2.5. Molecular diagnosis (where appropriate)							Required	Required	Required
	2.6. Analytical methods for identification & characterization of MCPA							Required	Required	Required
	2.7. Identification of plasmids or other extra chromosomal genetic material responsible for pesticide activity or pathogenicity or toxicity etc., where appropriate							Required	Required	Not required
	2.8. Whether wild type or genetically altered organism?							Required	Required	Not required
	2.9. Natural occurrence of organism and its relation to other related species							Required	Required	Not required
* Required only in those cases where technical grade is not registered but its formulation (readymade) is directly imported and is intended to be registered.										
A.3.	**Technical grade active ingredient/Technical concentrate of BP**									
	3.1. Source; name and address of manufacturer and addresses where manufactured	Required	Not required*	Not required	Required	Not required	Not required			
	3.2. Appearance (physical state, colour and odour)	Required	Not required*	Not required	Required	Not required	Not required			
	3.3. The minimum (and maximum) active ingredient content in g/kg	Required	Not required*	Not required	Required	Not required	Not required			
	3.4. Identity and amount of isomers, impurities and other by-products	Required	Not required*	Not required	Required	Not required	Not required			

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	***3A***	**3B**	**3C**	**4A**	**4B**	**4C**
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical concentrate of BPCA**	**Formulated product of BPCA**		**Active Agent of MCPA**	**Formulated product of MCBP**	
	3.5. Analytical test report of impurity profile	Required	Not required*	Not required						
	3.5. Outline of extraction process of active ingredient of BP				Required	Not required	Not required			
	3.6. Analytical test report of specifications.	Required	Not required*	Not required						
	3.7. Analytical test report				Required	Not required	Not required			
	3.7. Process of manufacturer	Required	Not required*	Not required						
	3.8. Shelf life	Required	Not required*	Not required	Required	Not required	Not required			
	3.9. Specification together with methods of analysis (and physicochemical properties)	Required	Not required*	Not required	Required	Not required	Not required			
* Required only in those cases where technical grade is not registered but its formulation (readymade) is directly imported and is intended to be registered.										
A.3.	**Biological properties of MCPA**								–	Not required
	3.1. Biological properties of active agent (target pest, microbial agent host range, life cycle), and mode of action of microbial agent, potential hazards (such as infectivity) to mammals (incl. humans), environment and other non-targeted species, if any							Required		
	3.2. Description of morphological types of MCPA and any unusual morphological, biochemical, resistance characteristics of the organism that is different from classic description of organism							Required		
	3.3. Determination of toxin content & potency of toxin by bioassay method							Required		
	3.4. specification together with method of analysis and shelf life							Required		
	3.5. If the organism in question is genetically altered one, method of DNA finger printing and identification of inserted or deleted transcripts, identification of gene control regions, identification of genetic markers etc.), where appropriate							Required		

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	2A	2B	*2C*	*3A*	3B	3C	4A	4B	4C
S. No.	Data parameters	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration
		Technical grade AI	Formulated product		Technical concentrate of BPCA	Formulated product of BPCA		Active agent of MCPA	Formulated product of MCBP	
A.4.	**Source of Active Agent of MCPA**									
	4.1. Name & address of supplier(s)							Required	Required	Required
	4.2. Suppliers' code number							Required	Required	Required
A.4.	**Material Safety Data Sheet (MSDS)**									
	4.1. Physical data (melting point, boiling point, flash point, etc.)	Required	Not required*	Not required						
	4.2. Chemical toxicity	Required	Not required*	Not required						
	4.3. Health Effects	Required	Not required*	Not required						
	4.4. First aid	Required	Not required*	Not required						
	4.5. Reactivity	Required	Not required*	Not required						
	4.6. Storage	Required	Not required*	Not required						
	4.7. Disposal	Required	Not required*	Not required						
	4.8. Protective equipments	Required	Not required*	Not required						
	4.9. Spill-handling procedure	Required	Not required*	Not required						
	4.10. Label including hazard symbol	Required	Not required*	Not required						
Formulated product										
A.5.	**Product identity**									
	5.1. Formulator's name and address		Required	Required		Required	Required		Required	Required
	5.2. Distinguishing name (proprietary name)		Required	Required		Required	Required		Required	Required
	5.3. Use category (herbicide, insecticide, etc.)		Required	Required		Required	Required		Required	Required
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)		Required	Required		Required	Required			
	5.4. Confidential statement of formula (this statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material)								Required	Required

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	***3A***	**3B**	**3C**	**4A**	**4B**	**4C**
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical concentrate of BPCA**	**Formulated product of BPCA**		**Active agent of MCPA**	**Formulated product of MCBP**	
A.6.	**Composition of product**									
	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)		Required	Required		Required	Required			
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert components		Required	Required		Required	Required			
	6.3. Water/other solvent content (where relevant)		Required	Required		Required	Required			
	6.4. Specification together with method of analysis					Required	Required			
	6.5. Analytical test report					Required	Required		Required	Required
	6.6. Shelf life					Required	Required		Required	Required
	6.1. Percentage composition (by weight) of each ingredient; the number of units per unit volume or weight is needed for microbial impurities; viability data in terms of PFU, CFU, etc., per unit weight or volume of product								Required	Required
	6.2. Identity of other ingredients included in the formulation, e.g. stickers, spreaders, etc.)								Required	Required
	6.3. Certification of Composition limits for each ingredient								Required	Required
	6.4. Analysis of contaminants, if any								Required	Required
	6.5. Specification together with method of analysis								Required	Required
A.7.	**Physical/Chemical properties of the product**									
	7.1. Appearance (physical state, colour and odour)		Required	Required		Required	Required			
	7.2. Storage stability (in respect to composition and physical properties related to use)		Required	Required		Required	Required			
	7.3. Density (for liquids only)		Required	Required		Required	Required			
	7.4. Flammability: liquids – flash-point; solids – a statement must be made as to whether the product is flammable		Required	Required						

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	***3A***	**3B**	**3C**	**4A**	**4B**	**4C**
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical concentrate of BPCA**	**Formulated product of BPCA**		**Active agent of MCPA**	**Formulated product of MCBP**	
	7.5. Acidity (where relevant)		Required	Required		Required	Required			
	7.6. Alkalinity (where relevant)		Required	Required		Required	Required			
	7.7. Other properties may in certain cases need evaluation		Required	Required		Required	Required			
A.8.	**Physical Properties of the Formulated product Related to Use**									
	8.1. Wettability (for dispersible powders)		Required	Required		Required	Required			
	8.2. Persistent foam (for formulations applied in water)		Required	Required		Required	Required			
	8.3. Suspendibility (for dispersible powders and suspension concentrates)		Required	Required		Required	Required			
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)		Required	Required		Required	Required			
	8.5. Dry sieve test (for granules, dusts)		Required	Required		Required	Required			
	8.6. Emulsion stability (for emulsifiable concentrates)		Required	Required		Required	Required			
	8.7. Corrosiveness (when necessary)		Required	Required		Required	Required			
	8.8. Known incompatibilities with other products, e.g., pesticides, fertilizers		Required	Required		Required	Required			
	8.9. Specification together with method of analysis		Required	Required						
	8.10. Analytical test report		Required	Required						
	8.11. Shelf life		Required	Required						

B. Toxicity data

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical grade AI**	**Formulated product**		**Technical grade AI**	**Formulated product**	
B.1.	**Acute toxicity tests**									
	1.1. Acute oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.2. Acute dermal toxicity/infectivity (i.e.,LD_{50} expressed as mg/kg of body weight)	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.3. Acute inhalation toxicity (LC_{50} in mg/L)	Required	Required	Required	Required	Required	Required	Required	Required	Required
B.2.	**Irritation tests**									
	2.1. Primary skin irritation	Required	Required	Required	Required	Required	Required	Required	Required	Required
	2.2. Eye irritation	Required	Required	Required	Required	Required	Required	Required	Required	Required
B.3.	**Allergy/sensitization test**	Required	Required	Required	Required	Required	Required	Required	Required	Required
B.4.	**Sub-chronic toxicity tests in (minimum of oral test of 90 days duration in rats)**	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	
B.5.	**Reproduction effects studies (minimum of two generations in rats)**	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	
B.6.	**Teratogenicity studies (in two species, one in rats and other in non-rodents)**	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	
B.8.	**Mutagenicity studies (minimum of Ames test and in vivo micronucleus test)**	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats**	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	
B.10.	**Medical data/Poisoning symptoms/Antidote**	Required	Required	Required						

C. Bio-efficacy data and pest information

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	2A	2B	*2C*	2A	2B	*2C*	2A	2B	*2C*
S. No.	Data parameters	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration
		Technical grade AI	Formulated product		Technical grade AI	Formulated product		Technical grade AI	Formulated product	
C.1.	**Bio-efficacy and pest information**									
	1.1. Pest (Common/Scientific Name)	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	1.2. Dosage/rate of application	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	1.3. No. of applications	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	1.4. Application Method (e.g. dusting/spraying (high volume/low volume/ultra low volume, etc.)/Appliances	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
C.2.	**Crop/Commodity information**									
	2.1. Crop/Commodity (Common/Scientific name)	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	2.3. Pre-harvest intervals	Not required	Required	Required	Not required	Required	Required			
C.3.	**Field trials planning/design (location/climatic data/statistical design/plot size/controls/ replications)**	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
C.4.	**Pesticide/MCPA evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
C.5.	**Method of sampling**	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
C.6.	**Recording field data**	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
C.7.	**Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence**	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required

D. Residue data

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	2A	2B	*2C*	2A	2B	*2C*	2A	2B	*2C*
S. No.	Data parameters	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration	Proprietary registration		Supplementary registration
		Technical grade AI	Formulated product		Technical grade AI	Formulated product		Technical grade AI	Formulated product	
D.1.	**Plant metabolism**									
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	1.3. Crop groupings	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	1.4. Use of radio labelling material (C-14, P-32, S-35)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	1.5. Dosage rate (at least equal to intended use)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	1.6. Identification & characterization of residues	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
D.2.	**Farm animal metabolism**									
	2.1. Species to be used (ruminants viz., lactating cows, goats) and poultry chicken	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	2.5. Parental compounds should be used	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
D.3.	**Farm animal feeding studies**									
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical grade AI**	**Formulated product**		**Technical grade AI**	**Formulated product**	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	3.5. Material used: usually parent compound.	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
D.4.	**Processing Studies**									
	4.1. Data on transfer of residues into processed commodities	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.4. Glasshouse trials (protected crops)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.5. Post-harvest treatment studies (wheat, potato)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical grade AI**	**Formulated product**		**Technical grade AI**	**Formulated product**	
	4.7. Decline Studies (4 sampling intervals, i.e., five samples) Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
D.5.	**Analytical methods/standards for residue determination**									
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	5.2. Analytical standards/reference chemicals	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required

E. Environmental data

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical grade AI**	**Formulated product**		**Technical grade AI**	**Formulated product**	
E.1.	**Human health exposure effects**									
	Operators exposure data (dermal exposure/ inhalation exposure, biological monitoring)	Required	Required*	Required*	Required*	Required*	Required*	Required*	Required*	Required*
	Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring)	Required	Required*	Required*	Required*	Required*	Required*	Required*	Required*	Required*
* Required only if the pest control agent proved to have allergic/toxic effects to human beings										
E.2.	**Evaluation of environmental fate & effects**									
	3.1. Data on translocation of pesticides in soil and water	Required								

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***	**2A**	**2B**	***2C***
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical grade AI**	**Formulated product**		**Technical grade AI**	**Formulated product**	
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)		Not required	Not required	Not required	Not required	Not required	Required	Required*	Not required
	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators etc.)	Required	Not required	Not required	Not required	Not required	Not required	Required	Required*	Not required
	3.3. Primary data on aquatic toxicity (e.g., fish and other aquatic animals)	Required								
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)		Not required	Not required	Not required	Not required	Not required	Required	Required*	Not required
	2.4. Primary data on phytotoxicity effects		Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	3.4. Primary data on persistence/translocation in plants	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	2.6. Primary data on treatment of effluents & disposal		Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
* Required if the TGAI of MCPA not registered in the country and only formulated product is required to be imported.										
E.4.	**Monitoring of environmental effects**									
	4.1. Monitoring of substantial change in use/application pattern	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests etc.)	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required
E.5.	**Post-registration data generation (occurrence of toxic residues and or/possible biological effects including pesticide resurgence/resistance)**	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required	Not required

F. Labelling/Packaging/Storage data

		Chemical Pesticides (CP)			Biochemical Pesticides (BPCA)			Microbial Pesticides (MCBP)		
	Annex:	**2A**	**2B**	***2C***	***3A***	**3B**	**3C**	**4A**	**4B**	**4C**
S. No.	**Data parameters**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**	**Proprietary registration**		**Supplementary registration**
		Technical grade AI	**Formulated product**		**Technical Concentrate of BPCA**	**Formulated product of BPCA**		**Active agent of MCPA**	**Formulated product of MCBP**	
F.1.	**Labelling**									
	1.1. Chemical name/Common name of MCPA	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.2. Product name	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	1.3. Formulation/contents of the product	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	1.4. Quantity (Wt/Vol.)	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.5. Registration Number/date of registration/date of expiry and or/import permit number/date of issue, where applicable	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.6. Manufacture licensing number/date of issue	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.7. Batch Number	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.8. Manufacturing date	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.9. Date of expiry of product	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.10. Precautions & Directions for use	Not required	Required	Required	Not required	Required	Required	Required	Required	Required
	1.11. Warning phrases & Symbols	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.12. Storage conditions	Required	Required	Required	Required	Required	Required	Required	Required	Required
	1.13. Recommended crop/commodity	Not required	Required	Required	Not required	Required	Required	Not required	Required	Required
	1.14. Pre-harvest intervals	Not required	Required	Required	Not required	Required	Required			
	1.15. Restrictions, if any	Not required	Required	Required	Not required	Required	Required			
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	Required	Required	Required	Required	Required			
	1.17. Manufacturer							Required	Required	Required
F.2.	**Packaging**									
	2.1. Specification of primary package	Not required	Required	Required	Not required	Required	Required	Required	Required	Required
	2.2. Specification of secondary package	Not required	Required	Required	Not required	Required	Required	Required	Required	Required
	2.3. Specification of bulk package for transport	Required	Required	Required	Required	Required	Required			
	2.4. Sterile packing condition							Required	Required	Required
F.3.	**Storage tests (Shelf life)**	Required	Required	Required	Required	Required	Required	Required	Required	Required
* Minimum data requirements have been finalized after taking into consideration of data requirements of Malaysia, Thailand and Philippines										

Modality for the implementation of the harmonized system in Southeast Asia

The following modalities were suggested to sustain the harmonization process initiated by the project:

i) put forth all guidelines developed under this project for adoption by the pesticide regulatory authorities of member countries and to review the existing regulations in line with the guidelines.

ii) provide assistance to member countries like Cambodia, Lao PDR and Myanmar to build-up their capacity to enable them to ratify international conventions as soon as possible; assistance should also be given for reviewing existing regulations and for adopting the guidelines developed under this project.

iii) set up a networks comprising of National Project Coordinators and technical experts of relevant government agencies to review periodically the progress of harmonization of pesticide management and render technical guidance to the member countries, if necessary.

2.1.3. Conclusions

National pesticide regulations have been established in all seven member countries to control pesticide use and to ensure food security without compromising safety to human health and the environment. However, the regulatory approaches adopted by each country are different due to national priorities.

The adopted guidelines outline the registration process and types of registrations, and provide minimum data requirements for the registration of chemical, biochemical and microbial pest control agents in line with the recommendations in the FAO *Addentum to the Guidelines for the registration and control of pesticides* (1988) and the FAO *Guidelines for the Registration of biological pest control agents* (1988). In some cases, the tables give greater details. The data requirements for biochemical and microbial pest control agents partially overlap with the recommendations in the *Guidelines for the Requirements for Biopesticide Registration* developed under the TCP project and would need to be harmonized so that minimum data requirements would be available for all types of pest control agents and the different types of registrations.

Instead of giving separate data requirement tables for each sub-category, it may be more practical to summarize the data requirements for each kind of pest control agent and indicate which data is required for which type of registrations.

2.1.4. Recommendations

Recommendation 1

Member countries should adopt the guidelines on pesticide registration harmonization developed under the TCP project and publish them in the official gazette to give them legal status. They should also provide adequate infrastructure to the Pesticide Regulatory Division or Unit including qualified and adequately trained manpower, especially in pesticide chemistry, medical toxicology and bio-efficacy, to speed up the process of critical and accurate evaluation of the data dossiers for the registration of pesticides in line with the FAO guidelines on pesticide registration harmonization.

Recommendation 2

Member countries should review periodically the status of implementation of the FAO Code of Conduct and other international conventions; further, they should develop an action plan for implementation and campaigns, and constitute a monitoring committee with all stakeholders including pesticide industry.

Recommendation 3

Member countries should agree on a harmonized data protection procedures and a common data protection period and publish them in the official gazette.

Recommendation 4

Member countries should adopt the modalities given below for sustaining the harmonization process initiated by the FAO-TCP project:

i) Put forth all guidelines developed under this project for adoption by the concerned pesticide regulatory authorities of the member countries and make amendments to their existing regulations so that they are in line with the harmonized guidelines. The harmonized guidelines should be published in the official gazette. This would greatly facilitate pesticide registration harmonization among the member countries.

ii) Assistance should be given to member countries like Cambodia, Lao PDR, Myanmar and Vietnam under the ASEAN umbrella to build-up their capacity to strengthen the existing pesticide regulations. This would greatly help these countries to adopt the guidelines developed under the TCP project as also to implement the FAO Code of Conduct and other international conventions relating to pesticides.

iii) Set up a network among National Project Coordinators and technical experts from relevant government agencies to review periodically the progress of harmonization of pesticide registration in the member countries and exchange experiences in order to further strengthen pesticide management in the region.

2.2. Summary and analysis of biopesticide registration requirements

2.2.1. Introduction and background

Biopesticides are either of botanical origin or microbial pathogens of insects and mites. The mode of action of these products is different from synthetic chemical pesticides and hence the data requirements for registration need to be different, too. Generally, the following types of biological pest control agents are considered for registration under relevant regulatory laws and rules:

i) phytochemicals toxic to pests and extracted from plants (botanical pesticides),
ii) microbial (microorganisms) pesticides (nematodes, algae, protozoa, bacteria, fungi and viruses),
iii) pheromones and other non-toxic semiochemicals (biochemicals),
iv) invertebrate biocontrol agents (macrobials) such as insects or mites.

In a strict sense, only those products that have a natural origin such as plants or microbes and do not contain synthetic chemical moieties are considered to be biopesticides or biological pesticides. Some countries also regulate Plant-Incorporated-Protectants (PIP) in genetically modified plants as biopesticides.

Advanced regulatory authorities such as the European Union, Canada, and the United States have special data requirements for the registration of biopesticides. OECD, EU and NAFTA arrived at consensus agreements for a harmonized regulatory process for various biopesticides. However, with the great diversity of biological pest control agents it is not always clear which product is classified as a biopesticides.

2.2.2. Summary of country status

- The eight Southeast Asian countries have registered certain formulations of biopesticides such as neem, rotenone and other products that were in style during the last decades.
- Cambodia has no specific procedure for biopesticide registration.
- Lao PDR has private companies that import biopesticides from Thailand, Vietnam and China. The rules and regulation for the control of pesticide require minimum data for the registration of biopesticides.
- Malaysia uses the EPA definition for biopesticides. Six active ingredients of biopesticide have been registered, namely azadirachtin, *Bacillus thuringiensis*, garlic oil, *Matarhizium*, spinosad and sethoxydim (phytochemical herbicide). Overall, 42 formulated biopesticides products have been registered.
- Myanmar has developed registration requirements for conventional biopesticides, biochemical pesticides and microbial pesticides. This includes living pest control agent, botanical pesticide, semiochemical pesticide, biochemical pest control agent and microbial pest control agent.
- Thailand distinguishes between biopesticide and biocontrol agents. A dossier is required for biopesticide registration. There are separate data requirements for microbial pesticide registration and for botanical pesticide registration. A total of 15 biopesticides have been registered.
- Vietnam requires the same data for biopesticides as for chemical pesticides. Most of biopesticides are imported from India and China. Some pesticides such as *Metarhizium, Sarcocystis and Beauveria* are produced in the country.

2.2.3. Project outputs

Guidelines for the registration of biopesticides for Southeast Asian countries

The guidelines on biopesticide registration harmonization were adopted by the project management committee meeting in November 2011. Their main objective was to assist countries in Southeast Asia towards achieving harmonization in the biopesticide regulatory process in line with provisions of FAO Code of Conduct on Pesticides. The pesticide registry of each country may evolve suitable information in order to harmonize the biopesticide registration process.

The pesticides included in these guidelines are a) phytochemicals, b) pheromones and c) microbials.

The guideline document contains the following sections:

1. Introduction
2. Scope and objectives
3. Background
4. Definitions
5. Guidelines
    i. Information requirements for botanical biopesticides
    ii. Information requirements for microbial biopesticides
    iii. Information on biocontrol agents such as predators or parasioids (regulation on this may be at the discretion of individual countries)
    iv. Behaviour modifying chemicals – Pheromones
6. References

Data requirements for registration of pesticides

The annexes of the guidelines were reorganized in such a way that Annex A gives the lists of recommended data requirements for concentrated and formulated phytochemicals, pheromones and microbial pest control agents, while Annex B gives the tables for harmonized data requirements for the registration of various biopesticides together with useful information on specification standards, bioassay methods and minimum infrastructure facilities for manufacturers of biopesticides. Finally, Annex C summarizes the issues involved with harmonization.

The tables with the data requirements for registration were summarized in the table below so that similarities and differences for the various categories could be easily seen. While there are clear patterns, the tables also reveal some inconsistencies that would need further explanations or corrections.

The following observations can be made:

- Data requirements for registration of biopesticides are mentioned in different parts of the guidelines: the main text, Annex A, Annex B and Annex C. For example, for the registration of botanical pesticides, the guidelines mention five broad areas, Annex A lists more than 80 data requirements, Annex B lists 13 requirements and Annex C identified six general areas crucial for harmonization. Thus, harmonize data requirements are not clearly identified and countries need to select those that are suitable for them.
- Information requirements for biological control agents are given in the main text of the guidelines but are not mentioned in the annexes.
- While some registration systems have no specific requirements for pheromones, a list of data requirements is given in Annex A.

- While much valuable information is provided, there are still questions with regard to which type of biological pest control agent should be included in the harmonized biopesticide registration requirements.

Table: Locations of data requirement information in the guideline document

Type of biopesticide	Guidelines	Annex A	Annex B
Phytochemicals – technical grade	x	x	x
Phytochemicals – formulation	x	x	x
Microbial pesticides	x	x	x
entomotoxic bacteria			x
NPV/GV			x
entomopathogenic fungi			x
antagonistic fungi			x
antagonistic bacteria			x
Pheromones	x	x	
Biocontrol agents	x		

- While the overall table on microbial pesticides does not require data for certain categories, such data are required in the tables on particular microbial pesticides (e.g. toxicity of mother cultures and data for provisional registration).
- It is not apparent why some data are required for one type of biopesticide while not for another.
- For some types of biopesticides, requirements are listed in detail, while for other types, the same requirements are given generally.
- The information tables destingish between technical grade and formulated biopesticides for phytochemicals and entomotoxic bacteria, but not for the other types.
- The information tables give the data requirements for provisional and regular registration, but do not mention requirements for supplementary (me-too) registrations.
- Phytochemicals generally refer to any chemical compound found in plants. A definition is not included in the "definition of terms" and here the term presumably refers to botanical pesticides.
- It needs to be clarified whether non-toxic biochemicals should be part of the harmonized pesticide registration requirements.
- Information requirements for invertebrate biocontrol agents are given in the main text of the guideline, but no further details are given in the annexes. It needs to be clarified whether biocontrol agents should be part of the harmonized pesticide registration requirements.

Data requirements for the registration of biopesticides

Particulars	BOTANICAL PESTICIDES		MICROBIAL PESTICIDES		Entomotoxic bacteria				Baculoviruses NPV & GV		Entomopatho-genic fungi		Antagonistic fungi		Antagonistic bacteria	
Technical grade/Formulated product	Techn.	Form.			Technical		Formulation									
Provisional/Regular registration	Prov.	Reg.	Prov.	Reg.	Prov.	Reg.	Prov.	Reg.	Prov.	Reg.	Prov.	Reg.	Prov.	Reg.	Prov.	Reg.
A. BIOLOGICIAL CHARACTERISTICS AND CHEMISTRY																
Systematic name: (Genus, species, serotype)	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
Strain name	NR	NR	NR	R					R	R			R	R		
Common name	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
Cry toxin classification (delta endotoxin)					R*	R*	R*	R*								
Source of origin	R	R	R	NR					R	R	R	R	R	R	R	R
Natural occurrence of the organism and morphological description					R	R	R	R			R	R	R	R	R	R
Specification of the product	R	R	R	R					R	R	R	R			R	R
Physical specification					R	R	R	R								
Form and appearance					R	R	R	R								
pH, particle size, suspensibility, miscibility					R	R	R	R								
Composition of the product	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
CFU/g of the product											R	R	R	R	R	R
Viral Unit: POB/Capsule count pr ml/g of the product									R	R						
Percent content of the biocontrol organism in the formulation and nature of biomass									R	R	R	R	R	R	R	R
Percent of carrier/filler, wetting/dispersing agent, stabilizers/emulsifiers, containments/impurities etc.									R	R	R	R	R	R	R	R
Moisture content					R	R	R	R	R	R	R	R	R	R	R	R
Delta endotoxin content – through housefly bioassay test					R	R	R	R								
Beta Exotoxin content – to be ruled out through bio-efficacy test (housefly bio-assay method)					R	R	R	R								
Adjuvants					R	R	R	R								
Human pathogens (culture method)					R	R	R	R								
Other microorganisms (not more than 10^4)					R	R	R	R								
Chemical and botanical pesticide contaminants					R	R	R	R								
Manufacturing process	R	R	R	R					R	R	R	R			R	R
Test procedures and criteria for identification	NR	NR	NR	NR	R	R	R	R	R	R						
Pathogencity test on insect											R	R				

Particulars	BOTANICAL PESTICIDES		MICROBIAL PESTICIDES		Entomotoxic bacteria				Baculoviruses NPV & GV		Entomopatho-genic fungi		Antagonistic fungi		Antagonistic bacteria	
Technical grade/Formulated product	**Techn.**	**Form.**			**Technical**		**Formulation**									
Provisional/Regular registration	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**
Dual culture for antagonistic bacteria to attain at least 35% reduction in target organism															R	R
Method of analysis/biological assay	R	R	R	R												
Viral unit counts									R	R						
Biological assays for determining the LC_{50}/LD_{50} of the formulation									R	R						
Bioassay for NPV by the Diet Surface Contamination Method															R	R
Bioassay for GV against *Chilo infuscatellus*																
Bioassay for GV against *Plutella xylostella*											R	R				
Bioassay for GV against *Acheae janta*																
Morphology description, particle size					R	R	R	R								
Immunology assays: Elisa/Dot Blot assay test					R	R	R	R								
Potency of product by bioassay method (LC_{50} on target larvae and potency against a reference using artificial diet or leaf disc method or in the water for mosquito larvae					R	R	R	R								
Separation and purification of crystals required (R) if antisera is to be developed for the strains delta endoxin					R/NR	R/NR	R/NR	R/NR								
Qualitative analysis											R	R	R	R	R	R
CFU on selective medium											R	R	R	R	R	R
Contaminants	NR	NR	NR	R					R	R						
Pathogenic contaminants (*Salmonella, Shigella, Vibrio,* etc.)									R	R	R	R	R	R	R	R
Other microbial contaminants									R	R						
Chemicals and botanical pesticide contaminants									R	R	R	R	R	R	R	R
Moisture content											R	R	R	R	R	R
Shelf life																
Shelf life claim	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
Additional data in support of shelf life claim					R	R	R	R	R	R	R	R	R	R	R	R
Sample for verification	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R

Particulars	BOTANICAL PESTICIDES		MICROBIAL PESTICIDES		Entomotoxic bacteria				Baculoviruses NPV & GV		Entomopatho-genic fungi		Antagonistic fungi		Antagonistic bacteria	
Technical grade/Formulated product	**Techn.**	**Form.**			**Technical**		**Formulation**									
Provisional/Regular Registration	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**
B. BIO-EFFICACY																
Field studies	R	R	R	R					R**	R***	R**	R***	R**	*R****	R**	R***
Data on bioeffectiveness and phytotoxicity generated at approved institutes					NR	R***	R**	R***								
Data on non-target organisms: One season/one year data on the effect of the product on natural predators/parasites					NR	R	R	R			R	R			R	R
Laboratory studies	R	R	R	R							R	R				
Laboratory studies data on LC_{50} values for each target insect species should be generated at the approved laboratory					R	R	R	R	R	R			R	R	R	R
C. TOXICITY**																
Single exposure studies					R	R	R	R								
For mother culture	NR	NR	NR	NR												
Oral toxicity/pathogenicity					R	R	R	R								
Single dose oral (rat and mouse)									R	R	R	R	R	R	R	R
Inhalation toxicity/pathogenicity					R	R	R	R								
Single dose pulmonary									R	R	R	R	R	R	R	R
Single dose intravenous									R	R						
Dermal toxicity/pathogenicity					R	R	R	R								
Single dose dermal											R	R	R	R	R	R
Single dose intra-peritoneal											R	R	R	R	R	R
Cell culture									R	R						
Human safety records.									R	R	R	R	R	R	R	R
For formulation	NR	NR	NR	R												
For formulated products to be directly manufactured (mammalian toxicity)	NR	NR	NR													
Data on mother culture as above									R	R	R	R	R	R	R	R
Single dose oral (rat and mouse)									R	R	R	R	R	R	R	R
Single dose pulmonary									R	R	R	R	R	R	R	R
Primary skin irritation					R	R	R	R	R	R	R	R	R	R	R	R
Primary eye irritation									R	R	R	R	R	R	R	R

Particulars	BOTANICAL PESTICIDES		MICROBIAL PESTICIDES		Entomotoxic bacteria				Baculoviruses NPV & GV		Entomopatho-genic fungi		Antagonistic fungi		Antagonistic bacteria	
Technical grade/Formulated product	**Techn.**	**Form.**			**Technical**		**Formulation**									
Provisional/Regular registration	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**
Mucous membrane irritation					R	R	R	R								
Allergy/sensitization/immuno supression					R	R	R	R								
Human safety records									R	R	R	R	R	R	R	R
For formulated product to be directly manufactured: (Mammalian toxicity testing of formulations)																
Toxicity/Infectivity/Pathogenicity																
Single dose oral (rat and mouse)									R	R	R	R	R	R	R	R
Single dose pulmonary (intratracheal preferred)									R	R	R	R	R	R	R	R
Single dose dermal											R	R	R	R	R	R
Single dose intravenous									R	R						
Single dose intraperitoneal (infectivity)											R	R	R	R	R	R
Primary skin irritation									R	R	R	R	R	R	R	R
Primary eye irritation											R	R	R	R	R	R
Human safety records (effect/lack of effects)									R	R	R	R	R	R	R	R
Cell culture									R	R						
Environment safety testing/Eco-toxicology	NR	NR	NR	R												
Non-target vertebrates																
Mammals[a]									NR	R	NR	R	NR	R	NR	R
Birds(two species)/Toxicity to birds					NR	NR	NR	R	NR	R	NR	R	NR	R	NR	R
Fresh water fish[c]					NR	NR	NR	R	NR	R	NR	R	NR	R	NR	R
Non-target invertebrates																
Terrestrial invertebrates[d]									NR	R						
Soil invertebrates[e]									NR	R	NR	R	NR	R	NR	R
Toxicity to honeybees					NR	NR	NR	R								
Toxicity to silkworm					NR	NR	NR	R								
D. PROCESSING, PACKAGING AND LABELLING																
Processing																
Manufacturing process/process of formulation	R	R	R	R												
Raw material									R	R	R	R	R	R	R	R
Plant and machinery									R	R	R	R	R	R	R	R
Unit Process operation/Unit process									R	R	R	R	R	R	R	R
Out-put (Finished product and generation of waste)									R	R	R	R	R	R	R	R

Particulars	BOTANICAL PESTICIDES		MICROBIAL PESTICIDES		Entomotoxic bacteria				Baculoviruses NPV & GV		Entomopatho-genic fungi		Antagonistic fungi		Antagonistic bacteria	
Technical grade/Formulated product	**Techn.**	**Form.**			**Technical**		**Formulation**									
Provisional/Regular registration	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**	**Prov.**	**Reg.**
Packing																
Packaging requirements as per ISI or as per the approval of RC					R	R	R	R								
New packaging system approved by FAO/ASPM/ other global standards (relevant)					R	R	R	R								
Classification-solid, liquid or other types of product									R	R	R	R	R	R	R	R
Unit pack size – In metric system									R	R	R	R	R	R	R	R
Specification – Details of primary, secondary and transport pack					R	R	R	R	R	R	R	R	R	R	R	R
Compatibility of primary pack with the product as per approved national protocols									NR	R	NR	R	NR	R	NR	R
Labels and leaflets																
Common name, composition, antidote, storage, statements etc.	R	R	R	R					R	R	R	R	R	R	R	R
Labelling specification of primary packing					R	R	R	R								
Labelling specification of secondary packing					R	R	R	R								
Labelling specification of transport packing					R	R	R	R								
7 copies of L/Ls upto 250 ml					R	R	R	R								
7 copies of L/Ls upto 500 ml					R	R	R	R								

Abbreviations: R = required; NR = Not required

Please mention, any other data required/not required besides above in your country.

** Except parts or extract of neem including azadiractin (Toxicity)

** Except Bacillus thuringiensis aizawai, Bacillus thuringiensis kurstaki, Nuclear Polyhedrosis Virus (NPV), Nematode of Steinernema spp. (Neoaplectana spp.) and Heterorhabditis spp.

R* If H-Serotype is not known, it is mandatory to provide the details of Cry toxin to confirm that it is Bacillus thuringiensis

R** = Two seasons/years data on bioeffectiveness from minimum of two agro-climatic conditions

R*** = Two seasons/years data on bioeffectiveness from minimum of three agro climatic conditions

Modality for a sustainable process

It was proposed that a new *ASEAN Working Group on Pesticides* be formed under the SOM-AMAF mechanism in addition to various other working groups that have already been established. It was also proposed that the project management committee would be a member of this new working group. The working group will become a formal forum for ASEAN pesticide regulatory authorities to discuss matters related to pesticides control and management in the region including in harmonization efforts under the current FAO-TCP project.

2.2.4. Conclusions

- Registration of biopesticides also should be guided by the general requirements for pesticide registration process.
- The guidelines on the registration of biopesticides describe general pesticide registration procedures as well as specific data requirements for biopesticides. The general aspects overlaps with the guidelines for the harmonization of pesticide registration requirements.
- There is a need to discriminate the regulatory requirements between botanical origin biopesticides and microbial biocontrol agents.
- Recommendations on the harmonization of biopesticide registration are contained in two guidelines under this TCP project: (1*) Guidelines for Harmonization of Pesticide Registration Requirements*, and (2) *Guidelines on Data Requirements for the Registration of Biopesticides*. For the most part, each of the guidelines covers different types of registrations and different categories of biopesticides as shown in the following table:

Sources of biopesticide registration requirements

Type of registration / Type of biopesticide	Technical grade			Formulated product		
	Provisional	Proprietary	Supplem.	Provisional	Proprietary	Supplem.
	Guideline*					
Biochemicals		I	I		I	I
Botanical pesticides/phytochem.	II	II		II		
Microbial pesticides		I	I	II	I, II	I
entomotoxic bacteria	II	II		II	II	
NPV/GV				II	II	
entomopathogenic fungi				II	II	
antagonistic fungi				II	II	
antagonistic bacteria				II	II	

* I = Guidelines for Harmonization of Pesticide Registration Requirements
II = Guidelines on Data Requirements for the Registration of Biopesticides

- The major differences with regard to biopesticides between the two guidelines are:
  - Data requirements for biochemicals are only mentioned in Guideline I, not in Guideline II.
  - Guideline I deals with proprietary and supplementary registration requirements, while Guideline II deals only with provisional and proprietary registrations.
  - The only overlap between the two guidelines is the registration requirements for proprietary registration of formulated microbial pesticides; there are considerable differences between the two sets of recommendations.
  - Data requirements for the registration of biocontrol agents are only mentioned in the text of Guideline II, not in its annexes.

2.2.5. Recommendations:

Based on the above aspects, the following recommendations were made:

- The registration of biopesticides should follow the project-approved guidelines for biopesticides.
- The member countries may adjust their national policies to facilitate the harmonization of the pesticide registration process.
- The pesticide registration systems need to be funded by governments or generate their own funds. The registration process that generates its own revenues must ensure adequate financial transparency. Government-supported special research in universities should develop expertise for handling issues of biopesticide registration. Private-public investments may also be considered in this regard.
- An annual conference of pesticide registries of all countries should be creates as an ideal platform for exchange of information and for planning next year's implementation agenda. A SWOT analysis of the current implementation status of the harmonization process in each country should be part of the conference. A systematic exchange of information along with educational programmes for experts would strengthen and facilitate the registration process.
- The annual conference should also review biopesticide labelling, registration, appeal by the applicants, monitoring status of registration, conditional registration, amendments to previous registration, re-registration, denial of registration, supplemental registration, licensing of manufacturing and repacking facilities, licensing of stockiest and distributors, licensing of pest control operators, etc.
- Capacities of regulatory systems to handle science-based and knowledge-driven registration and post registration enforcement need to be enhanced.
- Professional and innovative media-supported (print, audio and electronic) education programmes on bio-control pesticide regulations and good agricultural practices using biopesticides should be developed for all stakeholders, including farming families.

The following recommendations should also be considered:

- The proposed registration requirements for biopesticides in different guidelines should be unified in a single document that covers all categories of biopesticides and all types of registrations.
- More consultations among the countries are needed to arrive at unified lists of minimum data requirements for the registration of different biopesticides that could serve as the basis for regional harmonization.

2.3. Summary and analysis of bio-efficacy testing requirements

2.3.1. Introduction and background

Since many of the FAO efficacy test protocols for insecticides, fungicides and herbicides were developed in 1990-92 and are thus 20 years old, they require updating in light of new detailed guidelines published by FAO in June 2006 and the EPPO standards for the efficacy evaluation of plant protection products which were adopted in 2009-10.

The proposed modality gives guidance to Southeast Asian countries for preparing bio-efficacy test protocols with regard to the number of trials to be conducted for a major pest on a major crop or for minor uses; number of replications and plot size to be taken; doses of pesticides to be considered; type, time and frequency of assessment; and guidance on phytotoxicity assessment. Furthermore, there is a need to follow good experimental practices which are increasingly applied to efficacy studies of plant protection products. It is essential that efficacy trials are conducted in a scientific manner and follow international standards without disturbing the basic format of the guidelines. Without such guidance, variable parameters would be applied to the evaluation of pesticide efficacy, resulting in inconclusive data for registration.

The provisions of the guidelines and the test protocols shall enable an evaluation of pesticide efficacy in a more harmonized manner. This would help registration authorities to evaluate a registration application more easily, thus improving the efficiency and cost effectiveness of the registration process.

2.3.2. Summary of country status

All Southeast Asian countries have provisions for evaluating the efficacy of pesticides before registering a product. There exist reasonable laboratory facilities and qualified staff to conduct such efficacy trials. In some countries like Malaysia, Thailand and Philippines, bio-efficacy test protocols are approved by the concerned departments and communicated to the collaborators before the start of the trials. Thus registrants and registration authorities are involved in the conduct of the trials from the beginning to the end.

Yet, there exist substantial differences in a number of aspects. By and large, a maximum two trials in one season are considered sufficient for accepting the efficacy data in most countries. This also applies to major pests in major crops when there is an urgency of bringing a product in the market and saving experimentation costs. However, this is not in line with international guidelines which suggest that 8-10 trials are conducted for major pests on a major crops and 2-6 with for minor uses. To obtain a high degree of confidence in the trial results, they should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons.

In many countries, bio-efficacy trials are conducted far away from the Departments of Agriculture, which reduces the supervisions of the trials by the officials concerned.

In Thailand full bio-efficacy trials are conducted for an already registered product with same active ingredient for approval of a new trade name because it is feared that even the same technical material in a different formulation may behave differently. While the efficacy of a product largely depends on the active ingredient, the formulations may show symptoms of phytotoxicity on crops due to different inert materials. As such, data may be necessary for phytotoxicity but not for bio-efficacy. A full-scale efficacy trial is time-consuming and involves costs which can be avoided.

In Malaysia and Thailand, a product is presently registered for a period of 5-6 years and new bio-efficacy data is needed for re-registration because pests may have developed resistance to the product. Since the

generation of valid bio-efficacy data may take 2-3 years, the registration period of 5 years appears very short and not proportional to the use of time, costs, equipment and manpower needed for the field trials. It could be avoided unless the product shows signs of inefficacy or other environmental problems like resistance or resurgence of the pest.

In Thailand petroleum products are tested for the control of insect pests in the field and treated like pesticides for the purpose of registration. Even though petroleum products do not fall under the category of pesticides, their effects on the environment may be substancial.

Since the screening of bio-efficacy data for insecticides, fungicides and herbicides involves entomology, plant pathology and herbology, experts of these three disciplines are needed.

Specifically, the following procedures exist in the member countries:

Malaysia

The country has adopted the FAO guidelines for bio-efficacy data generation. Efficacy trials are conducted under local or similar climatic conditions. Evaluations of crop safety, pest resistance and effects on natural enemies are part of the registration requirement. Any claim of efficacy on the label must be substantiated with data. Pesticides rules require the following information for registration: proposed uses and recommendations rates; evidence that the pesticide performs as claimed; data on compatibility; available evidence on safety on crops and other hosts; and effects of pesticides on parasitoids and predators.

For herbicides registration, at least two seasons of trials in two locations are required. For other products, a minimum of one season in two locations is required.

Thailand

The country requires three phases of trials, namely 1) preliminary experiment, 2) provisional clearance and 3) final evaluation for registration. The DOA has issued a guidance for efficacy tests for agricultural hazardous substance which are based on FAO guidelines. For the preparation of bio-efficacy test protocols, six steps are to be followed.

The following protocols are currently available for bio-efficacy tests in Thailand:

95 protocols for insects, mites, snail and rats;
26 protocols for plant diseases; and
67 protocols for weeds.

There is a need for five efficacy test protocols for thrips, beet army worm, fruit flies, leaf miner and cotton bollworm to be developed.

Myanmar

Biological efficacy data are required for registration. Importers, manufacturers or distributers should carry out the field trials. After completion, the results should be submitted for evaluation.

Local efficacy trials have been conducted on 38 insecticides, 28 fungicides and 30 herbicides.

Philippines

There are guidelines and standards for bio-efficacy test protocols. A company requesting registration of a pesticide must file an application in a prescribed form. Accredited researcher who have undergone training on bio-efficacy protocol evaluation and are approved by the Fertilizer and Pesticides Authority of the Philippines conduct the trials.

2.3.3. Project outputs

Guidelines for the preparation of bio-efficacy test protocols

The guidelines are divided into two parts:

a. Chemical insecticides, fungicides and acaricides
b. Herbicides

The annex contains 25 test protocols for:

Armyworms on Rice
Mealy bugs on Cassava
Flea beetle on Cabbage
Tirathaba sp. on Corn
Pomacea in Rice
Thrips on Eggplant
Leafminer on Chrysanthemum
Weeds in Groundnut
Pod borer on Green gram
Anthracnose of Mango
Shoot and Fruit borer on Eggplant
Spodoptera on Tomato
Thrips on Orchid
Thrips on Citrus
Dirty Panicles of Rice
Spodoptera on Grape
Mealy bug on desert Rose
Bollworm on Asparagus
Powdery mildew of Cucumber
Weeds in Mango
Weeds in Marigold
Weeds in Chinese kale (Broccoli)
Weeds in Cassava
Club root of Cabbage
Gram pod borer in Chickpea

Modality for the implementation of the harmonized system in Southeast Asia

The following views for sustainability the efforts on harmonization of bio-efficacy test protocols requirements in Southeast Asia were expressed:

A new ASEAN Working Group on Pesticides should be formed under the SOM-AMAF mechanism similar to other working groups. The working group would become an official forum for ASEAN pesticide regulatory authorities to discuss matters related to pesticides control and management in the region, including the harmonization efforts initiated under the FAO-TCP Project. The project management committee should be a member of this working group.

If it is not possible to establish a new working group, the matters related to pesticides control and management should be included in one of the existing ASEAN working groups such as the Working Group on Crops or Good Experimental Practices (GEP).

2.3.4. Conclusions

It is essential that efficacy trials follow international standards and good experimental practices (GEP) so that the results can be used with confidence by the different registration authorities. GEP is concerned with organization, design, conduct, interpretation and reporting of efficacy trials, so that the results are reliable and comparable. GEP provides guidance on various aspects such as organization and staff qualifications, equipment and facilities, trial protocols and operating procedures as well as recording and verification of results.

The proposed modality gives guidance to Southeast Asian countries for preparing bio-efficacy test protocols with regard to the number of trials to be conducted for a major pest on a major crop or for minor uses; number of replications and plot size to be taken; doses of pesticides to be considered; type, time and frequency of assessment. It also provides guidance on phytotoxicity assessment of pesticides by indicating a scale of common phytotoxicity symptoms. In the absence of such a common scale, each worker would develop his own scale which would lead to variable results. The inclusion of major phytotoxicity symptoms in the efficacy test protocols on individual crops will make it easier to assess them. Finally, the modality provides guidance for the reporting of the trial results so that registration authorities can evaluate the efficacy of the product.

Since biological insecticides have different evaluating parameters and they may be used in combination with IPM, their level of efficacy may need to be assessed in combination with other measures.

Implementing the proposed modality for the preparation of efficacy test protocols would lead to the use of the same parameters for the evaluations of pesticides efficacy and therefore the results could be easily shared among Southeast Asian countries.

2.3.5. Recommendations

For complete harmonization:

- Adoption of the proposed modality for the preparation of efficacy test protocols;
- Adoption of the new efficacy test protocols;
- Adoption of the 40 modified FAO bio-efficacy test protocols;
- Review of the existing efficacy test protocols within Southeast Asia and preparation of new test protocols using the new modality guidelines for preparation of efficacy test protocols.

For partial harmonization:

- Implementation of Good Experimental Practices (GEP) by Southeast Asian countries;
- Updating the guidelines on efficacy evaluations which are available in Southeast Asian countries;
- Capacity building and up-gradation of skills of the workers who are conducting efficacy evaluations of pesticides.

2.4. Summary and analysis of pesticide labelling requirements

2.4.1. Introduction and background

Pesticide labels are very important since they provide information to the user about how to use the products correctly for effective pest control and how to handle them safely to avoid adverse effects to the applicator, non-target organisms or the environment. The labels provide essential warnings and safety precautions to be observed by transporters, distributors, retailers and users. In many countries pesticide labels are considered legally binding documents, and it is illegal to use a product inconsistent with its label.

Pesticide labels provide the user with the following information: (i) how to identify it as a registered product; (ii) what is in the container; (iii) the hazard it represents; (iv) associated safety information; (v) directions for use; and (vi) supplier identification.

In order to ensure that labels are read, understood and followed, it is important that they are kept as simple and direct as possible, but without omitting important messages, information and symbols for their effective and safe use. Labels that are too complex, too technical or too difficult to understand will discourage the users from reading then. The use of symbols and pictograms to indicate hazards, advice and instructions are very useful, especially for farmers in developing countries with limited reading abilities. Therefore, it is a great challenge to design labels that contain clear directions which can be easily understood by all potential users.

Lastly, labels should be physically durable. They should be resistant to the normal wear and tear during transport, storage and use. These requirements apply equally to the print on the label and the material on which the information is printed. Sometimes, a product may be stored for several years before it is finally used. If the label would fade or tear off during this period, the pesticide product could become a serious potential hazard if its properties are unknown and it would be handled incorrectly.

Currently, there exist different international pesticide labelling and classification systems. The three main classification and labelling guidelines are:

(i) FAO Guidelines on Good Labelling Practice for Pesticides, 1995, and the revised draft version of 2009;

(ii) WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification, 2004 and 2009; and

(iii) Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

It is important to harmonize pesticide labels in Southeast Asia because (i) in certain countries, there is a rampant distribution and use of pesticides with labels in foreign languages; (ii) unregistered pesticides are sometimes illegally imported without proper labelling and (iii) pesticide are often used in violation of label recommendations. Therefore, enforcement of label requirements is an important aspect of pesticide management. During the development of these harmonized guidelines, existing labelling systems and regulations in selected Southeast Asian countries were considered.

2.4.2. Summary of country status

- All countries have already appropriate legislations in place for the legal requirement of pesticide labelling.
- All countries have adopted the FAO Guidelines on Good Labelling Practice for Pesticides (1995) and require the following information on the labels:

a) Information to identify the product
b) Hazard and safety information
c) Instructions to use the product
d) Other relevant information

- All countries have adopted the WHO Recommended Classification of Pesticide by Hazard. While some countries follow exactly the FAO Guidelines and WHO Scheme, others made slight modifications to suit local conditions.
- So far, none of the countries requires pesticides to be classified and labelled according to the GHS system.

Table: Comparison of pesticide label requirements in Southeast Asian countries

	Cambodia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam	Harmonized Standard
1. Product trade name				x	x	x	x	x	x
2. Product use category					x		x		x
3. Formulation type by International Formulation Coding System					?		x	x	x
4. Active ingredient name					x	x	x	x	x
5. Active ingredient content					x		x	x	x
6. Registration number as assigned by the authority				x	x	x	x	x	x
7. Name, address and telephone number of registrant					x	x	x	x	x
8. Net contents					x	x	x		x
9. Batch number					x				x
10. Manufacturing/formulation date					x		x	x	x
11. Expiry date (optional)							x	x	(x)
12. General safety statements					x	x	x		x
13. Directions for use (in table form)				x	x	x		x	x
14. Withholding period (use of harmonized pre-harvest interval or pre-slaughtering interval statements)					x	x		x	
15. Re-entry period						x			
16. Safety statements (use of harmonized standard precautionary statements and warning phrases)				x	x			x	x
17. Good agricultural practice (GAP) statements (use of harmonized statements)									x
18. First aid instructions				x	x	x	x	x	x
19. Symptoms of poisoning						x	x		
20. Medical treatments/advice to doctors							x		
21. Physical hazard symbol									x
22. Physical hazard statement									x
23. Health hazard symbol									x
24. Health hazard statement				x	x	x			x

	Cambodia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam	Harmonized Standard
25. Color band						x		x	x
26. Environmental hazard symbol									x
27. Environmental hazard statement									x
28. Signal word									x
29. FAO/CropLife safety pictograms						x		x	x
30. Standardized panel layout									
Other:									
Storage-disposal					x	x			
Warrenty									

Table: Summary of hazard classifications and symbols for pesticide labelling in Southeast Asia

	Cambodia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam	Harmonized Standard
Class Ia									
Class Ib									
Class II			*(No symbol)*	*(No symbol)*					
Class III	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*		*(No symbol)*	*(No symbol)*		
Table 5 (Class IV)	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*	*(No symbol)*

Table: The summary of hazard statements for different hazard classes that are currently being used in ASEAN countries

	Cambodia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam	Harmonized Standard
Class Ia	VERY TOXIC	VERY POISONOUS	EXTREMELY TOXIC	VERY HIGHLY POISONOUS	DANGER	DANGER: POISON	VERY TOXIC	VERY TOXIC	Danger
Class Ib	TOXIC	POISONOUS	HIGHLY TOXIC	HIGHLY POISONOUS	POISON	WARNING: HARMFUL	TOXIC	HIGHLY TOXIC	Danger
Class II	HARMFUL	HARMFUL	DANGEROUS	POISONOUS	WARNING	CAUTION	HARMFUL	TOXIC	Danger
Class III	CAUTION	CAUTION	ATTENTION	HARMFUL	WARNING	*(No hazard statement)*	CAUTION	CAREFUL	WARNING
Table 5 (Class IV)	*(No hazard statement)*	*(No hazard statement)*	*(No hazard statement)*	*(No hazard statement)*	*(No hazard statement)*	*(No hazard statement)*	*(No hazard statement)*	*(No hazard statement)*	

Table: The summary of hazard color band for different hazard classes that are currently being used in ASEAN countries

	Cambodia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam	Harmonized Standard
Class Ia-1	Red	Brown	Red	Black	Red	Red	Red	Red	Red
Class Ib-2	Red	Red	Red	Red	Red	Red	Red	Red	Red
Class II-3	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Class III-4	Blue	Blue	Blue	Blue	Blue	Blue	Blue	Blue	Blue
Table 5-5 (Class IV)	*(No color)*	Green	Green	*(No color)*	Green	Green	Blue	Green	Green

2.4.3. Project outputs

Guidelines of harmonized pesticide labelling requirements for Southeast Asian countries

Three main classification and labelling guidelines for chemicals or pesticides were considered for the development of the harmonized guidelines i.e.

(i) FAO Guidelines on Good Labelling Practice for Pesticides (1995) and the draft Revised Version, (2009);
(ii) WHO Recommended Classification of Pesticides by Hazard (2004, 2009) and
(iii) Globally Harmonized System for Classification and Labelling of Pesticides, 2009 (GHS).

The proposed guidelines for Southeast Asian countries do not differ from those referred above. They were developed with the objective of helping pesticide regulatory authorities and pesticide registrants and ensuring that pesticide products in this region will be classified and labelled in accordance with international principles. It is important that proper labels provide information to the user on how to use the product correctly for effective control of intended pests, and to provide information regarding hazards and how to handle them safely to avoid any adverse effects to applicators, non-target organisms and the environment. The guidelines also stress the benefits and advantages of cooperation and collaboration between countries in matters related to pesticide regulatory system including pesticides labelling and classification as promoted and encouraged under the Code of Conduct.

The document is divided into four sections: (1) introduction, (2) label contents, (3) designing a label and (4) hazard/risk classification.

Modality for the implementation of the harmonized pesticide labelling in Southeast Asia

The following steps were proposed for implementing the harmonized labelling guidelines:

(i) Adoption of the guidelines
(ii) Revising national legislations
(iii) Training and education about new labelling requirements
(iv) Commitment of participating countries to allocate resources and expertise
(v) Sustainability of the efforts through ASEAN pesticide regulatory authorities (ASEAN working group on pesticides)

After considering all the options, it was proposed that a new ASEAN working group on pesticides be formed under the SOM-AMAF mechanism. It was also proposed that the PMC will be the member of this new working group. The working group will become a formal forum for ASEAN pesticide regulatory authorities to discuss matters related to pesticides control and management in the region including harmonization efforts initiated by the FAO-TCP Project.

The meeting also discussed the option that the progress of pesticide regulatory harmonization activities be reported to the Standing Committee on Pesticides Management under the Asia and Pacific Plant Protection Commission (APPPC) of FAO which meet every two years.

2.4.4. Conclusions

When preparing a pesticide label, it is also important to take into considerations some of the practical aspects of good, clear label design and layout and the use of optional pictograms. Therefore a special section on ‘Designing a label’ was included in the guidelines. Examples of different labels layout are given in order to show a clear application of the principles of good labelling. It is recommended that

these example labels are used as guidance not only by the pesticide authority but also by the industry which has to submit the proposed label for registration. This section specifically deals with;

(i) Layout of information on the label;
(ii) Labels for small packs/supplementary leaflets;
(iii) Style and wording of text;
(iv) Print size and style;
(v) Effective use of space; and
(vi) Use of color.

One of the important elements in pesticide labelling is hazards or risk classification. Besides providing information on how to use a product, the label also has to warn the user of the hazard of the pesticide and, where possible, of the risk of its specific use. Therefore the harmonized guidelines provide a section on 'Hazards/Risk Classification'. The document explains the three types of hazards to be shown on the pesticide label, i.e. physical hazards, health hazards and environmental hazards.

The physical hazard classification recommended for pesticide labels follows the GHS in terms of classification criteria and label elements. However, only eight out of sixteen physical hazards classification recommended under the GHS were found relevant for pesticide labelling and are included in these guidelines.

As for the health hazard, risk classification is preferred over hazard classification, because risk assessment takes into account the level of exposure to the pesticide. However, it is also recognized that risk assessments for local conditions may not always be feasible in Southeast Asia, and it may impossible to extrapolate risk assessments carried out elsewhere. Therefore for the purpose of the harmonized guidelines, classifications of acute and chronic health effects for labelling purposes are based on hazard classification instead of risk assessment. The label elements recommended by the GHS and FAO/WHO for the various health hazard categories are provided in the guidelines. For acute toxicity, signal words and hazard statements are required in addition to hazard symbols, and each hazard category will also be assigned a specific color band.

Similarly for environmental hazards of pesticides, a risk assessment is desirable over a hazard assessment. However, the GHS stipulates that the classification of environmental aspects should be done on the basis of a hazard classification. Under the harmonized guidelines, only classifications of aquatic hazards and hazards to the ozone layer are covered following the recommendations of the GHS.

Label elements crucial to be harmonized

It is crucial that the following label elements are made mandatory as harmonized requirements for the labelling of pesticide in Southeast Asia. It is recognized that most countries have already adopted the requirements of the FAO Guidelines on Good Labelling Practice for Pesticides (1995), and all countries have adopted the WHO Recommended Classification of Pesticide by Hazard. for hazard classifications, Therefore, the following label elements should appear on all harmonized labels:

1. Information to identify the product

a) Product trade name
b) Product category
c) Type of formulation
d) Active ingredient name
e) Active ingredient content
f) Name of any dangerous co-formulants (e.g. solvents, etc.)

g) Net contents
h) Batch number
i) Registration or approval number assigned by the Pesticides Authority
j) Name, address and telephone number of the registrant

2. Hazard and safety information

k) Appropriate symbol for physical, health and environmental hazard
l) Appropriate signal word depending on the hazard category
m) Appropriate hazard statement(s) depending on the hazard category
n) Appropriate color band depending on the hazard category
o) Appropriate safety statements to warn the user on the potential hazard
p) Safety/advice pictograms
q) First aid and medical advice

3. Use instructions

r) Directions for use to clearly indicate how, when and where the product can be legally used with maximum efficiency and safety

4. Other information

s) Product or user category
t) Good agricultural practice statements
u) Date of manufacture or formulation
v) Expiry date (optional)

Label elements desirable to be harmonized, but not essential

The section on 'Designing a label' was included in the guidelines as part of the requirement for good labelling practice. It explains how to layout of information on the label, labelling for small packs/ supplementary leaflets, style and wording of the text, print size, effective use of space and use of color.

This section considers the practical aspects of good, clear label design and layout, including the use of pictograms. However, it is not meant to be harmonized at the present moment.

2.4.5. Recommendations

The following plan of actions has been proposed to be taken by the participating countries:

- After the adoption of the Guidelines on Harmonization of Pesticides Labelling by the TCP project, they are referred to the member countries for implementation.
- In order for the guidelines to be implemented at national level, the national regulations on labelling are to be amended to accommodate new elements proposed by the guidelines.
- Good understanding of new labelling requirements in the guidelines is vital to the success of implementing the guidelines. Therefore, training of relevant personnel from regulatory authorities who are directly involved in the evaluation of pesticide labels for approval during the registration process is required. It is also necessary for the pesticide industry to be aware of the new guidelines and to have their people properly trained as well.
- Based on experiences from other regional groupings like OECD, NAFTA and EU, harmonization of pesticide regulatory systems is a long-term process that requires resources and expertise. Therefore there should be a long-term commitment from the participating countries.

2.5. Summary and analysis of pesticide residue analysis requirements

2.5.1. Introduction and background

With the increase in the use of pesticides there are increasing concerns about their adverse effects on human health and the environment resulting from possible residues in the food, soil, water and air. Particularly in view of growing concern for food safety, there is a need to monitor and analyze pesticide residues in agricultural commodities from different agro-ecological regions in Southeast Asia.

There are no specific international guidelines for establishing a pesticide residue monitoring system. However, the FAO *International Code of Conduct on the Distribution and Use of Pesticides* and relevant documents by OECD and EU give some guidance on various aspects of a pesticide residue monitoring programme such as sampling, sample preparation, analytical pesticide standards, analytical methods, validation of testing protocols, analytical calibration, reporting and interpretation of results should be taken into consideration. For the selection of commodity-pesticide combinations, assignment of food commodities to laboratories, selection of geographical location and source of sample collection, the monitoring programmes by US-FDA, European Union and the national monitoring programme in India were considered for developing the Southeast Asian guidelines.

2.5.2. Summary of country status

At present, there is no harmonized system for monitoring pesticide residues in food commodities and environmental samples among Southeast Asian countries. The following systems are in place in the respective countries:

Thailand has a well established system under the Department of Agriculture for the monitoring of pesticide residues in local, imported and exported food commodities. There are nine pesticide residue analysis laboratories, one with ISO 17025 accreditation and with GC, HPLC, GC-MS and LC-MS instrumentation. Residues of cypermethrin, chlorpyrifos, profenophos, triazophos and dimethoate were most frequently detected in food commodities and MRL values were exceeded in about 2-5 percent of the samples. The laboratories analyzed about 60 000 samples of various fruits, vegetables, spices and rice during the last 8 years.

Philippines has six pesticide residue analysis laboratories under the Department of Agriculture (DOA). The main laboratory in Manila is equipped with GC, GC-MS and HPLC. Residues of cypermethrin, chlorpyrifos, profenophos and permethrin were regularly detected in food commodities with 2-4 percent of the samples exceeding the MRL values. The National Pesticide Analytical Laboratory NPAL is testing about 4 000 samples per year while the satellite laboratories process about 300 samples per year.

Malaysia has nine major pesticide residue analysis laboratories under the DOA and Ministry of Health, two with ISO 17025 accreditation. Residues of chlorpyrifos, profenophos, fenvalerate, cypermethrin, cyfluthrin, ethion, prothiophos, phosalone, dichlorvos and dithiocarbamate were detected in the food samples. Residues exceeding MRL values were detected in 2-3 percent of the samples. The laboratories analyse about 1 000 samples per year.

Vietnam has five residue analysis laboratories and all are ISO 17025 accredited. Two labs are under the PPD, while three are under the Ministry of Science. In a survey conducted on plant food during March – July, 2007, residues were detected in 53 percent of the vegetable and 42 percent of the fruit samples. The levels of residues above the MRL were 9.5 percent in vegetables and 32 percent in fruit samples. The laboratories analyse about 5 000 samples per year.

Myanmar, Lao PDR and **Cambodia** do not have national pesticide residue monitoring systems. In Myanmar, the Pesticide Analytical Laboratory (PAL) is testing for residues in food samples from different parts of the country. During 2000 to 2010, approximately 1 000 samples of pulses, rice, sesame seeds, fruits, vegetables and environmental samples were analysed for pesticide residues. In Cambodia, the National Agriculture Laboratory (NAL), General Directorate of Agriculture is responsible for monitoring pesticide residues. In Lao PDR, the Food and Drug Quality Center of the Department of Food and Drug under the Ministry of Public Health is the only laboratory capable of monitoring pesticide residues in the country.

Table: Comparative status of pesticide residues

	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam
Annual samples			1 000	100	4 300	7 500	5 000
Detection range					~50	~50	
% exceeding MRL							
– Local food			2-3%	0%	2-4%	4-8%	veg = 9.5% grapes: 31.6% tea = 8.5% peanut = 0%
– Export					2-3%	3-4%	
– Import						<2%	

Table: Maximum Residue Limits (MRL) followed in different countries

	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam
Local food			National MRL	Codex and ASEAN MRL	Codex based (FPA approved)	Own MRL	Codex and ASEAN MRLs
Imported food			National Codex and ASEAN MRL		Codex based (FPA)	Own MRL	Codex and ASEAN MRLs
Exported food			Importing country		Importing country	Importing country	Importing country

2.5.3. Project outputs

Guidelines on pesticide residue monitoring system

The guidelines were developed after taking the following into consideration:

- international guidelines of FAO, EU, OECD and NAFTA;
- international pesticide residue monitoring systems;
- existing pesticide residue monitoring systems and the relevant regulations in Southeast Asian countries;
- diversity of languages and levels of pesticide regulations.

The guidelines give details about the evaluation of pesticide residues, their metabolites and other related contaminants in fruits, vegetables and agricultural commodities in wholesale markets across the Southeast Asia countries, as well as the need to

- identify crops and regions in the country having preponderance of pesticide residue contamination in order to focus extension efforts for Integrated Pest Management (IPM) and Good Agriculture Practices (GAP) aimed at judicious use of pesticides,
- assess the contamination of pesticide residues in imported food commodities,
- check and certify presence of pesticide residues in food for exports,
- establish a baseline and determine changes in the level of pesticide residues in food with time, and to
- give an indication of the effectiveness of measures taken to reduce food contamination.

The guidelines elaborate on the commodity-pesticide combinations, location for sample collection, number of samples to be analyzed, sampling strategy, sampling method, analytical method, detection limits, MRLs and interpretations of results.

The document distinguishes between general and specific requirements:

General requirements

1. Designation of authority
2. Organization/Management structure of PRMS
3. Role and responsibilities
4. Infrastructure, equipment and facilities
5. Human resources/Training requirements
6. Plan of operation
7. Designation of national referral laboratory
8. Documentation
9. Quality assurance
10. Accreditation of laboratory

Specific requirements

11. Selection of commodity/pesticide combination
12. Assignment of food commodities to laboratories
13. Sampling plan
14. Analytical pesticide standards
15. Analytical methods
16. Analytical calibration
17. Stability investigations
18. Validation of testing protocols
19. Reporting/submission of results
20. Interpretation of results

Manual on pesticide residue analysis

A detailed step-by-step manual for pesticide residue analysis was prepared for the training course that was conducted in June 2011 for participants from Thailand, Malaysia, Vietnam, Myanmar, Lao PDR and Cambodia.

Modality for the implementation of a harmonized pesticide residue monitoring system

To operate a pesticide residue monitoring system, a country needs to make available sufficient resources. It needs to upgrade the knowledge and skills of the assigned staff by offering regular refresher training programmes and Proficiency Testing (PT). Furthermore, Inter Laboratory Comparison (ILC) should be conducted.

The concerned government departments in Myanmar, Lao PDR and Cambodia would need to set up pesticide residue testing laboratories before they could become part of a harmonized pesticide residue monitoring system across Southeast Asia. To achieve this, Thailand, Malaysia, Philippines and Vietnam should provide them technical support. The laboratories need to be supported in terms of

- technical guidance and support,
- practical training on pesticide residues analysis,
- need-based exchange visits of the scientific and technical staff, and
- Certified Reference Materials (CRM's), if required.

2.5.4. Conclusions

For setting up a pesticide residue monitoring system, the following general and background information are not part of any specific harmonization:

1. Designation of authority
2. Organization and management structure of the pesticide residue monitoring system
3. Roles and responsibilities
4. Human resources and training requirements
5. Documentation

The following items are crucial for an effective regional harmonization:

1. Sampling plan
2. Analytical pesticide standards
3. Reporting and submission of results
4. Interpretation of results
5. Validation of testing protocols
6. Analytical methods
7. Sample preparation and processing

The following items are desirable to be harmonized:

1. Accreditation of laboratory
2. Infrastructure, equipment and facilities

Some items vary according to local conditions and do not need to be harmonized, but other countries should be kept informed through information exchange:

1. Selection of commodity-pesticide combination
2. Assignment of food commodities to laboratories
3. Quality assurance
4. Designation of National Referral Laboratory
5. Selection of geographical location

2.5.5. Recommendations

1. The concerned departments of Myanmar, Lao PDR and Cambodia should give priority to setting up pesticide residue testing laboratories;
2. The countries that have a well established pesticide residue monitoring system, i.e. Thailand, Malaysia, Philippines and Vietnam, should provide technical support to Myanmar, Lao PDR and Cambodia;
3. Training programmes for the Southeast Asian countries should be conducted annually to update the knowledge and skills of the chemists on the latest techniques and developments in the area of pesticide residue analysis;
4. Practical training programmes in this highly specialized field should have a duration of about three weeks for maximum effectiveness;
5. Pesticide residue chemists should be exposed to quality management as per ISO/IEC 17025.

Specific suggestions for improvement

Thailand

1. Strengthen satellite laboratories located outside Bangkok with equipments such as by GC-MS and practical training in pesticide residue analysis.
2. Fully utilized the LC-MS in the Pesticide Residue Laboratory at Chatuchak, Bangkok, for routine analysis.
3. Hire additional manpower for the smooth operation of the laboratory.
4. Have all pesticide residues laboratories participate in a PT/ILC programme.

Philippines

1. Equip satellite laboratories with GC-MS for residue analysis.
2. Equip the National Pesticide Analytical Laboratory with a LC-MS.
3. Provide practical training to chemists in pesticide residue analysis.
4. Allow utilization of the LC-MS in the Food Development Center, National Food Authority (DOA) by the National Pesticide Analytical Laboratory for confirmation of a wide range of pesticides.
5. Hire contractual manpower for the smooth operation of the laboratory.
6. Have all pesticide residues laboratories participate in a PT/ILC programme.

Malaysia

1. Equip the Pesticides Residue Laboratory of the Dept. of Agriculture and the Public Health Laboratory of the Ministry of Health with LC-MS-MS
2. Provide practical training to the chemists in the QuEChERS method and residue analysis by LC-MS-MS.
3. Have all pesticide residues laboratories participate in a PT/ILC programme.

Vietnam

1. It was noticed that the PPD laboratory is using the Luke method, which is an old technique for the extraction of pesticide, and injecting the samples into GC, GC-MS or LC-MS without clean-up. Clean-up is a very important steps for trace-level analysis to ensure quality results and maintain good equipment sensitivity. The laboratory is adviced to adopt the latest sample preparation method like QuEChERS for extraction and clean-up.

2. The LC-MS-MS room needs additional air conditioning for maintaining optimum temperature for a smooth functioning of the equipment.
3. Since Quatest 1 laboratory is analysing various kinds of food samples included packaged and processed food, it needs LC-MS-MS equipment and more working space for a smooth functioning of the laboratory.
4. The pesticide residue chemists in the different laboratories need practical training to familiarize them with advanced analytical techniques, sampling, sample preparation, multi residue analysis and methods to gain accuracy and reliability.

Myanmar, Cambodia and Lao PDR

1. Establish accredited laboratories for pesticide residue analysis;
2. Strengthen laboratories by providing adequate facilities and equipments;
3. Provide training to have technically competent staff;
4. Provide sufficient financial resources for a smooth functioning of the laboratories.

2.6. Summary and analysis of information exchange requirements

2.6.1. Introduction and background

Information exchange is an important activity for harmonizing pesticide regulations and has been mentioned in several international treaties as a means to encourage a transparent implementation. The revised *International Code of Conduct on the Distribution and Use of Pesticides* includes Article 9 **'**Information exchange' and Article 12 'Monitoring and observance' of the Code of Conduct. To assist in this matter, FAO has published in 2006 the *Guidelines on Monitoring and Observance of the Code of Conduct* to provide guidance on reporting on the implementation of the Code. Further, WHO/FAO have issued in 2009 the *Guidelines on Developing a Reporting System for Health and Environmental Incidents Resulting from Exposure to Pesticide*. The Rotterdam Convention requires member countries to notify its secretariate of final regulatory actions in respect of certain hazardous chemicals and pesticides covered in Annex III. Likewise, the notification of regulatory actions is also covered under the Basel and Stockholm conventions.

For these reasons, the FAO TCP Project on Pesticide Regulatory Harmonization in Southeast Asian Countries included the strengthening of information exchange among pesticide regulatory authorities to facilitate pesticide regulatory harmonization. An APPPC website (www.apppc.org), which was recently developed in close collaboration with the IPPC Secretariat, was launched in July 2011 and may serve as a regional platform for the exchange of information relevant to plant protection including the pesticide management.

2.6.2. Summary of country status

- There is great diversity among Southeast Asian countries in the ways they exchange information related to pesticide;
- In Malaysia, Philippines, Thailand and Vietnam, national websites carry information on pesticide regulatory matters such as the pesticide act and regulations; registration process; registered pesticides; and lists of banned or severely restricted use products;
- An ASEAN website on pesticide regulatory matters that was established in 1998 under a Malaysian initiative became inoperable due to poor responses;
- Many participating countries in the region have inadequate information management systems and lack dedicated websites for sharing information relevant to pesticide matters.

In summary, the following problems are faced by countries in establishing an information exchange network:

(a) lack of specific legislation and regulations that permit information sharing:
(b) lack of dedicated websites and portals for sharing information on pesticide regulatory matters at the national, provincial and community levels;
(c) lack of specific guidelines and procedures for information sharing;
(d) lack of regional coordination and cooperation in information sharing;
(e) inadequate internal linkages and institutional collaboration for information sharing;
(f) inadequate communication skills in English and limited translation abilities (with the exception of Malaysia and the Philippines);
(g) inadequate technical manpower (particularly in Cambodia, Lao PDR and Myanmar);
(h) lack of trained technical personnel in information management:
(i) limited network connectivity (particularly in Cambodia and Lao PDR);

(j) inadequate computer facilities (particularly in Cambodia and Lao PDR); and
(k) limited resources for information management (particularly in Cambodia and Lao PDR).

2.6.3. Project outputs

Guidelines for information exchange on pesticide regulatory matters

A guidance document was developed that lists general and specific requirements for a regional information exchange system and provides 12 formats for a harmonized reporting of relevant information:

General requirements

Designation of a responsible authority
Contact point for information exchange
Communication language
Currency of information
Frequency of information exchange
Authenticity of information
Data protection and requirements of IPR
Information security
Login credentials
Establishment of specific regulations and administrative procedures
Type of information requires to be shared

Specific requirements

Pesticide act and regulations
Guidelines, standards and test protocols for pesticides
Minimum data requirements for registration
Registered pesticides
Banned and severely restricted use pesticides
Maximum Residue Limits (MRLs)
Implementation of FAO Code of Conduct and international conventions and agreements relevant to pesticide matters
Publications and reports
Projects and programmes
Meetings, conferences, workshops and training courses
Videos and publicity material
Pesticide news, events and alerts

Modality for the implementation of the harmonized system in Southeast Asia

The guidelines were recommended to the member countries. In addition, it was agreed that the Asia and Pacific Plant Protection Commission (APPPC) would be one of potential forums for the National Project Coordinators to collaborate and share information related to pesticide matters to facilitate harmonization. The member countries would utilize the APPPC website to exchange information regarding pesticide policy, regulations and legislations, country actions of restriction or prohibition of highly hazardous pesticides, new approaches, programmes and developments.

In order to facilitate the establishment of a Southeast Asian information network on pesticide management, it was agreed that an electronic working group would be established comprising of Malaysia, Thailand, Philippines and Vietnam; the group would be led by Malaysia in conjunction with APPPC SC-pesticides.

2.6.4. Conclusions

The following parameters were identified to be crucial for information sharing among the member countries in Southeast Asia:

- designation of responsible authority and contact point;
- specific regulations to promote information sharing;
- computer and internet facilities.

Five areas were identified as priority areas for the regional information exchange:

- pesticide regulations and registration requirements;
- list of banned, prohibited and restricted pesticides;
- list of registered pesticides;
- registration authorities and contact points;
- programmes, projects or upcoming events in each country related to pesticide management.

The appropriate modalities, means and mechanisms for information sharing among the participating countries in this region will be established. Other areas for information exchange may include:

- establishment of maximum residue limits;
- notification of regulatory actions covered under the international conventions relevant to pesticide matters;
- implementation of pesticide risk reduction programmes such as IPM;
- health and environmental monitoring;
- monitoring of residues in food and environment.

As a long-term strategy, it would be desirable to have a national information management system at national, provincial and community levels.

2.6.5. Recommendations

The following actions were recommended for strengthening information management related to pesticide regulatory matters and information sharing among participating countries:

- establishing specific legislation and regulations/guidelines/procedures for information sharing;
- designation of the responsible authority and contact points for information exchange together with areas of responsibility;
- developing an effective national information management system;
- capacity building in information exchange related to pesticide management;
- establishing a pesticide regulatory information management network centre for Southeast Asia (PRIMNSEA) for the effective management of a regional internet portal and a pesticide database; and
- harmonized formats for information sharing relevant to pesticide matters among Southeast Asian countries.

2.7. Summary and analysis of formulation analysis requirements

2.7.1. Introduction and background

Efficient pest control can only be achieved with high quality products. Products of inferior quality may include so-called generics, but also degraded, expired, and other kinds of sub-standard products. These may be imported or locally produced. Due to the variability in formulation processes, products with the same the same active ingredients may have different chemical compositions and different toxicological and efficacy properties. Therefore, inferior quality products can pose a serious threat to human health and the environment. There are also indications that counterfeit and adulterated compounds can significantly affect the quality of food crops and may cause considerable losses in yield.

Often, improper dosage and overuse are the consequences in the field. Such pesticides may also contribute to the accumulation of obsolete pesticide stocks in developing countries. Furthermore, reduced efficacy of sub-standard generic or obsolete pesticide products induces resistance of pests and increases residue levels on commodities resulting in risks to human health and the environment and wastage of national resources.

For these reasons, regulatory authorities require the quality of pesticide products to be monitored, particularly their active ingredient content. At the very least the physical and chemical properties of formulations and active ingredients contents of the pesticide products should be determined. Applicants are required to submit samples which need to be verified with regard to its specification, type of formulation, relevant physico-chemical parameters, analytical test report, chemical composition, impurity profile in technical product, methods for determination of active ingredient content and impurities content, interpretation of chromatogram and spectra, decision making on chemical equivalence as per JMPS guidelines, shelf life, etc. Thus, there is a strong link between registration and quality control.

The FAO *Manual on Pesticide Specifications* provides a basis for pesticide quality control. However, they are only valid for particular products and are not generally applicable because the nature and levels of impurities depend on the manufacturing process. Some impurities may increase the acute toxicity of a formulation. Thus checking for impurities is an important aspect for quality control. These may be the result from the use of cheap raw materials, uncontrolled reaction processes, or skipping of purification steps to save production costs.

Regular quality control of pesticides marketed in a country is essential to facilitate their safe and efficient use and for increasing agricultural productivity while at the same time protecting farmers, consumers and the environment. Pesticide Formulation Laboratories provide the analytical support necessary to enforce the marketing and use of plant protection products on the market.

The quality criteria outlined in the FAO Pesticide Specifications generally require collaboratively tested and validated methods approved by the Collaborative International Pesticides Analytical Council (CIPAC) or the Association of Official Analytical Chemists (AOAC International). CIPAC/AOAC methods of analysis for pesticide formulations have been validated collaboratively for the quantitative determination of individual active ingredients. In order to assure that the results of monitoring are valid, regulatory authorities require the quality of pesticide products to be monitored by means of fully validated methods such as those published through CIPAC/AOAC. Responsibility, confidentiality and transparency in the analytical system together with the need for codification of regulatory samples, internal auditing, cross verification, calibration and maintenance of instruments, pesticide repository are important aspects to be considered.

2.7.2. Summary of country status

All countries have legislations that include quality control measures, but not all countries have the required infrastructure.

Cambodia has established a laboratory for analyzing pesticide formulations and it is equipped with GC, HPLC, spectrophotometer and pH meter. The Philippines and CIPAC methodologies are followed to test for active ingredient content only. Common pesticides used in the country are cypermethrin, permethrin, chlorpyrifos, carbaryl, diazinon, fenvalerate, mancozeb, glyphosate, difenconazole, 2,4-D and abamectin. Types of formulations are EC, WP, SC and WG. Specific requirements include specifications and methods of analysis.

Lao PDR has not yet established a pesticide testing laboratory but is planning to do so. The formulation analysis trainee is working in the registration wing and expressed her interest in FAO specifications, method for analyzing active ingredient content and information on impurities. Common pesticides used in the country are cypermethrin, glyphosate, carbendazim and malathion.

Malaysia has a laboratory for the testing of pesticides which is equipped with GC, HPLC and GC-MS. The methods of analysis are based on FAO and manufacturer specification. Common pesticides used are glyphosate, chlorpyrifos and cypermethrin. Types of formulations are EC, WP, SL and AE. Testing is done only for active ingredient content. Specific requirements include testing of technical grade pesticide, impurities, and testing of physical parameters.

Myanmar has established a laboratory for the testing of pesticides. It is equipped with GC and HPLC. The testing is done only for active ingredient content .Common pesticides used are cypermethrin, glyphosate, dimethoate and chlorpyrifos. Types of formulations are EC, WP, SC and WG. FAO and CIPAC testing methodologies are followed. Specific interests include testing of physical parameters and impurities.

Thailand has established pesticide testing laboratory well equipped with GC, HPLC, Spectrophotometer and other necessary general equipments. The analytical procedures are based on self-developed methods. Common pesticides used are cypermethrin and carbaryl. Types of formulations are EC, WP, SL and WG. Specific requirement include testing for impurity and other parameters.

Vietnam has established pesticide testing laboratory equipped with GC, HPLC, GCMS and LCMS. It follows FAO and CIPAC methodologies and national standards. Specific interests include quality assurance, problem area in instrumental analysis, biological and botanical pesticides.

2.7.3. Project outputs

Capacity building workshop

A training workshop for pesticide formulation analysis was held at the quality control laboratory of Pesticide Control Division of the Department of Agriculture in Bangkok, Thailand, from 1-12 June 2011.The training was attended by participants from six member countries. The sessions provided practical operation of GLC, HPLC and IR spectrometer as well as analysis of formulated pesticides such as butachlor, cypermethrin, chlorpyrifos, deltamethrin, imidacloprid, fipronil, dichlorvos and carbendazim. Glyphosate, paraquat, tridemorph and mancozeb were also considered. Theoretical sessions gave the trainees knowledge, confidence and technical competence for strengthening the quality control capacities and to initiate collaboration among the countries to monitor the flow of poor quality pesticides in the region.

The training topics were:

(1) Principles and design of equipment such as GLC, HPLC, UV-visible spectrophotometer and infrared spectrometer (IR)

(2) Specification, preparation of test sample solution and calculation
(3) Pesticide repository
(4) Testing of physico-chemical parameters
(5) Critical area in the practical instrumental analysis
(6) Impurities in pesticides
(7) Quality assurance
(8) Role of the analyst
(9) Minimum infrastructure facilities required in the pesticide testing laboratory
(10) Important reference books and literature

Modality and sustainability

- FAO may nominate a lead institution to formulate a work plan for mutual cooperation and the modality of implementation.
- Trainees may help upgrade laboratories by selecting and justifying standard instruments with appropriate accessories for pesticide formulation analysis together with other infrastructural inputs.
- Trainees may train fellow analysts and thus contribute to building national capacity and capability in pesticide formulation analysis.
- The analysts may suggest improved chemistry data requirement for registration.
- Laboratory staff from different countries may share their experiences with analytical problems and get expertise advice from more advanced countries.
- The countries may collaborate to generate data for registration, especially for newly introduced pesticides, and to monitor the quality of pesticides across the region.
- Mutual cooperation may include sharing analytical facilities with another country in need. An analyst of the needy country may travel to the other laboratory with the samples, or analysts from an advanced laboratory may be invited to demonstrate practical techniques whenever necessary.
- Mutual cooperation may help curb the flow of substandard pesticides by tracing their movement through the comparison of analytical data.

2.7.4. Conclusions

The following constraints for an effective pesticide quality control programme have been identified:

- Lack of adequate infrastructural facility in the laboratory,
- Lack of modern instruments (GLC, HPLC) with required accessories for pesticide analysis according to CIPAC,
- Lack of trained and experienced analysts,
- Limited capacity to analyze all types of pesticides,
- Limited capacity to test physico-chemical properties of all samples as per FAO specification,
- Lack of coordination between laboratory and registration authority,
- Non-availability of required specifications and recommended testing protocols,
- Non-availability of CIPAC handbooks,
- Insufficient stock of pesticide standards in pesticide repository,
- Lack of maintainance and supplies such as regular servicing of instruments, chemicals, glassware and gases,
- Financial constraints.

Close coordination between the testing laboratory and the registration authority is essential for an effective control of the quality of pesticides.

For a successful cooperation, each country has to strengthen its own quality control set-up and improve the infrastructure of the laboratories. They need to address the constraints in the laboratories and – if necessary – increase in number of skilled analysts and instruments. Sufficient budget allocations are needed to meet investment and recurring expenditures.

2.7.5. Recommendations

- A laboratory should be nominated to coordinate regional follow-up activities.
- The test methodologies and procedures for monitoring of the quality of pesticides should be standardized
- The countries should conduct training programme for the analysts in the laboratory. Refresher trainings should be organized at regular intervals. Such training may be given by trained staffs or by external experts.
- Samples from imported consignments should not only comprise ready formulations and technical products, but also intermediates and other precursors (may sometimes be labelled as general chemicals rather than pesticides); testing should be done for the most commonly sold pesticides.
- To monitor the flow of substandard and adulterated pesticides in the region, mutual cooperation among the countries is essential. Information on the batch numbers of poor quality samples should be shared among the countries and proper follow-up actions may be initiated.
- Inter-country meetings or conference may be organized at regular intervals to share experiences among the chemists and to find solution to analytical problems. Information exchange should also cover pre- and post-registration samples and newly introduced pesticides.
- Regional and in-country training courses and refresher workshops may be organized for the analysis of active ingredients and testing of physical-chemical properties.
- Inter-countries collaborative studies may validate analytical methods and generate data on storage stability and impurities in technical grade pesticides.
- A website may also be used to exchange quality control information, share experiences and solve analytical problems.

2.8. Summary and analysis of risk assessment requirements

2.8.1. Introduction and background

Risk assessment is a process designed to characterize potential risks and the probability that a product will cause harm. The risk of a product depends on its intrinsic hazardous properties and the likelihood of exposure to other organisms. Risk assessment plays a critical role in pesticide registration in order to evaluate the potential harm to human health and the environment, and to issue new regulations and use restrictions. Usually, risk assessment focuses on pesticides that have the greatest hazard. Once the risk has been fully characterized, regulators may develop a strategy for responding to that risk. This is called *risk management* and is separate from risk assessment.

2.8.2. Summary of country status

There is a wide range of pesticide risk assessment practices among Southeast Asian countries. They are more advanced in Thailand, Philippines and Malaysia. These three countries have similar practices and require a wide range of hazard identification data at the time of registration. Generally, acute toxicology data are required for formulated products and a full set of data (acute, subacute, chronic, carcinogenicity, mutagenicity and teratogenecity) are required for the technical ingredients.

The process of risk assessment is largely limited to hazard identification. In Malaysia and Thailand, a technical committee looks at the hazard data, carries out risk assessment and makes recommendations for registration. In the Philippines, a panel of accredited experts, makes recommendations to the board.

The following tables compare the various hazard data requirements in Southeast Asian countries:

Toxicology data requirements	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam
Acute toxicology data requirements							
Acute oral toxicity			x		x	x	
Acute dermal toxicity			x		x	x	
Acute inhalation toxicity			x		x	x	
Skin irritation			x		x	x	
Eye irritation			x		x	x	
Sensitization			x		x	x	
Acute delayed toxicity			x				
Subacute toxicology data requirements							
90 day oral (Malaysia: in rats)			x		x	x*	
3-4 week dermal (Malaysia: in rats)			x		x 28d		
90 day dermal					x		
Delayed neurotoxicity if applicable (Malaysia: in hens)			x		x		
Chronic toxicology data requirements							
2 year study in rats			x 18-24 months		x	x	

Toxicology data requirements	Cambodia	Lao PDR	Malaysia	Myanmar	Philippines	Thailand	Vietnam
Special toxicology data requirements							
Carcinogenicity			x		x	x	
Teratogenicity			x		x	x	
Reproductive toxicity			x		x	x	
3 pack mutagenicity			x		x	x	
ADME, degradation products			x				
Metabolism						x	
Pharmacokinetics					x		
Ecotoxicology toxicology data requirements							
Acute fish, avian, bees and other animals			x		x	x	
Subacute data in fish and birds					x		
Reproductive toxicity data in fish and birds					x		

* Thailand = flexible

2.8.3. Project outputs

Capacity building

A training workshop on risk assessment was held in Air Keroh, Melaka, Malaysia from 3 to 7 October 2011. A total of 23 participants from Cambodia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand, and Vietnam attended the workshop.

The main focus of this workshop was to impart basic understanding on toxicology aspects of pesticides and hazard identification. The trainees learned to appreciate the importance of proper assessment of pesticide risks to human health and the importance of Good Laboratory Practice (GLP) for the generation of high quality data. The course covered the following topics: concepts of toxicology; concepts of risk assessment; comparison of pesticide toxicology requirements in various Southeast Asian countries; introduction to the proposed harmonized toxicology requirements; introduction to Good Laboratory Practice (GLP); eco-toxicity: fish toxicity demonstration; introduction to online toxicology databases; and practical exercises in hazard identification.

Modality for implementation of a harmonized system in Southeast Asia

The suggested modality for harmonizing pesticide risk assessment process was as follows:

1. Recruit or hire professional toxicologist consultants and medical doctors as members of the pesticide toxicology evaluation team.
2. Identify a team of junior staff within the pesticide registration authority who can work with these professional toxicologists and develop their skills.
3. Provide training on the harmonized toxicology and risk assessment data requirements, in line with OECD test guidelines.
    a. Firstly, identify appropriate staff and conduct multiple trainings at country level.
    b. Countries like Lao PDR, Myanmar, Cambodia and Vietnam should have a more rigorous and basic training programme in toxicology.
    c. Finally, bring together all countries in the region and train them on the harmonized process.

4. Provide training on Good Laboratory Practices
   a. Firstly, identify appropriate staff and conduct multiple trainings at country level.
   b. Finally, bring together all countries in the region and train them on the harmonized process.
5. Enlist more biologists and life science expertise in the pesticide registration group.
6. Encourage junior staff to undertake master's degree courses in toxicology.
7. Plan for a Southeast Asian Regional Referral Laboratory for pesticide toxicology.

2.8.4. Conclusions

The pesticide risk assessment processes and practices in Malaysia, Thailand and the Philippines are quite similar and more advanced than in the other Southeast Asian countries.

Generally, the following constraints for a harmonized risk assessment system in the region were identified:

1. Generally there is shortage of professional toxicologists and medical doctors within the pesticide evaluation group in all countries and toxicology laboratories are missing.
2. Presently, the toxicology data requirements for pesticide registration are processed by staffs who are chemists by qualification.
3. Very little biology and life science expertise is found in the pesticide registration group.
4. There is an interest to follow GLP, but properly trained staffs and guidance documents are missing.
5. Even though there is a desire to follow OECD test guidelines, there is no proper strategic guidance.
6. There is a need for clear guidance on toxicology data requirements for hazard identification and risk assessment, including dose-response relationship, exposure evaluation and risk characterization.

2.8.5. Recommendations

Recommendations for Malaysia, Thailand and Philippines

These countries have already fairly advanced assessments of pesticide toxicology for registration purposes.

1. There should be more emphasis on evaluating the toxicology data submitted to the agency. It is recommended that initially external toxicology consultants may be used to review toxicology data submitted and make recommendations for pesticide registration.
2. Train or recruit at least two members of the pesticide registration group in toxicology – one for mammalian toxicology and the other one for ecotoxicology.
3. Develop guidelines for using hazard data in pesticide risk assessment based on exposure scenarios. External experts may be used to develop this guidance.
4. Malaysia and Thailand recent became provisional members of the OECD GLP's mutual acceptance of data (MAD) scheme. Hence, there is an excellent opportunity to develop awareness of GLP principles and to implement the requirement of GLP data in pesticide registration. It is important to create an awareness of GLP requirements within the pesticide registration group by training personnel in the principles of GLP. External consultants may be used for such training.
5. Identify or develop a referral toxicology laboratory (either in the private or governmental sector) for pesticide toxicology.

Recommendations for the other Southeast Asian countries

1. Start the mandatory requirement of toxicology data for pesticide registration, specifically:
   i. Acute oral toxicity
   ii. Acute inhalation toxicity
   iii. Acute dermal toxicity
   iv. Skin irritation
   v. Eye irritation
   vi. Skin sensitization
   vii. Acute fish toxicity

2. Initially, make use of external toxicology consultants to review toxicology data submitted for registration and make recommendations to the registration authority.

3. Recruit or train at least two members of the pesticide registration group in toxicology: – one for mammalian toxicology and the other one for ecotoxicology.

4. In the long-term, full data on technical ingredients and Good Laboratory Practices should be required.

3. WAY FOREWARD

It was agreed that each country would make a follow-up action plan for the harmonization of pesticide registration and regulatory management. The plan should be put into practice within a specified time frame. Furthermore, a check list has been prepared to assist the countries in self-evaluating their progress in line with the five adopted guidelines (Attachment 7).

3.1. Indicators of successful harmonization

The following table lists 71 activities to achieve pesticide registration harmonization. Of these, 42 were rated as crucial for a successful harmonization, while 26 were considered as desirable and 3 activities were not rated. Such a large number of activities are unlikely to be implemented instantly and simultaneously, but would require further priorization and implementation in stages. Therefore, the follow-up country action plans should give realistic target dates for each activity and identify the person or unit responsible for implementation.

Indicators are given to assess the successful implementation of each activity. However, not all indicators are specific enough and measurable to allow an objective assessment whether an activity has been fully completed or not. Such parameters are expected to evolve over time as each country attempts to carry out an activity and communicates its implementation status to the other member countries.

Table: Activities and indicators for regional pesticide registration harmonization

S. No.	Activity for pesticide registration harmonization	Importance	Indicators
1. Legislation and regulations			
1.1.	Regulations to import/export, manufacture, transport, storage, distribution, sale and use of pesticides (FAO Code of Conduct)	Crucial	– Harmonized registration procedures, types of registration, validity period of registration and licensing, marketing, etc.
1.2.	Regulations to prohibit import/export, manufacture, transport, storage, distribution and sale of pesticides of WHO class 1a and 1b (FAO Code of Conduct)	Crucial	– Number of prohibited pesticides of WHO class of 1a and 1b
1.3.	Regulations for control of transboundary movement of hazardous wastes and their disposal (Basel convention)	Crucial	– Effective control of transboundary movement of hazardous wastes and their disposal
1.4.	Regulations for banning or severely restricting production, transport, storage, distribution, sale and use of persistent organic pollutants (POPs) (Stockholm Convention)	Crucial	– Number of banned and or severely restricted pesticides (POPs)
1.5.	Regulations for notification of final regulatory actions and prior informed consent procedures (PIC) in respect of hazardous chemicals and pesticides (Rotterdam Convention)	Crucial	– Notification of final regulatory actions and prior informed consent procedures in compliance with Rotterdam Convention
1.6.	Regulations for review of registered and re-registration of pesticides after initial grant of registration (FAO Code of Conduct)	Crucial	– Effective review of pesticides to eliminate highly hazardous pesticides based on additional data or new information emerging during its use and identification of less risky pesticides

S. No.	Activity for pesticide registration harmonization	Importance	Indicators
1.7.	Regulations for protecting proprietary data and confidential business information (WTO-TRIPS Agreement)	Crucial	– Implementation of harmonized data protection periods in compliance with WTO-TRIPS Agreement
1.8.	Regulations for restricting the production and use of methyl bromide, an ozone depleting substance (Montreal protocol)	Crucial	– Accreditation of fumigation operators – Quantitative reduction in methyl bromide consumption
1.9.	Regulations incorporating registration requirements for biopesticides, which include biochemical pest control agents & microbial pest control agents (FAO Code of Conduct)	Crucial	– Harmonized biopesticide registration requirements
1.10.	Regulations for controlling pesticide advertising norms (FAO Code of Conduct)	Crucial	– Effective control of advertising of pesticides to ensure approved label claims
1.11.	Regulations for controlling transport of pesticides (FAO Code of Conduct)	Crucial	– Effective control to prevent transport of pesticides along with consumer goods
1.12.	Regulations to permit information sharing with public on pesticide risks and health hazards and to facilitate public participation in pesticide regulatory process	Crucial	– Harmonized information sharing – Effective public participation in pesticide regulatory process
2. Chemical pesticide registration (minimum data requirements)			
	– Physico-chemical data (Folder A)	Crucial	– Harmonized minimum data requirements on physico-chemical aspects
	– Toxicity data (Folder B)	Crucial	– Harmonized minimum data requirements on toxicity
	– Bio-efficacy data (Folder C)	Crucial	– Harmonized minimum data requirements on bio-efficacy
	– Residue data (Folder D)	Crucial	– Harmonized minimum data requirements on residues
	– Human health exposure/Environmental fate and effects data (Folder E)	Crucial	– Harmonized minimum data requirements on human health exposure/environmental fate and effects
	– Labelling/packaging/storage/shelf life data (Folder F)	Crucial	– Harmonized minimum data requirements on labelling/packaging/storage/shelf life
	– Additional data requirements, if any (Folder G)	Desirable	– Harmonized minimum data requirements on other parameters, if required
3. Biopesticide registration (minimum data requirements)			
3.1.	***Biochemical pest control agents (BCPA)***		
	– Biochemistry data (Folder A)	Crucial	– Harmonized minimum biochemistry data requirements
	– Toxicity data (Folder B) (primary data)	Crucial	– Harmonized minimum toxicity data requirements
	– Bio-efficacy data (Folder C)	Crucial	– Harmonized minimum bio-efficacy data requirements
	– Residue data (Folder D)	Desirable	– Harmonized minimum residue data requirements
	– Human health exposure/Environmental fate and effects data (Folder E)	Desirable	– Harmonized minimum human health exposure/environmental fate and effects data requirements

S. No.	Activity for pesticide registration harmonization	Importance	Indicators
	– Labelling/packaging/storage data (Folder F)	Crucial	– Harmonized minimum labelling/ packaging/storage/shelf life data requirements
	– Additional data requirements (Folder G)	Desirable	– Harmonized additional data requirements for specific product of BCPA
3.2.	***Microbial pest control agents (MCPA)***		
	– Microbiological data (Folder A)	Crucial	– Harmonized minimum microbiological data requirements
	– Toxicity data (Folder B) (primary data)	Crucial	– Harmonized minimum toxicity data requirements
	– Bio-efficacy data (Folder C)	Crucial	– Harmonized minimum bio-efficacy data requirements
	– Residue data (Folder D)	Desirable	– Harmonized minimum residue data requirements
	– Human health exposure/Environmental fate and effects data (Folder E) (primary data)	Desirable	– Harmonized minimum human health exposure/environmental fate and effects data requirements
	– Labelling/packaging/storage data (Folder F)	Crucial	– Harmonized minimum labelling/ packaging/storage/shelf life data requirements
	– Additional data requirements (Folder G)	Desirable	– Harmonized additional data requirements for specified product of MCPA
4. Bio-efficacy test protocols			
4.1.	Adoption of new modality guidelines for preparation of efficacy test protocols in the harmonized process	Desirable	– Harmonized modality for efficacy test protocols assessment
4.2.	Adoption of 40 modified bio-efficacy protocols (developed by FAO during 1990-92)	Desirable	– Harmonized bio-efficacy test protocols for efficacy assessment
4.3.	Adoption of 29 new protocols developed under present mission	Desirable	– Harmonized bio-efficacy test protocols for efficacy assessment
4.4.	Adoption of adequate number of field trials (6-8 for major pests and on major crops and 2-6 for minor uses) needs to be conducted over at least 2 growing seasons for arriving at any valid conclusions	Desirable	– Valid field efficacy data generation
4.5.	Capacity building in bio-efficacy assessment		– Up-gradation of skills of the workers in bio-efficacy assessment
5. Labelling standards			
5.1.	Adoption of harmonized guidelines	Crucial	– Harmonized labelling requirements
5.2.	Bilingual format for labelling (English and national language)	Desirable	– Better label reading and comprehension
6. Risk assessment/evaluation/analysis			
6.1.	Recruitment of qualified and trained toxicologists for toxicology dossier evaluation	Crucial	– Effective evaluation of toxicity dossiers
6.2.	Establishment of full pledged toxicology laboratory in compliance with GLP	Desirable	– Generation of valid toxicological data that is internationally acceptable
6.3.	Adoption of harmonized toxicology testing protocols	Crucial	– Harmonized toxicological data generation

S. No.	Activity for pesticide registration harmonization	Importance	Indicators
6.4.	Capacity building in toxicology and risk assessment	Desirable	– Effective risk assessment in accordance with international guidelines and standards
7. Ecotoxicology assessments (soil, water, bees, birds, live stock, wild life, etc.)			
7.1.	Adoption of FAO guidelines/procedures for ecotoxicology assessment	Crucial	– Harmonized ecotoxicology assessment
7.2.	Capacity building in ecotoxicology assessment	Desirable	– Effective ecotoxicology assessment in line with international guidelines and standards
8. Formulation analysis methods and procedures			
8.1.	Strengthening pesticide testing laboratory facilities	Desirable	– Effective monitoring of pesticide quality
8.2.	Adoption of harmonized pesticide testing protocols	Crucial	– Harmonized standard testing protocols for quality control
9. Residue monitoring			
9.1.	Adoption of guidelines established for residue monitoring	Crucial	– Harmonized residue monitoring
9.2.	Implementation of residue monitoring plan as per the guidelines established for residue monitoring	Desirable	– Identification of high risk areas and high pesticide use crops
9.3.	Adoption of harmonized testing protocols for residue determination	Crucial	– Reliable residue data generation
9.4.	Implementation of pesticide risk reduction programmes such as IPM	Crucial	– Reduction of pesticide risks by implementation of IPM programmes
10. Enforcement procedures			
10.1.	Establishing enforcement procedures to deal with violations concerning pesticide quality	Crucial	– Number of cases registered/awarded punishments
10.2.	Establishing enforcement procedures to deal with violations concerning un registered use of pesticide	Crucial	– Number of cases registered/awarded punishments
10.3.	Establishing enforcement procedures to deal with violations concerning un approved use of pesticide	Crucial	– Number of cases registered/awarded punishments
10.4.	Establishing enforcement procedures to deal with violations concerning import, manufacture, storage, transport, distribution, sale and use of banned pesticides	Crucial	– Number of cases registered/awarded enhanced quantum of punishments
10.5.	Establishing procedures for detection and control of illegal trade in pesticides	Crucial	– Number of cases registered/awarded punishments
10.6.	Establishing enforcement procedures to deal with violations concerning transport and marketing of pesticides along with consumer goods		– Number of cases registered/awarded punishments
10.7.	Establishing enforcement procedures to deal with violations of norms concerning advertising of pesticides		– Number of cases registered/awarded punishments
11. Strengthening information management network			
11.1.	Developing national information management system for sharing information on pesticide regulatory matters at national/ provincial/community level	Desirable	– Expeditious sharing of information relevant to pesticide regulatory matters at national/provincial/community levels

S. No.	Activity for pesticide registration harmonization	Importance	Indicators
11.2.	Developing pesticide regulatory information management network for SEA by availing FAORAP-APPPC website	Desirable	– Effective management of information relevant to pesticide regulatory matters – Effective regional coordination and cooperation in information sharing
11.3.	Capacity building in information management on pesticide regulatory matters	Crucial	– Harmonization of information management relevant to pesticide regulatory matters
12. Information exchange contents and formats			
12.1.	Reporting of monitoring and observance of FAO Code of Conduct on pesticides (regular reporting as per Annex A and Adhoc reporting as per Annex B of FAO Guidelines	Crucial	– Regular/adhoc reports on monitoring & observance of Code of Conduct
12.2.	Notification of final regulatory actions and PIC procedures in respect of hazardous chemicals and pesticides as per formats annexed to Rotterdam Convention	Crucial	– Summary reports of all published notifications
12.3.	List of registered pesticides and or/registered pesticide database	Desirable	– Published list of registered pesticides/ pesticide data base
12.4.	Notification of banned and or/severely restricted pesticides	Desirable	– Published list of banned and or/severely restricted pesticides
12.5.	Reporting of Monitoring of health and environmental incidents arise out of exposure to pesticides	Desirable	– Monitoring reports (survey and methodology) as per FAO Guidelines
12.6.	Notification of maximum residue limits (MRLs) established by the country	Desirable	– Establishment of MRLs in line with international standards in compliance with CODEX standards
12.7.	Reporting of residue monitoring in food and environment	Desirable	– Monitored reports (survey and methodology)
12.8.	Reporting of monitoring quality control of pesticides	Desirable	– Monitored reports (sampling/ methodology of testing/enforcement)
12.9.	Reporting of monitoring of illegal trade in pesticides	Desirable	– Monitored reports (method of detection/ control)

3.2. Country work plans

To continue the harmonization process that was initiated by the FAO TCP project, each country prepared a work plan for the immediate activities to be carried out. Before a country could start preparing a detailed action plan, it would first need (1) translate and distribute the adopted guidelines and (2) conduct a self-assessment by comparing its procedures and requirements with those in the guidelines and identify the main areas to be harmonized together with the gaps to be filled. Then detailed action plans for short-, mid- and long-term periods can be worked out. It was estimated that the self-assessment would need about six months. After that period, the self-analysis results would be shared at a regional workshop.

Cambodia

- The supplementary regulations under the parent law will be produced in line with the five guidelines and put in practice after the new law on Pesticide Management is enacted. The guidelines need to be translated into the local language and distributed to concern organizations.

- Exchange programme: Training, workshop and study-tour related to pesticide management information exchange.
- Follow up activity for Rotterdam Convention ratification.
- Due to lacking pesticide laboratory capability, we are looking for an oversea laboratory to check pesticide quality for the purpose of quality control and registration.

Lao PDR

- Translation of the five guidelines on harmonized pesticide registration into the local language
- Compare existing own regulations with the five guidelines, and then prioritize and develop guidelines for use in the country.
- Setting up national pesticide information management system:
  - Scope of responsibilities among concerned ministries on pesticide
- Project proposal on establishment of laboratory of chemical pesticide formulation analysis and pesticide residue analysis:
  - Technical assistance
  - Analysis instrument
  - On the job training
- Pesticide quality inspection for monitoring purposes:
  - Set up inspection system in the central level, province and district
  - Training on pesticide inspection
  - Monitor in market
- Exchange information on pesticide regulation inside and between countries.

Malaysia

- To revise the current guidelines, rules pertaining to registration requirements and labelling following the adopted guidelines and to inform the industry on the new changes.
- Residue monitoring guidelines will be further improved in line with the adopted guidelines on residue monitoring.
- Revise guidelines on data requirements for biopesticide registration, acquire training of staff and to inform the industry.
- Malaysia will start compiling data on five areas of information exchange already identified and will inform the APPPC Secretariat accordingly.
- Translation of Guidelines will not be required so Malaysia will proceed with the printing of relevant Guidelines in English for distribution.
- The residue analysis facilities are available for training subject to availability of funding e.g. expert and consumable/reagents but prior notice is requested to allow for preparation of the training, request for approval and to reschedule present workload.
- Similarly, the formulation analysis facilities are also available and ready for training subject to availability of funding e.g. expert and consumable/reagents. Prior notice is requested for planning, request for approval and to reschedule present workload.
- Malaysia requests for capacity building on further training in pesticide labelling, biopesticide evaluation and analysis, risk assessment, and equivalence principles.

Myanmar

- Five new guidelines on harmonized pesticides regulation and registration need to be translated into local language.
- To upgrade pesticide analytical laboratory:
  - Infrastructure/equipment
  - Capacity building for analysts
  - In-country training/on job training

  There is still needed for capacity building of quality control due to limited number of trained person
- As articulated in new guidelines section, there are still a number of types of registration that remain to be developed for harmonization like the new types of registration.
- Amendment and additional types of registration need to be placed in the current pesticide law and the additional procedures need to be identified.
- Continued technical support will be needed to guide the Pesticide Registration Board members in the course of the development of pesticide registration regulations.

Philippines

- Review/adoption of pesticides regulatory harmonization policies on registration and licensing.
- Capacity building for formulation analysis of pesticides products.
- Strengthen pesticides information management system i.e. judicious use, personal protective equipment (PPE's) and proper education campaign.
- Monitor strictly transboundary movement of pesticides to minimize and control smuggling.
- Enforcement and imposition of penalties to violator of pesticides regulation i.e. warning, suspension of registration and license and impose fines.
- Proper monitoring of bio-efficacy test and experiment being conducted.
- Promulgation/adoption of rules and procedure on registration of biopesticides products.
- Need for training for toxicology and pesticides residue evaluators.
- Further training on pesticides formulation analysis.

Thailand

- Review the five guidelines – to find out what to be added or deleted
- Gap and situation analysis – to compare existing legislation with respective guidelines
- Amendment of existing legislation.
  - Notification of Ministry of Agriculture and Cooperatives entitled "Label and Toxicity Levels of Hazardous Substance under Responsibility of Department of Agriculture" to include classification and label in GHS system into the Notification.
  - Notification of Ministry of Agriculture and Cooperatives entitled "Production, Import, Export and Having in Possession of Hazardous Substance under Responsibility of Department of Agriculture" to include SDS in GHS system.
- Translate rules, notification and regulations relating to pesticide regulation for information exchange purpose.
- Assistant needed:
  - Analysis of microbial pesticide in international unit i.e. IU, SU, etc.
  - Protocols for efficacy test of pheromones
  - Training on equivalence principles.

Vietnam

- Translate the guidelines into local language, printed and distribute to pesticide management stakeholders.
- Adds the guideline into the New Pesticide Management Registration.
- Translate existing Pesticide Management Regulation into English for exchange information among member countries.
- Need assistance for training on test microbial pesticide quality.
- Need assistance for training on toxicology and risk assessment of pesticide.

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ATTACHMENTS

ATTACHMENT 1

GUIDELINES FOR HARMONIZATION OF PESTICIDE REGISTRATION REQUIREMENTS

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GUIDELINES FOR HARMONIZATION OF PESTICIDE REGISTRATION REQUIREMENTS AMONG COUNTRIES IN SOUTHEAST ASIA

1. INTRODUCTION

Pesticides are commonly used worldwide to control insect pests, diseases, weeds, rodents and other harmful organisms as well as vectors of human diseases. In an effort to sustain food production, farmers in countries in the SEA region use pesticides liberally without adhering to label/leaflet instructions. This causes serious health hazards and irreparable damage to the ecosystem. In recent years the trade volume and sale of pesticides has increased significantly in many countries due to political and economic developments as well as efforts to ensure food security and feed the growing population. Most countries in the region depend on importing pesticides from overseas, e.g. Japan and USA and from neighboring countries such as the People's Republic of China and India.Furthermore, there is competition among pesticide companies to promote their brand products and encourage farmers to make repeated pesticideapplications and use low-quality mixtures. Such developments warrant effective pesticide management capacities, particularly at the national level, to control and register the products, and to restrict or ban the use of highly toxic pesticides.

Therefore, an efficiently regulated and managed pesticide registration scheme is a pre-requisite for regulatory authorities to ensure that pesticides used in their countries are effective for controlling pests and would not cause adverse effects on human health and the environment. Harmonized pesticide registration in this region would play a crucial role in supporting this development as it would allow for the application of similar requirements and quality standards for agricultural products, e.g. for pesticide residues as well as precautionary measures related to the use of pesticides.

Harmonized pesticide registration would also be crucial for the implementation of a number of international conventions related to pesticides. These include the

- Rotterdam Convention[21] on the Prior Informed Consent Procedure for Certain Chemicals and Pesticides in International Trade;
- Stockholm Convention[22] on Persistent Organic Pollutants;
- Basel Convention[2] on the Trans-boundary Movement of Hazardous Wastes;
- Montreal Protocol[18] on substances that deal with ozone depletion; and the
- FAO International Code of Conduct on the Distribution and Use of Pesticides (FAO CCP, 2002).

The following parameters are considered crucial for pesticide registration harmonization namely

i. Registration process compliance with FAO Code of Conduct and international conventions,
ii. Designation of responsible authority and adequate facilities,
iii. Documentation of registration process,
iv. Establishing of Pesticide Board/Technical Committee,
v. Establishing of monitoring procedures for registration,
vi. Validity periods for different kinds of registration,
vii. Period of data protection (proprietary and confidential business information),
viii. Unified application format for pesticide registration,
ix. Establishment of separate fee structure for each kind of registration,
x. Minimum data requirements for each kind of registration,
xi. Technical evaluation of data dossiers by competent experts,

xii. Risk assessment and efficacy evaluation,
xiii. Compliance with good laboratory practices (toxicity data & residue data),
xiv. Issue of registration certificates with validity period,
xv. Establishing procedures for appeal,
xvi. Label claim/extension of label claim,
xvii. Pesticide review and re-registration,
xviii. Licensing of manufacturing facilities/stockiest/distributors/retailers & premises.

Registration parameters considered desirable but not crucial for harmonization are:

i. Conditional registration,
ii. Unconditional registration,
iii. Exemptions from pesticide registration requirements,
iv. Export registration requirements,
v. Licensing of pest control operators,
vi. Quality testing of pesticides.

2. SCOPE

This document provides guidance for harmonizing pesticide registration requirements among Southeast Asian countries (Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand, and Vietnam) including data requirements for registration of pesticides.

3. OBJECTIVES AND PURPOSE

The main objective of these guidelines is to assist countries in Southeast Asia (SEA) towards achieving harmonization in the pesticide regulatory process in line with provisions of FAO International Code of Conduct on the Distribution and Use of Pesticides[16].

The purpose of these guidelines is to facilitate harmonizing pesticide management among countries in SEA, so that the pesticides data generated and/oraccepted in one country for registration can be considered for registration of the same pesticide in another participating country in this region without compromising on risks to human health and environmental hazards.

4. BACKGROUND

Since 1982, FAO has played an important role in assisting and supporting the countries in Southeast Asia to prepare pesticide legislation for regulating their use in their country. The FAO initiatives were supported through a trust fund provided by the Government of Japan for the implementation of the *Revised International Code of Conduct on the Distribution and Use of Pesticides* (hereinafter referred as the Code of Conduct) within Asia and the Pacific. Nonetheless, many countries experienced serious problems enforcing their legal provisions.

These guidelines on Harmonization of Pesticide Registration Requirements among Countries in Southeast Asia were developed as part of a consultancy under the FAO-TCP project on Pesticide Regulatory Harmonization and are based on a comprehensive review of the current status of pesticide registration programmes in the member countries as well as in-depth discussions with pesticide regulating authorities, particularly in Thailand, Philippines, Vietnam, Malaysia and Lao PDR. Furthermore these guidelines were developed after taking into account the provisions of the Revised Code of Conduct on pesticides and the existing FAO Guidelines on pesticide management, as well as provisions of international conventions and agreements relevant to pesticide management, which are referenced to the document. To facilitate proper understanding of the guidelines and comprehending its provisions, appropriate definitions and

terms are incorporated in line with the Code of Conduct on Pesticides. These guidelines also take into consideration the OECD guidelines on minimum data requirements as well as the recommendations of the recent Joint Meeting on Pesticide Management (agenda 13, 13 bis). Furthermore, the draft guidelines have been circulated among all member countries, namely Cambodia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand and Vietnam and also Crop Life Asia and their comments were appropriately considered and incorporated. The revised guidelines were presented and thereafter adopted at the Third PMC Meeting at Kula Lumpur in October 2011.

These guidelines specify general requirements, which include regulations that incorporate the provisions of the revised Code of Conduct on Pesticides and other international conventions/agreements. Documenting the registration process and establishing a Pesticide Board/Technical Committee have been specified as means for assisting regulating agencies in pesticide risk evaluation and facilitating harmonization of pesticide registration among the member countries in this region. Moreover, appropriate procedures for monitoring the quality control of pesticides, health and environmental effects and accidental pesticide exposures are listed. Finally, data protection requirements for proprietary data and confidential business information are included.

The specific requirements incorporate guidance on unified application procedures, exemption requirements for pesticide registration, registration requirements for different types of registration, and minimum data requirements for each kind of registration (namely, proprietary technical, formulated and supplemementary registration of chemical and biochemical pesticides; microbial pest control agents have been identified separately) as well as the detailed process of technical evaluation of pesticides. Also incorporated are the requirements for licensing of manufacturing facilities/stockiest/distributors, retailers and pest control operators as well as import/export licensing and re-registration requirements.

5. DEFINITIONS OF TERMS

Active ingredient means the biologically active part of the pesticide (FAO CCP, 2010).

Acute dermal LD_{50} means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions (USDA-EPA).

Acute inhalation LC_{50} means a statistically derived estimate of the inhaled concentration of a substance that would cause 50 percent mortality to the test population under specified conditions (USDA-EPA).

Acute oral LD_{50} means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions (USDA-EPA).

Acute toxicity means the toxicity affects of a substance resulted from single and or multiple exposures in a short period of time (usually less than 24 hours).

Applicant means the party (producer, importer or their representative) that makes an application for registration of a pesticide to the Registration Authority (FAO CCP, 2010).

Aquatic toxicity means toxicity to fish and other aquatic animals.

Avian toxicity means toxicity to birds.

Banned pesticide means a pesticide for which all uses have been prohibited by final regulatory action, in order to protect human health or the environment. The term includes a pesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment (FAO CCP, 2010).

Biochemical pest control agents. A chemical must meet the following two criteria in order to be classified as a biochemical pest control agent and to be subject to the data requirements for this class of compounds:

- The chemical must exhibit a mode of action other than direct toxicity in the target pest (e.g. growth regulation, mating disruption, attraction). Pesticides such as strychnine, rotenone, nicotine, and pyrethrin which exhibit direct toxicity, are not considered biochemical pest control agents; and
- A biochemical must be naturally occurring, or if the chemical is synthesized by man, then it must be structurally identical to a naturally occurring chemical. For a synthetic chemical to be identical in chemical structure to a naturally occurring chemical, the molecular structure of the major component of the synthetic chemical must be the same as the molecular structure of the naturally occurring analog. Minor differences between the stereochemical isomer ratios (found in the naturally occurring compound compared to the synthetic compound) will normally not rule out a chemical being classified as a biochemical pest control agent unless an isomer is found to have significantly different toxicological properties than another isomer [FAO Guidelines on the Registration of Biological Pest Control Agents, 1988].

Biological pest control agents mean naturally occurring or genetically modified agents that are distinguished from conventional chemical pesticides by their unique modes of action, low use volume, and target species specificity. There are two major categories of biological pest control agents: the biochemical pest control agents and the microbial pest control agents. [FAO Guidelines on the Registration of Biological Pest Control Agents, 1988].

Chronic toxicity means toxic effects of a substance resulted from repeated exposures often at lower levels to a substance over a long time period (months or years).

Distribution means the process by which pesticides are supplied through trade channels to local or international markets (FAO CCP, 2002).

Distributor means one who distributes, sells or resells pesticide products for end use.

Equivalence means the determination of the similarity of the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk (FAO CCP, 2002-2010).

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the pesticide as purchased by users (FAO CCP, 2002).

Good Agricultural Practice (GAP) in the use of pesticides includes the officially recommended or nationally authorized uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable (FAO CCP, 2002).

Hazard means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property) (FAO CCP, 2002).

Inert ingredient means any inert substance, other than an active ingredient, which is intentionally mixed in a pesticide product.

Integrated Pest Management (IPM) means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce

or minimize risks to human health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms (FAO CCP, 2002).

Label means the written, printed or graphic matter on, or attached to, the pesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide (FAO CCP, 2002).

Licensing Authority means a government agency recognized under the pesticide regulation for granting license for domestic manufacturing facilities of pesticides, stockiest/distributors and pest control operators and working under direct supervision and/orin close coordination and cooperation with Registration Authority.

Manufacture means any act of preparing, compounding, formulating, mixing, making, packing, labelling or otherwise treating the pesticide for its sale, but does not include the carrying of a bona fide research or experiment relating to the pesticide or the doing of an act forming part of or incidental to such research or experiment.

Manufacturer means a corporation or other entity in the public or private sector or any individual engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product (FAO CCP, 2002).

Microbial Pest Control Agents are microorganisms (bacteria, alga, fungus, protozoan, virus, mycoplasma, rickettsia) and any associated metabolites, to which the effects of pest control are attributed (OECD, 2006)

Misbranded pesticide means any pesticide product that is manufactured, distributed and sold in the market without conforming to the labeling requirements of registration as to the kind, grade, quality or composition and/or that the pesticide product of one manufacturer is distributed or sold in the name of another manufacturer illegally.

Maximum Residue Limit (MRL) means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff (FAO CCP, 2002).

Packaging means the container together with the protective wrapping used to carry pesticide products via wholesale or retail distribution to users (FAO CCP, 2002).

Pesticide means any substance or mixture of substances, or micro-organisms including viruses, intended for repelling, destroying or controlling any pest, including vectors of human or animal disease, nuisance pests, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as insect or plant growth regulators, defoliant, desiccants, agents for setting, thinning or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term also includes pesticide synergists and safeners, where they are integral to the satisfactory performance of the pesticide. (FAO CCP, 2010).

Pesticide Inspector means technical personnel specifically authorized and or/designated by the Registration Authority for the purpose of drawing samples of pesticides for quality testing from the premises of importer/exporter/manufacturer/stockiest/distributor before, during or after sale and/or use.

Pesticide Analyst means technical personnel specifically authorized or designated by the Registration Authority for the purpose of quality testing of pesticide samples sent by pesticide inspector/authorized person and reporting of the results to the Registration Authority concerned.

Pesticide Board (sometimes referred to as Pesticide Registration Board, Pesticide Council or Pesticide Committee) is the officially or legally appointed body that takes final decision on the request for registration of pesticides. (FAO CCP, 2010).

Pesticide legislation means any law or regulation introduced to regulate the import, manufacture, marketing, distribution, labeling, packaging, use and disposal of pesticides in their qualitative, quantitative, health and environmental aspects (FAO CCP, 2002).

Pesticide product means the pesticide active ingredient (s) and other components in the form in which it is packaged and sold (FAO CCP, 2010).

Phytotoxicity means the toxic or harmful effects of the chemical to plants.

Registration means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment (FAO CCP, 2002).

Registration dossier means the set of data that is submitted by applicants, in a structured manner, in support of their application for registration. [FAO Guidelines for the Registration of Pesticides, 2010].

Re-registration means renewal of registration granted to the product after expiry of registration or the extension of registration.

Registration Authority means the government agency or agencies responsible for the registration of pesticides for import, export, manufacture, distribution, stock and sale of pesticide within the country.

Repackaging means the authorized transfer of a pesticide from any commercial package into any other container for subsequent sale (FAO CCP, 2002).

Residue means any specified substances in or on food, agricultural commodities or animal nourish resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance. The term “pesticide residue” includes residues from unknown or unavoidable sources (e.g. environmental) as well as known uses of the chemical (FAO CCP, 2002).

Risk is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide (FAO CCP, 2002).

Severely restricted pesticide means a pesticide for which virtually all use has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a pesticide that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment (FAO CCP, 2002).

Stockiest means the one who stocks the pesticides for retail distribution.

Sub-chronic toxicity means toxicity effects derived from studies that continue for 90 days or for up to 10 percent of a test subjects’ life span.

Substandard pesticide means a pesticide product manufactured, distributed and or/sold in the market, which does not conform to the quality standards established by the registration authority or as claimed by the registrant.

Spurious pesticide means a pesticide product, which lack authenticity or validity in essence or origin and/ornot genuine or false or fraudulently distributed and sold in the market.

Supplementary (me-too) registration means the registration granted to the similar/identical product manufactured by another manufacturer subsequent to the registration of the product by original manufacturer, with the written agreement of the original registrant. This is also referred to commodity product registration

Technical pesticide means technical grade materials and technical concentrates. Synonyms: technical material, technical grade active ingredient (TGAI), active ingredient, pure active ingredient (PAI) [FAO Glossary of Terms and Conditions for the Guidelines in Support of the Code of Conduct, 2011].

Toxicity means a physiological or biological property which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means (FAO CCP, 2002).

6. GENERAL REQUIREMENTS

6.1. The governments will review the existing pesticide legislations to incorporate the provisions of FAO Code of Conduct on Pesticides[16] and ensure compliance with international conventions such as Basel Convention[2], Montreal Protocol[19], Rotterdam Convention[22], Stockholm Convention[23], and other international instruments dealing with pesticides. The governments will take into account the guidance provided by the "D*esigning national pesticide legislation* FAO, 2007[3] in framing pesticide regulations. The governments will establish appropriate procedures after taking into account the *Guidelines on compliance and enforcement of a pesticide regulatory programme*, FAO, Rome, 2006 (*International Code of Conduct on the Distribution and Use of Pesticides*)[6].

6.2. The governments will ensure the adequate strengthening of necessary infrastructure facilities and will designate a registration authority for registration and control of pesticides and also will ensure that each and every product of pesticide is registered before import, export, manufacturing, distribution, sale and use in the country.

6.3. The governments will closely monitor and observe the FAO Code of Conduct after taking into account *Guidelines on monitoring and observance of the Code of Conduct,* FAO, Rome, 2006 (*International Code of Conduct on the Distribution and Use of Pesticides*)[11].

6.4. The Registration Authority will establish and document the entire registration process of pesticides imported, manufactured for distribution and sale and use in the country and exported outside the country after taking into account the *Guidelines for registration and control of pesticides,* FAO, Rome. 1985[13] and the *Guidelines for the registration of pesticides,* FAO, Rome, 2010 (*International Code of Conduct on distribution and use of pesticides*) (draft)[14]. Further it will adopt a harmonized registration process and exchange relevant information among member countries in the region.

6.5. The Registration Authority will establish an appropriate technical committee to assist in conducting pesticide risk evaluations and making risk management decisions based on all available data or information as part of the pesticide registration process and will establish a pesticide board to render advice on pesticide matters.

6.6. The governments will promote, develop and cooperate among each other in establishing harmonized pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards, and where possible incorporate these standards into their national legislation and establish a re-registration procedure to ensure periodic review of pesticides registered in their countries.

6.7. The governments will establish appropriate monitoring procedures and report health and environmental incidents resulting from exposure to pesticides and implement appropriate measures to minimize the incidents after taking into account the guidelines established by FAO[7].

Specific requirements

7. TYPES OF PESTICIDE REGISTRATION

7.1. Provisional (pesticide) registration:

When a pesticide is being introduced for the first time in the country, the Registration Authority may register it provisionally for a period of 2 years on such conditions as may be specified. Such provisional registration may be granted if – on the basis of a limited data set, – the assessment of efficacy, residues, hazard, and human and environmental risk is acceptable to the country.

7.2 Proprietary (pesticide) registration:

Where any pesticide product is submitted for registration for the first time and there are no identical product(s) which have already been registered prior to it, the applicant is responsible for submitting all of the information and data that are required to support the registration

The Registration Authority will be responsible for protecting the data submitted by the original applicant and maintain confidentiality of information provided in accordance with provisions of WTO-TRIPS Agreement, 1994[1].

7.3 Supplementary (me-too) pesticide registration:

An applicant, who wishes to register a similar/identical product that was previously registered by a company, will become a supplementary registrant for the company that has originally registered a product. This supplementary registration allows the new registrant to market the product under its own company and brand name. To use the supplementary registration process, both parties (the original registrant and the supplementary registrant) must:

- enter into a written agreement with one another;
- complete and file a notice of supplementary registration of a registered pesticide product with the Registration Authority; and
- ensure that the application for supplementary product registration is accompanied with data on the product which is related to the product originally registered.

8. EXEMPTIONS FROM REGISTRATION REQUIREMENTS

8.1. The Registration Authority will make necessary exemptions from registration requirements for non-pesticide active ingredient substances used in formulating pesticides (e.g. adjuvant, spreaders, stickers, antifoaming agents, dyes/brighteners, acidifying agents, buffering agents, suspension agents, wetting agents, emulsifiers, dispensing agents, etc.) or devices (e.g. sticky traps, glue traps, pheromone traps, UV light traps, light traps, etc.) and such information should be exchanged among the countries in the region to facilitate harmonization of pesticide registration.

8.2. The Registration Authority will make necessary exemptions from registration requirements of pesticides to meet emergency situations, when new pest out breaks are reported and existing registered pesticides will not offer any satisfactory control of the new pest. Such import of pesticides is permitted for emergency use based on registration in a foreign country and with conditions specified by the Registration Authority.

9. ADMINISTRATIVE ASPECTS OF REGISTRATION PROCESS

An applicant who wishes to register any pesticide product will submit a registration dossier to the Registration Authority, which includes:

- Application Form (in prescribed format),
- Payment of fee (by bank draft),
- Draft label for the pesticide product,
- Technical and scientific data that meet the data requirements related to the specific product which the applicant intends to import/manufacture,
- Objective summary of data and all conclusions from the applicant and a statement that he will comply with any data compensation requirements, and
- An appropriate sample of the pesticide intended to be registered

9.1. Application:

The Registration Authority will provide a single application form (Annex IA) for pesticide registration. The application should contain all essential information, namely the type of registration requested (e.g. provisional registration, proprietary (original) registration, supplementary (me-too) registration and/orre-registration); identity and working address of applicant; identity of technical grade/formulated product; intended use of the pesticide product; registration data requirements; additional information (such as draft labeling; certification of container/packaging material, licensing particulars, etc.); payment of fees; list of attached documents; and finally the verification/declaration by applicant.

9.2. Fees payment:

The Registration Authority will provide a separate fee structure for provisional registration, proprietary (original) pesticide registration, supplementary (me-too) registration, amendments to previous registration and/orre-registration. The Registration Authority will provide separate fee structure for issue of permit to import and/or export of pesticide products, license for manufacture of pesticide product and license for sale and storage for sale of pesticide products (as far as possible, the fee structure should be harmonized among the member countries in the SEA region).

9.3. Receipt of application/issue of acknowledgement:

The Registration Authority will establish an appropriate registration counter/desk to receive the application and issue an acknowledgement. However, in respect of on-line application, an automated system of acknowledgement may be issued electronically.

9.4. Check list of documents:

The Registration Authority will ensure that a check list (Annex IB) of documents be established for each kind of registration to facilitate verification of receipt of various documents by the registration counter/desk. The Registration Authority will also ensure that the information furnished in the application is correct and complete in all respects before accepting the application for registration.

9.5. Action taken in respect of incomplete applications:

The registration staff will ensure that all incomplete applications are promptly returned to the applicants indicating the required corrections/amendments/modifications to be affected to make the applications complete in all aspects and re-submit the same within the prescribed time period. Failing to resubmit completed applications in all respects within the time given may lead to cancellation of the applications. Such cancellation of incomplete applications may be communicated to the applicant, giving the reasons for cancellation.

9.6. Registration of complete applications:

The registration staff will allot a unique identification number for registration of the complete application and the same should be carried throughout the entire registration process. The particulars of the application will be entered in an appropriate register maintained for this purpose.

9.7. Monitoring status of registration:

The Registration Authority will implement a work plan with appropriate time periods to monitor the status of the registration application in order to avoid unjustifiable time delays in completing the entire registration process and to take appropriate corrective measures (for this purpose a flow chart should be made available indicating the time needed for evaluating different parameters).

10. DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES

10.1. The Registration Authority will establish specific data requirements for each kind of registration, namely proprietary (original) pesticide registration; provisional registration, supplementary (me-too) registration (commodity product registration) and or/re-registration. The data requirements for pesticide registration are given in Annex 2A to 2C for chemical pesticides; Annex 3A to 3C for biochemical pest control agents (BCPA); and Annex 4A to 4C for microbial pest control agents (MCPA); these may provide appropriate guidance for the harmonization of pesticide registration among the participating countries of SEA region.

10.2. The Registration Authority may also take into consideration the information on the intended use of the pesticide product and use patterns to seek any additional information such as authorization in other countries; information on existing FAO and WHO assessments; information on established residue limits in other countries; and information on intended container management and waste product disposal in order to determine specific additional registration data requirements.

10.3. The data requirements for pesticide registration as specified in Annex 2 to 4, will be submitted to the Registration Authority in the form of a registration dossier which contains separate sealed folders as listed below in order to facilitate the technical review by the experts concerned:

- Physico-Chemical Data (Folder A*)
- Toxicological Data (Folder B)
- Bio-efficacy data (Folder C)
- Residue Data (Folder D)
- Human Health Exposure/Environmental Fate & Effects Data (Folder E)
- Labeling/Packaging/Storage (Folder F)
- Additional Data (Folder G) (this may include extension of use; formulation changes; repacking and local formulation; on detection of residue levels exceeding the MRLs established by the Registration Authority or new evidences of pesticide hazard associated with field application as specified under FAO Guidelines on Pesticide Registration).

Note: * The 'Folder A' will contain biochemical data in case of biochemical pest control agents; and microbiological data in case of microbial pest control agents.

Data on pesticide products submitted by the applicants should be treated as confidential business information and will be handled by staff specifically authorized for this purpose and such documents should be held at all times in a secure location with appropriate measures against loss (fire, theft and damage by water).

11. TECHNICAL EVALUATION

The Registration Authority will take into account the following factors, while evaluating the pesticide product for registration:

- Intended use of the pesticide product and the consequences on expected routes of exposure
- Climatic and geographic characteristics of the registering country
- The nature of the proposed product
- Equivalence determination
- Data access and work sharing
- The scientific relevance of the test
- The scientific and technical feasibility of the test (substance is very volatile or unstable)

11.1. Verification of data:

The Registration Authority will verify that the data provided by the applicant at the time of submission of application fulfill the minimum data requirements for registration and that there are no data gaps, and/or – in the event of supplementary (me-too) pesticide registration – to verify that the data submitted for a similar product are complete.

11.2. Waiver of data requirements in certain instances:

The Registration Authority may grant a waiver of data requirements if the applicant provides proof or evidence of an existence waiver either by making a request for extension of an existing waiver already granted by the Registration Authority or by making a request for a new waiver with sufficient justifications for such a request.

11.3. Verification of analytical methods/test protocols:

The Registration Authority will request the applicant to provide at the time of submission of application a small quantity of technical grade active ingredient/formulated product of a pesticide together with analytical methods for verification of the product specifications as claimed by the registrant.

11.4. Verification of manufacturing process:

The Registration Authority will undertake a site visit to the manufacturing facility to verify the manufacturing process when considering registration of the pesticide product, where necessary.

11.5. Verification of specifications:

The Registration Authority will verify that the specifications of technical grade active ingredient and formulated pesticide product submitted by the applicant are in accordance with FAO/WHO specifications for pesticides where such specifications are available[17]. Where FAO/WHO specifications are not available, the Registration Authority may develop its own specifications based on international standards/guidelines.

11.6. Validation study of existing/new data:

The Registration Authority may take into account a validation study of existing data supported by citing published literature or a validation study of new data generated in an accredited test laboratory recognized by the Registration Authority to support existing data.

11.7. Preparation of summaries and conclusions by the reviewer:

The technical experts of the concerned technical evaluation units under the Registration Authority will prepare within a reasonable agreed time frame a summary listing of the data and their assessments that formed the basis of their conclusions. The technical evaluation section of Registration Authority will also identify and document data gaps, if any, and may require new data to support the registration.

Based on the recommendations of the experts, the Registration Authority may prepare a comprehensive summary of all relevant data and conclusions provided by the experts for consideration by the Pesticide Board, provided the review of the data is complete and the authority is ready for a decision.

11.8. Technical consultation:

The Pesticide Board/Committee will hold technical consultations for making a final decision after taking into account the comprehensive review prepared by the Registration Authority. The decision of the Pesticide Board/Committee may be either to grant a provisional or full registration, with or without restrictions and/or conditions, or refusal. The Pesticide Board/Committee may also decide to suspend a decision and request further data or assessments to be provided.

11.9. Acceptability of data:

The Registration Authority may accept data supplied by the applicant for registration purposes, data obtained under controlled laboratory conditions valid worldwide; or data obtained under similar agro-climatic conditions conditions in other countries or regions; Otherwise, the data may have limited value for extrapolation in accordance with the provisions of FAO Guidelines on Pesticide Registration.

The Registration Authority will ensure that such data were generated based on internationally accepted test protocols and adequate scientific standards.

11.10. Good laboratory practices (GLP):

All data provided/generated by the applicant should be in accordance with the general concept of good laboratory practices, in particular to those applied to health and safety data. Good laboratory practices are understood to mean that at the minimum level, the personnel involved in the conduct and supervision of the tests have the education, training and experience to carry out the work effectively. Furthermore, the testing facilities and equipment should be suitable and are maintained to a satisfactory standard; and test protocols and operating procedures are observed so as to assure the Registration Authority that the work is adequately supervised and that full records of all procedures and data are kept and accurately reported. Particularly the *Guidelines on good laboratory practice in pesticide residue analysis*. Codex Alimentarius. Volume 2a, Part 1. FAO, Rome. 2000[8] are relevant. There should be a statement confirming that the test facility follows a specific GLP, and this should be accompanied by a valid certificate or other testimony by an internationally accepted GLP certifying body.

11.11. Data protection:

The Registration Authority should establish appropriate regulations and guidelines to protect and safeguard the proprietary rights to data (CBI – confidential business information & RDP – regulatory data protection) after taking into account the provisions of WTO-TRIPS Agreement[1]. All data submitted by a company in support of its request for original registration of its product should be treated as confidential and should neither be disclosed nor used to evaluate a petition by another applicant, unless there is an agreement with the owner of the data or the period of proprietary rights to the data has expired. (The data protection period should be harmonized among the SEA countries).

11.12. Data access and information sharing:

The Registration Authority may give public access to health and safety data in support of pesticide registrations as long as this does not include the right to copy proprietary data.

The Registration Authority may share information about its system for pesticide regulatory management with other SEA countries in order to harmonize pesticide management in this region.

12. TIME PERIOD FOR REVIEW OF DATA

The Registration Authority should prescribe a specified time period for completing the registration process, provided that the applicant has supplied the minimum data requirements in accordance with guidelines established for the registration of pesticides and no data gaps have been identified. (The time period for review of data will be harmonized among the SEA countries).

13. NOTICE TO APPLICANT TO PROVIDE NEW DATA

The Registration Authority will issue an appropriate notice to the applicant to provide new data to fill data gaps identified during the technical review and will give an appropriate time period for the submission of the new data.

14. ADDITIONAL DATA REQUIREMENTS, IF ANY

The Registration Authority will seek additional data from the registrant applicant under situations such as extension of use, changes in formulation, repackaging or local formulation. It may also require additional data if residue levels exceeding the MRLs have been detected or new pesticide hazard have been identified, including hazards during field application. Such additional data would facilitate the review of the existing registration.

15. PESTICIDE RISK ASSESSMENT

The Registration Authority will carry out a risk assessment of human health hazards associated with pesticide. The assessment of risk should be carried out as per harmonized standards/guidelines established by the Registration Authority. Such assessment should take into account the detailed toxicological data, including long-term dietary exposure. The assessment should also include exposure to very low levels of pesticides.

A well-designed and conducted assessment can provide important and reliable information on what is likely to constitute an acute human health risk. For estimating the hazard of long-term dietary exposure to very low levels of pesticide residues or their metabolites, the concept of the acceptable daily intake (ADI) established by the FAO/WHO Joint Committee on Pesticide Residues is a useful example of the extrapolation of data from long-term animal feeding studies to the human dietary situation. Such evaluations will take into account the Guidelines on crop residue data. FAO, Rome. 1985[5] and the procedures laid down in Manual on the submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed, FAO, 2002, Rome[18].

In addition, the environmental fate and effects of pesticides, namely degradation/persistence and mobility in soil; persistence and translocation in plants; toxicity to bees and other pollinators; avian toxicity; aquatic toxicity; and phytotoxicity effects are also included in pesticide risk assessment as per the provisions of the *Guidelines on environmental criteria for the registration of pesticides (revised)*. FAO, Rome. 1989[22].

As a part of pesticide risk assessment, the Registration Authority may also assess the potential risk of resistance development to the pesticide product. The applicant should provide information about cases of pesticide resistance development in other countries. A risk assessment of pesticide resistance development may be made based on existing national policies and guidelines on the judicious use of pesticides in the context of integrated pest and vector management and national pesticide resistance management policies[12].

16. BIO-EFFICACY ASSESSMENT

The Bio-efficacy assessment will ensure that the pesticide approved would be efficacious for its intended use. The Bio-efficacy assessment will provide the Registration Authority the necessary information to

decide on appropriate usage statements on the label. In this context, the Guidelines on Bio-efficacy data for the registration of pesticides for plant protection. FAO, Rome. 1985[9] and the Guidelines on Bio-efficacy evaluation for the registration of plant protection products, FAO, Rome, 2006 ((International Code of Conduct on distribution and use of pesticides)[10] should be consulted. Further, WHO Bio-efficacy assessments and evaluations of public health pesticides are available from WHOPES[15].

17. PESTICIDE CLASSIFICATION

The pesticide products should be classified according to the WHO hazard classification of pesticides or a modified toxicity classification system that takes into account local or regional pesticide use practices[24]. The Registration Authority should particularly consider the use of colour bands, warning statements and pictograms to reflect the different hazard classes of pesticides.

18. REVIEW OF PESTICIDE LABELLING

The Registration Authority will evaluate the draft labels and leaflets provided by the applicant to ensure that they include in a clear manner all required information on the identity of product (chemical/ concentration of active ingredient(s)/trade name/formulation), permitted uses, dosage and other use recommendations, warning and precautionary statement, description of required personal protection, hazard class, warning statement against reuse of containers, and instruction on safe disposal or decontamination of empty containers. The Registration Authority will ensure that approved labels are written in the major languages of the country and also include the registration number, lot or batch number, date of manufacturing/expiry. Revised guidelines on good labelling practice for pesticides. FAO, Rome. 1995[20] provide appropriate guidance on pesticide labelling.

19. APPROVAL AND ISSUE OF REGISTRATION CERTIFICATE

The Registration Authority will issue an original registration certificate along with the approved pesticide label, all duly endorsed by the Registration Authority, provided the applicant fulfills all the requirements of registration. The registration certificate will carry a unique identification number, date of issue and validity and may bear a bar code and may be suitably laminated or printed on special material to prevent tampering of the certificates issued. The registration certificate will bear the date/signature and appropriate seal of Registration Authority and in the case of restricted use pesticides and/orconditional registration, it will also carry the terms and conditions of registration.

20. VALIDITY OF REGISTRATION

The Registration Authority will specify the validity period of registration separately for each kind of registration, namely experimental (new molecule) registration; proprietary registration; provisional registration, or supplementary (me-too) pesticide registration (The validity period for each kind of registration may be harmonized among the participating countries of the SEA region).

21. DENIAL OF REGISTRATION

In the event of denial of registration, the Registration Authority will issue within reasonable period of time a notice of denial to the applicant, giving the reasons for the denial The applicant may be given the opportunity to appeal against the decision giving grounds for the appeal. Such appeal is to be made by the applicant within 30 days from the date of issue of notice of denial by the Registration Authority.

22. APPEAL BY THE APPLICANT

The Registration Authority will allow the applicant to appeal against the decision made by the Registration Authority in the event of denial of registration or any restrictions imposed. A formal appeal procedure should be included in the pesticide regulations, describing the full procedure, the conditions of appeal

and time limits for all steps in the appeal procedure. The Registration Authority will communicate this information to the applicants, where appropriate. However, the appeal procedures explicitly should not allow questioning the validity criteria. Such appeals will be disposed off after giving reasonable opportunity of hearing and the decision taken in the case of appeal should be communicated to the applicant in a reasonable time (The appellate authority should be clearly defined under the pesticide regulation of the country).

23. NOTIFICATION OF PRIOR INFORMED CONSENT (PIC) PROCEDURES

The designated national authority for pesticides in a country (DNA), which is a party to the Rotterdam Convention[22], should inform the Secretariat of the Rotterdam Convention, whether or not they consent to the future import of chemicals listed in Annex-III of the Rotterdam Convention. In line with Article 10 of the Rotterdam Convention, a decision not to consent to a future import should be accompanied by a prohibition of (i) the import of the chemical from any source and (ii) a prohibition of domestic production of the chemical for domestic use. This should be followed by the cancellation of its registration. Detailed information on notification of final regulatory action as well as the operation of the PIC procedure can be obtained from the text of the Rotterdam Convention[22].

24. UN-CONDITIONAL/CONDITIONAL REGISTRATION

24.1. Un-conditional registration:

The Registration Authority will lay down appropriate criteria for an un-conditional registration, which include:

- that the application was complete and was accompanied by all materials required for registration, including but not limited to, evidence that the applicant had complied with the data compensation requirements;
- all relevant data in its possession were reviewed and accepted;
- no additional data were necessary to make the determinations required under the pesticide regulation with respect to the product;
- the composition of the product is such as to warrant its bio-efficacy claims, if bio-efficacy data were required;
- the product will perform its intended function without adverse effects on the environment, and when used in accordance with best pesticide management practice and the label instructions, the product will not cause adverse effects on the environment; and,
- provided that the proposed label bears directions for use on food, animal feed, or food or feed crops if the intended use of the pesticide results and/or may be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient in or on food or animal feed. In that case, all necessary tolerances or exemptions from the requirement of a tolerance, and food additive regulations, have been accounted for.

Unconditional registrations can be granted for a variety of applications such as identical/ substantially similar (me-too) (described below), new uses, or new active ingredients as long as all criteria described above are met.

24.2. Conditional registration:

The Registration Authority may conditionally approve an application for registration or amend a registration of a pesticide product. This may occur if the Registration Authority determines that, while a registration decision can be made, further data, studies, or actions by the registrant is required for the Registration Authority to carry out its review. This conditional registration may be granted for a new active ingredient, a new use, or an identical/substantially similar (formerly "me-too") product.

However, the Registration Authority may not approve a conditional registration for a new use if the pesticide is the subject to a special review, based on concerns that its proposed new use on a major food or feed crop may result in human dietary exposure. It may also not grant a conditional registration in the case of a new use on a minor food or feed crops if an effective alternative registered pesticide is available that meets the risk criteria associated with human dietary exposure.

25. AMENDMENTS TO PREVIOUS REGISTRATION

Any amendments issued to previous registration certificates should be limited to extensions of label claims, formulation change, repacking and local formulation. This may be subject to additional data requirements. Any amendment issued to a previous registration certificate should be properly endorsed by the Registration Authority and should refer to the previous registration certificate.

26. RE-REGISTRATION

The Registration Authority may issue a re-registration certificate to the original applicant for previously registered products prior to expiry. Before any such re-registration is granted, the Registration Authority will review previous data submitted by the applicant as well as any new data generated consequent to previous registration. The re-registration certificate issued will refer to the previous registration and is valid for a prescribed period *(The validity period of re-registration may be harmonized among the participating countries in SEA region. However, no banned and/or severely restricted pesticide should be re-registered)*.

27. SUPPLEMENTARY REGISTRATION

The Registration Authority may consider supplementary (me-too) registration only after the expiry of of the original registration. Such a supplementary registration requires a written agreement between the original registrant and the supplementary (me-too) applicant.as described in the guidelines established under the FAO/WHO chemical equivalence process for supplementary registration. (The validity period for supplementary (me-too) registration may be harmonized among the participating countries in SEA region).

28. IMPORT/EXPORT REGISTRATION OF PESTICIDES

28.1. The Registration Authority will ensure that all pesticides imported into their territory from foreign manufacturers are covered under the import license system. Before they are further processed (where applicable), distributed, sold and used, they need to be registered and meet all the requirements applicable to domestic producers. However, a sample quantity of a new pesticide may be imported under a provisional registration as a registration sample for experimental purposes. The provisional registration by Registration Authority will specify whether the import is, for generating data or for use as an analytical standard by an authorized institute/organization. Only pesticides with a provisional registration by the Registration Authority will be issued an import permit.

28.2. The Registration Authority will ensure that all pesticides exported conform to the registration requirements of the importing country. The pesticides must be registered in the country in which they are manufactured even if they are produced exclusively for export and are covered under a valid export license.

29. LICENSING OF MANUFACTURING/REPACKING FACILITY

The licensing authority, mandated by the pesticide legislation, will undertake site visits to manufacturing facilities to ensure that they operate compliance with the pesticide regulations and other relevant regulations. They will also verify that appropriate safeguards are in place to protect workers' safety, and – where applicable – effluents are treated and air pollutants monitored.

30. LICENSING OF STOCKIEST/DISTRIBUTORS/RETAILERS

The registration and/or licensing authority, mandated by the pesticide legislation, will inspect premises for the purpose of licensing stockiest and distributor to stock, distribute or sell or store for sale pesticide in compliance with the provisions of the pesticide regulations. The licensed stockiest and distributor will ensure that all pesticides in his premises are registered and he is responsible for fulfilling all conditions stipulated by in the license, such as proper storage of pesticide products, prompt detection and removal of leaking containers and removal of expired pesticides and misbranded products to prevent their distribution. The licensing authority should undertake surprise inspections to the premises of stockiest/ distributor to ensure the licensee abides by the pesticide regulation and to draw samples for quality testing.

31. LICENSING OF PEST CONTROL OPERATORS

The licensing authority, mandated by the pesticide legislation, will undertake licensing of pest control operators according to the provision of the pesticide regulation. A licensed pest control operator must comply with all requirements under the pesticide legislation. They should have adequate knowledge of the pesticide regulation and maintain up-to-date records of all pest control operations. Furthermore, they must take appropriate safety precautions when applying pesticides in the field and take special precautionary measures when applying restricted use pesticides such as fumigants. Such licensing of pest control operators requires a certification programme that provides training and tests the competency of skills.

32. QUALITY CONTROL OF PESTICIDE

The Registration Authority will appoint and/or designate appropriately qualified technical personnel as pesticide inspectors. At periodical intervals, the pesticide inspectors will take pesticide samples from the premises of stockiests or distributors, following the guidelines for sampling of pesticides established by the Registration Authority. They will then be appropriately sealed and secured , and sent to accredited test laboratories for quality testing and reporting (The sampling of pesticides for quality testing should be harmonized among the member countries in this region).

The Registration Authority will employ appropriately qualified technical personnel as pesticide analysts for undertaking quality analysis of pesticides. This should be done in accordance with internationally accepted methods or any national standards/specifications established by the Registration Authority. In the event of a legal dispute, the Registration Authority will designate an apex laboratory to make reference analyses of pesticide samples.

33. CANCELLATION/SUSPENSION OF REGISTRATION/LICENSING

The Registration Authority may suspend a registration granted to an applicant after serving a notice of suspension to the registrant describing the grounds of suspension. This may be done if the registrant fails to comply with registration requirements and/or violates provisions of pesticide regulations. Subsequent to the suspension, the Registration Authority, may order the manufacturing premises to be sealed and/or the stock of sub-standard/misbranded pesticide to be confiscated to prevent its sale and distribution. The Registration Authority may revoke the suspension after ensuring that corrective measures are implemented. The Registration Authority will cancel the registration granted to the applicant in case of repeated violations of pesticide regulations, after serving a notice of cancellation. However, if the registrant appeals within 30 days from the date of notification, such cancellation of will only be carried out after the registrant was given a reasonable opportunity for a hearing.

The designated licensing authority may suspend the license granted to manufacturing facility/stockiest/ distributor/pesticide applicator, if the licensee fails to comply with licensing requirements and/or violates the provisions of pesticide regulation.

34. REVIEW OF REGISTRATION

The Registration Authority will re-evaluate registered pesticides on a regular cycle or when there are public complaints about its bio-efficacy or toxicity or when new data indicate a change or previously unknown characteristic in the pesticide profile. This review after a specified period should make sure that the assessments of human health and environmental risks evolve as policies and practices change, and that all pesticide products in the market can still be used safely. Such reviews may identify pesticides for banning or restricted use or other appropriate measures. *(The period for review of registration may be harmonized among the participating countries in the SEA region).*

35. REFERENCES

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2. *Basel Convention on the Control of Trans-boundary Movements of Hazardous Wastes and their Disposal,* UNEP, Geneva. 1989. (http://www.basel.int).
3. *Designing National Pesticide legislation,* FAO, 2007. FAO Legislative study No. 97, Rome. (http://www.fao.org/docrep/010/a1467e/a1467e00.html).
4. *Globally Harmonized System for Classification and Labelling* (GHS), UN. 2003. (http://www.unece.org/trans/danger/public/ghs/ghs rev00/00files.e.html).
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7. *Guidelines on developing a reporting system for health and environmental incidents resulting from exposure to pesticide,* FAO, Rome, 2009. (*International Code of Conduct on distribution and use of pesticides*) (http://www.fao.org./agriculture/crops/core-themes/theme/pests/pm/code/guidelines/en/).
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12. *Guidelines on pesticide management in support of International Code of Conduct on the Distribution and Use of Pesticides,* FAO, Rome. (Various dates). (http://www.fao.org./agriculture/crops/core-themes/theme/pests/pm/code/guidelines/en/).
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15. *Guidelines for testing,* WHO, 2006.. WHO *Pesticide Evaluation Scheme* (WHOPES), World Health organization, Geneva (www.who.int/whopes/guidelines/en/).

16. *International Code of Conduct on the Distribution and Use of Pesticides,* FAO, Rome. 2002. *(Reprinted in 2006)* (http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/code/en/).

17. *Manual on Development and Use of FAO and WHO Specifications for Pesticides. First Edition,* FAO, Rome. 2002. (Revised in 2006). (http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/manual/en/).

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Annex 1A

APPLICATION FORM FOR REGISTRATION OF PESTICIDE

To _____ _____ _____ _____ **(Name/Designation/Address of registration authority)**	Registration No: Date of receipt: Name and signature of registration staff: _____ With seal

Application made for (√ appropriate box)			
	Import of technical pesticide for domestic manufacturing of formulated pesticide product		Provisional registration
	Import of Formulated pesticide product for domestic consumption		Proprietary registration
	Export of formulated pesticide product (which is domestically manufactured)		Supplementary (me-too) registration
			Re-registration
Identity of the applicant			
	Name of the applicant		
	Mailing address		
	Telephone/Fax No		
	E-mail ID, if any		
	Authorized agent (name/designation)		
	Company registration No/date of issue/validity (if registered previously)		
Identity of the Technical Pesticide (TG/TC)/Formulated Pesticide Product (FPP)			
	Chemical name of the TG/TC/FPP (as the case may be)		
	Trade name of the FPP		
	Formulation type/% active ingredient		

Chemical toxicity category (WHO classification) (√ appropriate box)	
	WHO (Class I a) – Extremely hazardous
	WHO (Class I b) – Highly hazardous
	WHO (Class II) – Moderately hazardous
	WHO (Class III) – Slightly hazardous
	Unlikely hazardous (U)
	Others (UNEP-PIC/POP)

Category of pesticide (√ appropriate box)					
	Acaricide		Chemosterilant		Pheromone
	Algaecide		Herbicide		Plant hormone
	Antibiotic		Insecticide		Nematicide
	Avicide		Insect repellent		Molluscicide
	Bacteriocide		Fumigant		Rodenticide
	Biocide		Fungicide		Others (specify)

Identity of Manufacturer/Supplier	
Name of manufacturer/Address of location of manufacturing facility (applicable for domestic manufacturing)	
Particulars of licensing issued for manufacturing facility for pesticide for domestic consumption (where applicable)	

Name and address of authorized supplier (s) (applicable for import of technical/pesticide)			
Particulars of registration, if any (applicable for import of technical pesticide/formulated pesticide product)			
Country in which it is registered (applicable for import of technical pesticide/formulated pesticide product)			
Intended use of pesticide product (√ appropriate box)			
	Use categories		**Use patterns**
	Terrestrial		Terrestrial food use
			Terrestrial feed use
			Terrestrial non-food use
	Aquatic		Aquatic food use
			Aquatic non-food use
	Greenhouse		Greenhouse food use
			Greenhouse non-food use
	Forestry/plantation		Forest use
			Plantation (food) use
			Plantation (non-food) use
	Residential (outdoor)		Residential (outdoor) use
	Indoor		Residential (indoor) use
			Indoor non-food, non-residential use
			Indoor food use
	Direct Application on human/animals		Direct application to humans/animals
Registration data requirements/Compliance with (√ appropriate box)			
Registration data requirements		**Compliance with**	
	Physico-chemical data (**Folder A***)		Complied with
	Toxicological data (**Folder B**)		Complied with
	Bio-efficacy data (**Folder C**)		Complied with
	Residue data (**Folder D**)		Complied with
	Human health exposure/Environmental fate & effects data (**Folder E**)		Complied with
	Labelling/Packaging data (Folder F)		Complied with
	Additional data requirements, if any (Folder G)		Compiled with
Note: * The Folder A contains biochemical data in the case of biochemical pest control agents and microbiological data in case of microbial pest control agents			
Give reasons, if any data requirements are not complied with:			
Additional Information			
Letter of authorization to use data issued by the original data submitter (applicable in the case of supplementary (me-too) registration)			
Particulars of payment of fee			
Amount of fee (in figures and words)			
Demand draft/Pay order No.			
Name of the bank			
Address of branch			

List of documents enclosed	
1.	4.
2.	5.
3.	6.
7.	8.

Verification/Declaration

I _____do hereby solemnly verify that to the best of my knowledge and belief the information given in the application and the Annex and statements/accompanying it, is correct and complete.

I further declare that I am making this application in my capacity as _____ and that I am competent to make this application and verify it by virtue of _____ a photo copy of the applicant's identification document duly attested by competent authority which is enclosed herewith.

Place: _____ Signature _____

Date: _____ With seal _____

Acknowledgement

I hereby by acknowledge the receipt of application of M/s_____ and the same is registered under Register No:_____ dated: _____.

Name:_____

Signature:_____

With seal **(Registering staff)**

Instruction/guidelines for filling the application:

1. The application should be submitted in five sets (original + 4 copies) in A4 size paper duly filled and signed by an authorized agent under the seal of the company.
2. The applicant should consult the latest guidelines for the registration of pesticides established by the registration authority regarding the registration data requirements.
3. The registration data should be submitted in distinct folders for each kind of data (e.g., chemistry data) submitted in double cover with the inner cover marked on the top as **"confidential business information"** affixed with the seals of the data submitter and such folders should be opened only by the specifically authorized personnel of the Registration Authority in accordance with the procedures laid down for handling confidential business information prescribed by the Registration Authority.
4. The application should be accompanied by a crossed bank draft or pay order drawn in favour of appropriate authority as specified under the guidelines towards payment of fees for registration/ re-registration and other charges as prescribed by the Registration Authority.
5. The application should be type written and if hand written should be clearly legible and should be filled complete without leaving any one blank. If the entry is not relevant to applicant, it should be indicated "**not applicable**". Any corrections on the application should be appropriately attested.

6. The application should be accompanied by five copies of the draft product label intended to be registered and five copies of the tamper-proof certification of the containers in which the product is packed for end use (primary packing). However, this does not apply to cases of technical product intended solely for further processing and not for end-use purposes.

7. The application should be accompanied by an attested valid photocopy of the applicant's business registration certificate issued by the appropriate authority e.g. registrar of companies.

8. The application should be accompanied by an attested copy of a valid license issued by an appropriate authority for domestic manufacturing facility, in the event that the application is for the import of a technical chemical for the domestic manufacture of the product.

9. A separate application is required if the pesticide product is different from another product. A pesticide product is considered different if:

   (a) the active ingredient is different;

   (b) the trade name or trade mark is different;

   (c) the ingredients are different in type, number, proportion, concentration, or in other respects; e.g. glyphosate isopropylamine 13.6 percent w/w soluble concentrate (SL) and glyphosate isopropylamine 41.0 percent w/w soluble concentrate (SL) must be registered separately under each concentration;

   (d) the formulation is differently, e.g. if alpa-cypermethrin is formulated as an emulsifiable concentrate (EC) and also as suspension concentrate (SC), they must be registered separately under each formulation;

   (e) the manufacturer is different; e.g. if benomyl is manufactured by two companies, the products from both companies must be registered separately even if the products are identical; or

   (f) the quality, nature, characteristics or bio-efficacy is different; e.g. if one azadirachtin product is different in quality, nature, characteristics or bio-efficacy from another product they must be registered separately.

10. The application should be accompanied by a letter from the source(s) confirming that they are the suppliers of the pesticide intended to be registered. Such letter shall state clearly the specifications of the pesticide product which should be identical to that being applied for registration. The letter should be in original or an attested photocopy, and state clearly the time period of the supply agreement between the source and the applicant, and should be renewed, if applicable, with a validated copy to the Registration Authority. If no such renewals are made and notified, the Registration Authority may cancel the registration of the pesticide product.

11. The applicant should submit an original letter of authorization for using the data from the original data submitter along with four copies of the draft label, in the event the application is made for a supplementary (me-too) registration. Such a letter should be in original and state clearly the time period for which the authorization is given.

12. The applicant should enclose the original registration certificate issued by the registration authority along with four copies of amended draft label in the event the application is made for re-registration.

13. The application should be accompanied by a registration sample of the technical chemical/pesticide product packed in a original tamper-proof container, where required.

Annex 1B

CHECK SHEET (FOR OFFICIAL USE ONLY)

	Item verified (√ in appropriate box left side)	Sign of reg. staff with date
Part A: Registration authority (Administration unit)		
A.1.	Application in prescribed format and required copies and attached documents received	
A.2.	Acknowledgement of receipt of application issued	
A.3.	Application and attached documents verified & registration number assigned	
A.4.	Payment of prescribed registration fee and other charges by bank draft/pay order received	
A.5.	Draft label of intended pesticide product for registration received in required copies	
A.6.	Certificate of tamper-proof container/packaging material received.	
A.7.	Registration data requirements submitted in distinct sealed folders (registration dossiers), as required indicated below (**strike out the one, whichever is not applicable**):	
	– Physico-chemical data (**Folder A***)	
	– Toxicological data (**Folder B**)	
	– Bio-efficacy data (**Folder C**)	
	– Residue data (**Folder D**)	
	– Human health exposure/Environmental fate & effects data (**Folder E**)	
	– Labelling/packaging data (Folder F)	
	– Additional data requirements, if any (Folder G)	
Note: * The Folder A contains biochemical data in the case of biochemical pest control agents and microbiological data in case of microbial pest control agents		
A.8.	Proprietary certificate/partnership deed/Board of directors resolution received	
A.9.	Letter of authorization for use of data by original data submitter in the case of supplementary registration	
A.10.	Original registration certificate received in the case of re-registration	
A.11.	Copy of applicant business certificate/license issued by relevant authority e.g. registrar of companies	
A.12.	Licensing certificate for manufacturing facility of pesticide submitted, where required	
A.13.	Communicated document deficiencies, if any to the applicant	
A.14.	Amendments/modifications/corrections to the application & attached documents received from the applicant to make it complete	
A.15.	Communicated denial of application for registration, if the applicant does not meet the registration requirements prescribed by the registration authority	
Part B: Registration authority (Technical evaluation unit)		
B.1.	One set of application along with attached documents along with sealed registration data folders submitted to specified expert of technical evaluation section	
B.2.	Verification of data/analytical methods/test protocols/specifications/validation of test protocols, if required/verification of manufacturing process, if any & identification of data gaps by the experts of the following units of the technical evaluation section	
	B.2.1. Chemistry unit	
	B.2.2. Toxicology unit	
	B.2.3. Bio-efficacy unit	
	B.2.4. Residue unit	
	B.2.5. Health/Environmental monitoring unit	
	B.2.6. Labelling/Packaging evaluation unit	
	B.2.7. Biochemistry/Microbiology unit	

	Item verified (√ in appropriate box left side)	Sign of reg. staff with date
B.3.	Preparation of summary report of technical evaluation of pesticide product intended to be registered, including recommendations for review by the registration committee/ pesticide board, as the case may be	
B.4.	Technical consultation/review of summary report of technical evaluation of pesticide product intended to be registered by the registration committee/pesticide board, as the case may be	
B.5.	Issue of notice to the applicant for additional and/or new data requirements	
B.6.	Additional and/or new data received from the applicant and evaluated by the registration committee/pesticide board, as the case may be	
B.7.	Approval and issue of the registration certificate in the prescribed format by the registration authority	
B.8.	Issue of notice of denial of registration to the applicant by the registration authority giving reasons for denial	

Final verification of actions by registration authority to ensure registration process is complete.

Date: _____ Name: _____

Place: _____ Signature _____

With Seal (**Registration authority**)

Annex 2A

DATA REQUIREMENTS FOR REGISTRATION OF CHEMICAL PESTICIDES (CP)

S. No.	Data parameters	Proprietary registration	Comments
		Technical grade AI	
	A. Physico-chemical data		
Active Ingredient (AI)			
A.1.	**Chemical identity**		
	1.1. Chemical abstract services number	Required	
	1.2. Common name proposed or accepted by ISO and synonyms	Required	
	1.3. Structural formula	Required	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Required	
	1.5. Empirical formula and molecular weight	Required	
	1.6. Analytical standards/samples	Required	
	1.7. Specification together with method of analysis of active ingredient	Required	
A.2.	**Physico-chemical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour and odour)	Required	
	2.2. Melting/decomposition/boiling point	Required	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 ºC), but only when above 10-3 Pascal)	Required	
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25 ºC)	Required	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Required	
	2.6. Density (for liquids only)	Required	
	2.7. Hydrolysis rate under stated relevant conditions.	Required	
	2.8. Photolysis under stated relevant conditions.	Required	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Required	
A.3.	**Technical grade active ingredient**		
	3.1. Source; name and address of manufacturer and addresses where manufactured	Required	
	3.2. Appearance (physical state, colour and odour)	Required	
	3.3. The minimum (and maximum) active ingredient content in g/kg	Required	
	3.4. Identity and amount of isomers, impurities and other by-products	Required	
	3.5. Analytical test report of impurity profile	Required	
	3.6. Analytical test report of specifications	Required	
	3.7. Process of manufacturing	Required	
	3.8. Shelf life	Required	
	3.9. Specification together with methods of analysis and physicochemical properties	Required	
A.4.	**Material Safety Data Sheet (MSDS)**		
	4.1. Physical data (melting point, boiling point, flash point, etc.)	Required	
	4.2. Chemical toxicity	Required	
	4.3. Health effects	Required	

S. No.	Data parameters	Proprietary registration	Comments
		Technical grade AI	
	4.4. First aid	Required	
	4.5. Reactivity	Required	
	4.6. Storage	Required	
	4.7. Disposal	Required	
	4.8. Protective equipments	Required	
	4.9. Spill-handling procedure	Required	
	4.10. Label including hazard symbol	Required	
B. Toxicological data			
B.1.	**Acute toxicity tests**		
	1.1. Acute oral toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Acute dermal toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Acute inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Primary eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests in (minimum of oral test of 90 days duration) in rats**	Required	
B.5.	**Reproduction Effects studies (minimum of two generations in rats)**	Required	
B.6.	**Teratogenicity studies (in two species, one in rats and other in non-rodents)**	Required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Required	
B.8.	**Mutagenicity studies (minimum of Ames test and in vivo micronucleus Test)**	Required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats (combined if possible)**	Required	
B.10.	**Medical Data/Poisoning symptoms/Antidote**	Required	
C. Bio-efficacy data			
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Not required	
	1.2. Dosage/rate of application	Not required	
	1.3. No. of applications	Not required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume, etc.)/Appliances	Not required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Not required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Not required	
	2.3. Pre-harvest intervals	Not required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Not required	
C.4.	**Pesticide evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Not required	
C.5.	**Method of sampling**	Not required	
C.6.	**Recording field data**	Not required	

S. No.	Data parameters	Proprietary registration	Comments
		Technical grade AI	
C.7.	**Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence**	Not required	
	D. Residue data		
D.1.	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Required	
	1.3. Crop groupings	Required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Required	
	1.5. Dosage rate (at least equal to intended use)	Required	
	1.6. Identification & characterization of residues	Required	
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e., lactating cows, goats) and poultry chicken	Required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)	Required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Required	
	2.5. Parental compounds should be used	Required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Required	
	3.5. Material used: usually parent compound	Required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Required	
	4.4. Glasshouse trials (protected crops)	Required	
	4.5. Post-harvest treatment studies (wheat, potato)	Required	

S. No.	Data parameters	Proprietary registration Technical grade AI	Comments
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Required	
	4.7. Degradation studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Required	
	5.2. Analytical standards/reference chemicals	Required	
	E. Human health exposure/environmental data		
E.1.	**Operators exposure data (dermal exposure/inhalation exposure, biological monitoring), while manufacturing**	Required	
E.2.	**Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring), while manufacturing/repacking**	Required	
E.3.	**Evaluation of environmental fate & effects**		
	3.1. Data on translocation of pesticides in soil and water	Required	
	3.2. Primary data on toxicity to birds and non-targeted beneficial organisms (e.g. honey bees, pollinators, etc.)	Required	
	3.3. Primary data on aquatic toxicity (e.g. fish and other aquatic animals)	Required	
	3.4. Primary data on persistence/translocation in plants	Required	
E.4.	**Monitoring of environmental effects**		
	4.1. Monitoring of substantial change in use/application pattern	Not required	
	4.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	4.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Required	
E.5.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence/resistance)**	Not required	
	F. Labelling/Packaging/Storage data		
F.1.	**Labelling**		
	1.1. Chemical name	Required	
	1.2. Product name	Not required	
	1.3. Formulation/contents of the product	Not required	
	1.4. Quantity (Wt/Vol.)	Required	
	1.5. Registration number/date of registration/date of expiry and/orimport permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry and or/shelf life (months/years)	Required	
	1.10. Precautions & directions for use	Not required	
	1.11. Warning phrases/Hazard symbols/pictograms/colour code, etc.	Required	
	1.12. Storage conditions	Required	

S. No.	Data parameters	Proprietary registration	Comments
		Technical grade AI	
	1.13. Recommended crop/commodity	Not required	
	1.14. Pre-harvest intervals	Not required	
	1.15. Restrictions on use, if any	Not required	
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	
F.2.	**Packaging**		
	2.1. Specification of primary package	Not required	
	2.2. Specification of secondary package	Not required	
	2.3. Specification of bulk package for transport	Required	
F.3.	**Storage tests (Shelf life) (Temp/RH/Refrigeration)**	Required	

Annex 2B

DATA REQUIREMENTS FOR REGISTRATION OF CHEMICAL PESTICIDES (CP)

S. No.	Data parameters	Proprietary registration Formulated product	Comments
	A. Physico-chemical data		
Active Ingredient (AI)			
A.1.	**Chemical identity**	Not required*	
	1.1. Chemical abstract services number	Not required*	
	1.2. Common name proposed or accepted by ISO and synonyms	Not required*	
	1.3. Structural formula	Not required*	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Not required*	
	1.5. Empirical formula and molecular weight	Not required*	
	1.6. Specification together with method of analysis of active ingredient	Not required*	
A.2.	**Physical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour and odour)	Not required*	
	2.2. Melting/decomposition/boiling point	Not required*	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 ºC), but only when above 10-3 Pascal)	Not required*	Applicable for fumigants and gaseous chemicals
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25 ºC)	Not required*	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Not required*	
	2.6. Density (for liquids only)	Not required*	
	2.7. Hydrolysis rate under stated relevant conditions	Not required*	
	2.8. Photolysis under stated relevant conditions	Not required*	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Not required*	
A.3.	**Technical grade active ingredient**	Not required*	
	3.1. Source; name and address of manufacturer and addresses where manufactured	Not required*	
	3.2. Appearance (physical state, colour and odour)	Not required*	
	3.3. The minimum (and maximum) active ingredient content in g/kg	Not required*	
	3.4. Identity and amount of isomers, impurities and other by-products	Not required*	
	3.5. Analytical test report of impurity profile	Not required*	
	3.6. Analytical test report of specifications	Not required*	
	3.7. Process of manufacturing	Not required*	
	3.8. Shelf life	Not required*	
	3.9. Specification together with methods of analysis and physicochemical properties	Not required*	
A.4.	**Material Safety Data Sheet (MSDS)**		
	4.1. Physical data (melting point, boiling point, flash point, etc.)	Not required*	
	4.2. Chemical toxicity	Not required*	
	4.3. Health effects	Not required*	

S. No.	Data parameters	Proprietary registration	Comments
		Formulated product	
	4.4. First aid	Not required*	
	4.5. Reactivity	Not required*	
	4.6. Storage	Not required*	
	4.7. Disposal	Not required*	
	4.8. Protective equipments	Not required*	
	4.9. Spill-handling procedure	Not required*	
	4.10. Label including hazard symbol	Not required*	
Formulated product			
A.5.	**Product identity**		
	5.1. Formulator's name and address	Required	
	5.2. Distinguishing name (proprietary name) of product	Required	
	5.3. Use category (herbicide, insecticide, etc.)	Required	
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	Required	
A.6.	**Composition of product**		
	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, this information should be given for each ingredient separately)	Required	
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvant and inert components	Required	
	6.3. Water/other solvent content (where relevant)	Required	
A.7.	**Physical/Chemical properties of the product**		
	7.1. Appearance (physical state, colour and odour)	Required	
	7.2. Storage stability (in respect to composition and physical properties related to use)	Required	
	7.3. Density (for liquids only)	Required	
	7.4. Flammability: liquids – flashpoint; solids – a statement must be made as to whether the product is flammable	Required	
	7.5. Acidity (where relevant)	Required	
	7.6. Alkalinity (where relevant)	Required	
	7.7. Other properties may in certain cases need evaluation	Required	
A.8.	**Physical properties of the formulated product related to use**		
	8.1. Wettability (for dispersible powders)	Required	
	8.2. Persistent foam (for formulations applied in water	Required	
	8.3. Suspendibility (for dispersible powders and suspension concentrates)	Required	
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	Required	
	8.5. Dry sieve test (for granules, dusts)	Required	
	8.6. Emulsion stability (for emulsifiable concentrates)	Required	
	8.7. Corrosiveness (when necessary)	Required	
	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	Required	
	8.9. Specification together with method of analysis	Required	
	8.10. Analytical test report	Required	
	8.11. Shelf life	Required	

S. No.	Data parameters	Proprietary registration Formulated product	Comments
	B. Toxicological data		
B.1.	**Acute toxicity tests**	Required	
	1.1. Acute oral toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Acute dermal toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Acute inhalation toxicity (LC_{50} in mg/L).	Required	
B.2.	**Irritation tests**	Required	
	2.1. Primary skin irritation	Required	
	2.2. Acute eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats**	Not required	
B.10.	**Medical data/Poisoning symptoms/antidotes**	Required	
	C. Bioefficacy data		
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Required	
	1.2. Dosage/rate of application	Required	
	1.3. No. of applications	Required	
	1.4. Application method (e.g. dusting/spraying, high volume/low volume/ ultra low volume, etc.)/Appliances	Required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Required	
	2.3. Pre-harvest intervals	Required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Required	
C.4.	**Pesticide evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Required	
C.5.	**Method of sampling**	Required	
C.6.	**Recording field data**	Required	
C.7.	**Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence**	Required	
	D. Residue data		
D.1.	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	

S. No.	Data parameters	Proprietary registration	Comments
		Formulated product	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studie**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required: meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation Studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	

S. No.	Data parameters	Proprietary registration Formulated product	Comments
	E. Human health exposure/environmental data		
E.1.	**Human health exposure effects**		
	1.1. Operators exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application.	Required*	
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Not required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Not required	
	2.3. Experimental data on infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Not required	
	2.4. Primary data on phytotoxicity effects.	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence**	Not required	
	F. Labelling/Packaging/Storage data		
F.1.	**Labelling**		
	1.1. Chemical name	Required	
	1.2. Product name	Required	
	1.3. Formulation/contents of the product	Required	
	1.4. Quantity (Wt/Vol.)	Required	
	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry and or/shelf life (months/year)	Required	
	1.10. Precautions & directions for use	Required	
	1.11. Warning phrases/Hazard Symbols/Pictograms/colour code	Required	
	1.12. Storage conditions	Required	
	1.13. Recommended crop/commodity	Required	
	1.14. Pre-harvest intervals	Required	
	1.15. Restrictions, if any	Required	
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	

S. No.	Data parameters	Proprietary registration	Comments
		Formulated product	
F.2.	**Packaging**		
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Specification of bulk package for transport	Required	
F.3.	**Storage tests (Shelf life) (Temp/RH/Refrigeration)**	Required	

* Required only in those cases where technical grade is not registered but its formulation (readymade) is directly imported and is intended to be registered. In normal cases, technical grade product is registered together with its formulation to be sold in the market. NA: Not available.

Annex 2C

DATA REQUIREMENTS FOR REGISTRATION OF CHEMICAL PESTICIDES (CP)

S. No.	Data parameters	Supplementary registration: Formulated product	Comments
A. Physico-chemical data			
Active Ingredient (AI)			
A.1.	**Chemical identity**		
	1.1. Chemical abstract services number	Not required	
	1.2. Common name proposed or accepted by ISO and synonyms	Not required	
	1.3. Structural formula	Not required	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Not required	
	1.5. Empirical formula and molecular weight	Not required	
	1.6. Specification together with Method of analysis of active ingredient	Not required	
A.2.	**Physical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour and odour)	Not required	
	2.2. Melting/decomposition/boiling point	Not required	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 ºC), but only when above 10-3 Pascal)	Not required	
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25 ºC)	Not required	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Not required	
	2.6. Density (for liquids only)	Not required	
	2.7. Hydrolysis rate under stated relevant conditions	Not required	
	2.8. Photolysis under stated relevant conditions.	Not required	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Not required	
A.3.	**Technical Grade Active Ingredient**		
	3.1. Source; name and address of manufacturer and addresses where manufactured	Not required	
	3.2. Appearance (physical state, colour and odour)	Not required	
	3.3. The minimum (and maximum) active ingredient content in g/kg	Not required	
	3.4. Identity and amount of isomers, impurities and other by-products	Not required	
	3.5. Analytical test report of impurity profile	Not required	
	3.6. Analytical test report of specifications	Not required	
	3.7. Process of manufacturing	Not required	
	3.8. Shelf life	Not required	
	3.9. Specification together with methods of analysis and physicochemical properties	Not required	
A.4.	**Material Safety Data Sheet (MSDS)**		
	4.1. Physical data (melting point, boiling point, flash point, etc.)	Not required	
	4.2. Chemical toxicity	Not required	
	4.3. Health effects	Not required	
	4.4. First aid	Not required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product	
	4.5. Reactivity	Not required	
	4.6. Storage	Not required	
	4.7. Disposal	Not required	
	4.8. Protective equipments	Not required	
	4.9. Spill-handling procedure	Not required	
	4.10. Label including hazard symbol	Not required	
Formulated product			
A.5.	**Product identity**		
	5.1. Formulator's name and address	Required	
	5.2. Distinguishing name (proprietary name)	Required	
	5.3. Use category (herbicide, insecticide, etc.)	Required	
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	Required	
A.6.	**Composition of product**		
	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	Required	
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvant and inert components	Required	
	6.3. Water/other solvent content (where relevant)	Required	
A.7.	**Physical/Chemical properties of the product**		
	7.1. Appearance (physical state, colour and odour)	Required	
	7.2. Storage stability (in respect to composition and physical properties related to use)	Required	
	7.3. Density (for liquids only)	Required	
	7.4. Flammability: liquids – flashpoint; solids – a statement must be made as to whether the product is flammable	Required	
	7.5. Acidity (where relevant)	Required	
	7.6. Alkalinity (where relevant)	Required	
	7.7. Other properties may in certain cases need evaluation	Required	
A.8.	**Physical properties of the formulated product related to use**		
	8.1. Wettability (for dispersible powders)	Required	
	8.2. Persistent foam (for formulations applied in water	Required	
	8.3. Suspendibility (for dispersible powders and suspension concentrates)	Required	
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	Required	
	8.5. Dry sieve test (for granules, dusts)	Required	
	8.6. Emulsion stability (for emulsifiable concentrates)	Required	
	8.7. Corrosiveness (when necessary)	Required	
	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	Required	
	8.9. Specification together with method of analysis	Required	
	8.10. Analytical test report	Required	
	8.11. Shelf life	Required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product	
B. Toxicological data			
B.1.	**Acute toxicity tests**		
	1.1. Acute oral toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Acute dermal toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Acute inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Acute eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats**	Not required	
B.10.	**Medical data/Poisoning symptoms/antidotes**	Required	
C. Bioefficacy data			
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Required	
	1.2. Dosage/rate of application	Required	
	1.3. No. of applications	Required	
	1.4. Application Method (e.g. dusting/spraying, high volume/low volume/ ultra low volume, etc.)/Appliances	Required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Required	
	2.3. Pre-harvest intervals	Required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Required	
C.4.	**Pesticide evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Required	
C.5.	**Method of sampling**	Required	
C.6.	**Recording field data**	Required	
C.7.	**Statistical Analysis of Data and results on Effectiveness, Phytotoxicity, Compatibility with other chemicals, Effects on natural enemies, Information on potential occurrence to resistance/resurgence**	Required	
D. Residue data			
D.1.	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analyzed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet ((currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation Studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	
	E. Human health exposure/environmental data		
E.1.	**Human health exposure effects**		
	1.1. Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Not required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Not required	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Not required	
	2.4. Primary data on phytotoxicity effects	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence**	Not required	
	F. Labelling/Packaging/Storage data		
F.1.	**Labelling**		
	1.1. Chemical name	Required	
	1.2. Product name	Required	
	1.3. Formulation/contents of the product	Required	
	1.4. Quantity (Wt/Vol.)	Required	
	1.5. Registration number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry	Required	
	1.10. Precautions & directions for use	Required	
	1.11. Warning phrases/Hazard symbols/Pictograms/Colour code, etc.	Required	
	1.12. Storage conditions	Required	
	1.13. Recommended crop/Commodity	Required	
	1.14. Pre-harvest intervals	Required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product	
	1.15. Restrictions, if any	Required	
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	
F.2.	**Packaging**		
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Specification of bulk package for transport	Required	
F.3.	**Storage tests (Shelf life) (Temp./RH/Refrigeration)**	Required	

Annex 3A

DATA REQUIREMENTS FOR REGISTRATION OF BIOCHEMICAL PEST CONTROL AGENTS (BPCA)

S. No.	Data parameters	Proprietary registration: Tech. grade AI/Tech. conc. of BPCA	Comments
	A. Biochemical data		
Active Ingredient of BPCA			
A.1.	**Biochemical identity**		
	1.1. Chemical abstract services number, if any	Required	
	1.2. Common name proposed or accepted by ISO and synonyms	Required	
	1.3. Structural formula	Required	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Required	
	1.5. Empirical formula and molecular weight	Required	
	1.6. Plant species (common/scientific name) from which the active ingredient extracted	Required	
	1.7. Specification together with Method of analysis of active ingredient	Required	
A.2.	**Physical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour and odour)	Required	
	2.2. Melting/decomposition/boiling point	Required	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 ºC), but only when above 10-3 Pascal)	Required	
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25 ºC)	Required	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Required	
	2.6. Density (for liquids only)	Required	
	2.7. Hydrolysis rate under stated relevant conditions	Required	
	2.8. Photolysis under stated relevant conditions	Required	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Required	
	2.10. Methods of analysis of physic chemical properties	Required	
A.3.	**Technical Grade Active Ingredient (TGAI)/Technical Concentrate (TC) of BPCA**		
	3.1. Source; name and address of manufacturer and addresses where manufactured	Required	
	3.2. Appearance (physical state, colour and odour)	Required	
	3.3. The minimum (and maximum) active ingredient content in g/kg	Required	
	3.4. Identity and amount of isomers, impurities and other by-products, together with	Required	
	3.5. Outline of extraction process of active ingredient of BPCA	Required	
	3.6. Specification together with method of analysis.	Required	
	3.7. Analytical test report	Required	
	3.8. Shelf life	Required	
	B. Toxicological data		
B.1.	**Acute toxicity tests:**		
	1.1. Acute oral toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	

S. No.	Data parameters	Proprietary registration	Comments
		Tech. grade AI/Tech. conc. of BPCA	
	1.2. Acute dermal toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Acute inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies**	Not required	
* Toxicological data in respect of B.1 to B.3, essentially required. If the biochemical pest control agent proved to have toxic effects, further data in respect of B.4 to B.9 is also required.			
	C. Bioefficacy data		
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Not required	
	1.2. Dosage/rate of application	Not required	
	1.3. No. of applications	Not required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume)/Appliances	Not required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Not required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Not required	
	2.3. Pre-harvest intervals	Not required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Not required	
C.4.	**Pesticide evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Not required	
C.5.	**Method of sampling**	Not required	
C.6.	**Recording field data**	Not required	
C.7.	**Statistical analysis of data and results on effectiveness, phytotoxicity, compatibility with other chemicals**	Not required	
	D. Residue data		
D.1.	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	

S. No.	Data parameters	Proprietary registration Tech. grade AI/Tech. conc. of BPCA	Comments
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analysed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation Studies (4 sampling intervals, i.e. five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	

S. No.	Data parameters	Proprietary registration Tech. grade AI/Tech. conc. of BPCA	Comments
E. Human health exposure/environmental fate & effects data			
E.1.	**Human health exposure effects**		
	1.1. Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
* Only if the microbial pest control agent proved to have allergic/toxic effects to human beings			
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Not required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Not required	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Not required	
	2.4. Primary data on phytotoxicity effects	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence)**	Not required	
F. Labelling/Packaging/Storage test data			
F.1.	**Labelling**		
	1.1. Chemical name	Required	
	1.2. Product name	Not required	
	1.3. Formulation/contents of the product	Not required	
	1.4. Quantity	Required	
	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture Licensing Number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry of product	Required	
	1.10. Precautions & directions for use	Not required	
	1.11. Warning phrases/hazard symbols/pictograms/colour code, etc.	Required	
	1.12. Storage conditions	Required	
	1.13. Recommended crop/commodity	Not required	
	1.14. Pre-harvest intervals	Not required	
	1.15. Restrictions on use, if any	Not required	
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	

S. No.	Data parameters	Proprietary registration	Comments
		Tech. grade AI/Tech. conc. of BPCA	
F.2.	**Packaging**		
	2.1. Specification of primary package	Not required	
	2.2. Specification of secondary package	Not required	
	2.3. Specification of bulk package for transport	Required	
F.3.	**Storage tests (Shelf life) Temp./RH/Refrigeration**	Required	

Annex 3B

DATA REQUIREMENTS FOR REGISTRATION OF BIOCHEMICAL PEST CONTROL AGENT (BPCA)

S. No.	Data parameters	Proprietary registration	Comments
		Formulated product of BPCA	
Active Ingredient of BPCA			
A.1.	**Biochemical identity**		
	1.1. Chemical abstract services number, if any	Not required	
	1.2. Common name proposed or accepted by ISO and synonyms	Not required	
	1.3. Structural formula	Not required	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Not required	
	1.5 Empirical formula and molecular weight	Not required	
	1.6. Plant species (common/scientific name) from which the active ingredient extracted	Not required	
	1.7. specification together with method of analysis of active ingredient	Not required	
A.2.	**Physical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour and odour)	Not required	
	2.2. Melting/decomposition/boiling point	Not required	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 ºC), but only when above 10-3 Pascal)	Not required	
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25 ºC)	Not required	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Not required	
	2.6. Density (for liquids only)	Not required	
	2.7. Hydrolysis rate under stated relevant conditions	Not required	
	2.8. Photolysis under stated relevant conditions	Not required	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Not required	
	2.10. Methods of analysis of physic chemical properties	Not required	
A.3.	**Technical Grade Active Ingredient (TGAI)/Technical Concentrate of BPCA**		
	3.1. Source; name and address of manufacturer and addresses where manufactured	Not required	
	3.2. Appearance (physical state, colour and odour)	Not required	
	3.3. The minimum (and maximum) active ingredient content in g/kg	Not required	
	3.4. Identity and amount of isomers, impurities and other by-products, together with	Not required	
	3.5. Outline of extraction process of active ingredient of BPCA	Not required	
	3.6. Specifications together with method of analysis	Not required	
	3.7. Analytical test report	Not required	
	3.8. Shelf life	Not required	
Formulated BPCA product			
A.5.	**Product identity**		
	5.1. Formulator's name and address	Required	
	5.2. Distinguishing name (proprietary name) of product	Required	

S. No.	Data parameters	Proprietary registration Formulated product of BPCA	Comments
	5.3. Use category (herbicide, insecticide, etc.)	Required	
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	Required	
A.6.	**Composition of formulated BPCA product**	Required	
	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	Required	
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert components	Required	
	6.3. Water/other solvent content (where relevant)	Required	
	6.4. Specification together with method of analysis	Required	
	6.5. Analytical test report	Required	
	6.6. Shelf life	Required	
A.7.	**Physical/Chemical properties of the formulated BPCA product**		
	7.1. Appearance (physical state, colour and odour)	Required	
	7.2. Storage stability (in respect to composition and physical properties related to use)	Required	
	7.3. Density (for liquids only)	Required	
	7.4. Acidity (where relevant)	Required	
	7.5. Alkalinity (where relevant)	Required	
	7.6. Other properties may in certain cases need evaluation	Required	
A.8.	**Physical properties of the formulated product related to use**		
	8.1. Wettability (for dispersible powders)	Required	
	8.2. Persistent foam (for formulations applied in water	Required	
	8.3. Suspendibility (for dispersible powders and suspension concentrates)	Required	
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	Required	
	8.5. Dry sieve test (for granules, dusts)	Required	
	8.6. Emulsion stability (for emulsifiable concentrates)	Required	
	8.7. Corrosiveness (when necessary)	Required	
	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	Required	
	B. Toxicological data		
B.1.	**Acute toxicity tests**		
	1.1. Acute oral toxicity (i.e. LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Acute dermal toxicity (i.e. LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Acute inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Acute Eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	

S. No.	Data parameters	Proprietary registration Formulated product of BPCA	Comments
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies**	Not required	
	C. Bioefficacy data		
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Required	
	1.2. Dosage/rate of application	Required	
	1.3. No. of applications	Required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume)/Appliances	Required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Required	
	2.3. Pre-harvest intervals	Required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Required	
C.4.	**Pesticide evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Required	
C.5.	**Method of Sampling**	Required	
C.6.	**Recording field data**	Required	
C.7.	**Statistical analysis of data and results on effectiveness, phytotoxicity, compatibility with other chemicals**	Required	
	D. Residue data		
D.1	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The “marker compound concept” should be used for enforcement and “toxicological relevant compounds” should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analysed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower then 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	

S. No.	Data parameters	Proprietary registration Formulated product of BPCA	Comments
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation Studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	
E. Human health exposure/environmental fate & effects data			
E.1.	**Human health exposure effects**		
	1.1. Operators exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
* Only if the Biochemical Pest Control Agent (BPCA) proved to have allergic/toxic effects to human beings			
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Not required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Not required	

S. No.	Data parameters	Proprietary registration Formulated product of BPCA	Comments
	2.3. Experimental data on infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Not required	
	2.4. Primary data on phytotoxicity effects	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence)**	Not required	
	F. Labelling/Packaging/Storage test data		
F.1.	**Labelling**	Required	
	1.1. Chemical name	Required	
	1.2. Product name	Required	
	1.3. Formulation/contents of the product	Required	
	1.4. Quantity	Required	
	1.5. Registration Number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry	Required	
	1.10. Precautions & directions for use	Required	
	1.11. Warning phrases/hazard symbols/pictograms/colour band, etc.	Required	
	1.12. Storage conditions	Required	
	1.13. Recommended crop/commodity	Required	
	1.14. Pre-harvest intervals	Required	
	1.15. Restrictions, if any	Required	
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	
F.2.	**Packaging**	Required	
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Specification of bulk package for transport	Required	
F.3.	**Storage tests (Shelf life) (Temp/RH/Refrigeration requirements)**	Required	

* Required only in those cases where technical grade is not registered but its formulation (readymade) is directly imported and is intended to be registered. In normal cases, technical grade product is registered together with its formulation to be sold in the market

Annex 3C

DATA REQUIREMENTS FOR REGISTRATION OF BIOCHEMICAL PEST CONTROL AGENTS (BPCA)

S. No.	Data parameters	Supplementary registration: Formulated product of BPCA	Comments
Active Ingredient of BPCA			
A.1.	**Biochemical identity**		
	1.1. Chemical abstract services number, if any	Not required	
	1.2. Common name proposed or accepted by ISO and synonyms	Not required	
	1.3. Structural formula	Not required	
	1.4. Chemical name (according to internationally agreed nomenclature, preferably IUPAC	Not required	
	1.5 Empirical formula and molecular weight	Not required	
	1.6. Plant species (common/scientific name) from which the active ingredient extracted	Not required	
	1.7. Specification together with Method of analysis of active ingredient	Not required	
A.2.	**Physical properties of pure active ingredient**		
	2.1. Appearance (physical state, colour and odour)	Not required	
	2.2. Melting/decomposition/boiling point	Not required	
	2.3. Vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25 ºC), but only when above 10-3 Pascal)	Not required	
	2.4. Solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25 ºC)	Not required	
	2.5. Partition coefficient between water and an appropriate non-miscible solvent (e.g. n-octanol)	Not required	
	2.6. Density (for liquids only)	Not required	
	2.7. Hydrolysis rate under stated relevant conditions	Not required	
	2.8. Photolysis under stated relevant conditions	Not required	
	2.9. Absorption spectra, e.g. ultra-violet, visible, infra-red, etc.	Not required	
	2.10. Methods of analysis of physic chemical properties	Not required	
A.3.	**Technical Grade Active Ingredient (TGAI)/Technical concentrate (TC) of BPCA**		
	3.1. Source; name and address of manufacturer and addresses where manufactured	Not required	
	3.2. Appearance (physical state, colour and odour)	Not required	
	3.3. The minimum (and maximum) active ingredient content in g/kg	Not required	
	3.4. Identity and amount of isomers, impurities and other by-products, together with	Not required	
	3.5. Outline of extraction process of active ingredient of BP	Not required	
	3.6. Specification together with method of analysis	Not required	
	3.7. Analytical test report	Not required	
	3.8. Shelf life	Not required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product of BPCA	
Formulated product of BPCA			
A.5.	**Product identity**		
	5.1. Formulator's name and address.	Required	
	5.2. Distinguishing name (proprietary name)	Required	
	5.3. Use category (herbicide, insecticide, etc.)	Required	
	5.4. Type of formulation (water dispersible powder, emulsifiable concentrate, etc.)	Required	
A.6.	**Composition of formulated BPCA product**	Required	
	6.1. Content of technical grade active ingredient(s) (where more than one active ingredient, information should be given on each ingredient separately)	Required	
	6.2. Content and nature (identify if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert components	Required	
	6.3. Water/other solvent content (where relevant)	Required	
	6.4. Specification together with method of analysis	Required	
	6.5. Analytical test report.	Required	
	6.6. Shelf life	Required	
A.7.	**Physical/Chemical properties of the formulated BPCA product**		
	7.1. Appearance (physical state, colour and odour)	Required	
	7.2. Storage stability (in respect to composition and physical properties related to use)	Required	
	7.3. Density (for liquids only)	Required	
	7.4. Acidity (where relevant	Required	
	7.5. Alkalinity (where relevant)	Required	
	7.6. Other properties may in certain cases need evaluation	Required	
A.8.	**Physical properties of the formulated BPCA product related to use**		
	8.1. Wettability (for dispersible powders)	Required	
	8.2. Persistent foam (for formulations applied in water	Required	
	8.3. Suspendibility (for dispersible powders and suspension concentrates)	Required	
	8.4. Wet sieve test (for dispersible powders, suspension concentrates)	Required	
	8.5. Dry sieve test (for granules, dusts)	Required	
	8.6. Emulsion stability (for emulsifiable concentrates)	Required	
	8.7. Corrosiveness (when necessary)	Required	
	8.8. Known incompatibilities with other products, e.g. pesticides, fertilizers	Required	
B. Toxicity data			
B.1.	**Acute toxicity tests**		
	1.1. Acute oral toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Acute dermal toxicity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Acute inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Acute eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product of BPCA	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies**	Not required	
	C. Bioefficacy data		
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Required	
	1.2. Dosage/rate of application	Required	
	1.3. No. of applications	Required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume)/Appliances)	Required	
C.2.	**Crop/Commodity information:**		
	2.1. Crop/Commodity (Common/Scientific name)	Required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Required	
	2.3. Pre-harvest intervals	Required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Required	
C.4.	**Pesticide evaluation parameters (e.g. tiller counts, yield, percent incidence, etc.)**	Required	
C.5.	**Method of sampling**	Required	
C.6.	**Recording field data**	Required	
C.7.	**Statistical Analysis of Data and results on effectiveness, phytotoxicity, compatibility with other chemicals**	Required	
	D. Residue data		
D.1	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The “marker compound concept” should be used for enforcement and “toxicological relevant compounds” should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product of BPCA	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analysed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower then 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation Studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	
E. Human health exposure/environmental fate & effects data			
E.1.	**Human health exposure effects**		
	1.1. Operators exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
* Only if biochemical pest control agent (BPCA) proved to have allergic/toxic effects to human beings			

S. No.	Data parameters	Supple-mentary registration Formulated product of BPCA	Comments
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Not required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Not required	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Not required	
	2.4. Primary data on phytotoxicity effects.	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence)**	Not required	
	F. Labelling/Packaging/Storage test data		
F.1.	**Labelling**	Required	
	1.1. Chemical name	Required	
	1.2. Product name	Required	
	1.3. Formulation/contents of the product	Required	
	1.4. Quantity	Required	
	1.5. Registration number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry and or/shelf life (months/year)	Required	
	1.10. Precautions & directions for use	Required	
	1.11. Warning phrases/hazard symbols/pictograms, etc.	Required	
	1.12. Storage conditions	Required	
	1.13. Recommended crop/commodity	Required	
	1.14. Pre-harvest intervals	Required	
	1.15. Restrictions, if any	Required	
	1.16. Signs/symptoms of pesticide poisoning & treatment	Required	
F.2.	**Packaging**		
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Specification of bulk package for transport	Required	
F.3.	**Storage tests (Shelf life) (Temp/RH/Refrigeration)**	Required	

Annex 4A

DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PEST CONTROL AGENTS (MCPA)

S. No.	Data parameters	Proprietary registration	Comments
		Technical gr. AI/Tech conc. of MCPA	
Active Agent			
A.1.	**Identity of Active Agent (MCPA)**		
	1.1. Chemical abstract services number, if any	Required	
	1.2. Common name	Required	
	1.3. Scientific name	Required	
	1.4. Synonyms	Required	
	1.5. Taxonomical position (Class/Order/Family/Sub-family)	Required	
	1.6. Strain/serotype/biotype:	Required	
A.2.	**Identification characteristics of MCPA**		
	2.1. Morphological characteristics	Required	
	2.2. Cultural characteristics	Required	
	2.3. Biochemical properties	Required	
	2.4. Serological identification (where appropriate)	Required	
	2.5. Molecular diagnosis (where appropriate)	Required	
	2.6. Analytical methods for identification & characterization of MCPA	Required	
	2.7. Identification of plasmids or other extra chromosomal genetic material responsible for pesticide activity or pathogenicity or toxicity, etc., where appropriate	Required	
	2.8. Whether wild type or genetically altered organism?	Required	
	2.9. Natural occurrence of organism and its relation to other related species	Required	
A.3.	**Biological properties of MCPA**		
	3.1. Biological properties of active agent (target pest, microbial agent host range, life cycle, and mode of action of microbial agent, potential hazards (such as infectivity) to mammals (including human beings), environment and other non-targeted species, if any	Required	
	3.2. Description of morphological types of MCPA and any unusual morphological, biochemical, resistance characteristics of the organism that is different from classic description of organism	Required	
	3.3. Determination of toxin content & potency of toxin by bioassay method*	Required	
* Level of beta exotoxins by house fly bioassay method; LC_{50} on target larvae and potency against a reference product using artificial diet method or leaf disc method or in water for mosquito larvae; housefly bioassay for beta exotoxin; viable spore count; field trial results on bio-efficacy; method of analysis.			
	3.4. specification together with method of analysis and shelf life	Required	
	3.5. If the organism in question is genetically altered one, method of DNA finger printing and identification of inserted or deleted transcripts, identification of gene control regions, identification of genetic markers, etc.), where appropriate	Required	
A.4.	**Source of active agent of MCPA**		
	4.1. Name & address of supplier(s)	Required	
	4.2. Suppliers' code number	Required	

S. No.	Data parameters	Proprietary registration Technical gr. AI/Tech conc. of MCPA	Comments
	B. Toxicity data*		
B.1.	**Acute toxicity tests:**		
	1.1. Oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation.	Required	
	2.2. Acute eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies**	Not required	
* Toxicity data in respect of B.1 to B.3 essentially required. If MCPA proved to have toxic effects further data in respect of B.4 to B.10 is also required.			
	C. Bioefficacy data		
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Not required	
	1.2. Dosage/rate of application	Not required	
	1.3. No. of applications	Not required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume)/Appliances)	Not required	
C.2.	**Crop/Commodity information**	Not required	
	2.1. Crop/Commodity (Common/Scientific name)	Not required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Not required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Not required	
C.4.	**Evaluation parameters of MCPA (e.g. tiller counts, yield, percent incidence, etc.)**	Not required	
C.5.	**Method of Sampling**	Not required	
C.6.	**Recording field data**	Not required	
C.7.	**Statistical analysis of data and results on la and field trials**	Not required	
	D. Residue data		
D.1	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	

S. No.	Data parameters	Proprietary registration	Comments
		Technical gr. AI/Tech conc. of MCPA	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analysed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	

S. No.	Data parameters	Proprietary registration Technical gr. AI/Tech conc. of MCPA	Comments
E. Human health exposure/environmental fate & effects data			
E.1.	**Human health exposure effects**		
	1.1. Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
* Required only if the microbial pest control agent proved to have allergic/toxic effects to human beings			
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Required	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Required	
	2.4. Primary data on phytotoxicity effects	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence)**	Not required	
F. Labelling/Packaging/Storage test data			
F.1.	**Labelling**		
	1.1. Common name of MCPA	Required	
	1.2. Product name (Applicable to formulated MCPA product)	Not required	
	1.3. Formulation/contents of MCPA product	Not required	
	1.4. Quantity of the product per package	Required	
	1.5. Registration number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue (applicable for domestic facility)	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry and/or shelf life (months/year)	Required	
	1.10. Manufacturer	Required	
	1.11. Precautions & directions for use	Required	
	1.12. Warning phrases/hazard symbols/pictograms/colour band	Required	
	1.13. Storage conditions	Required	
	1.14. Recommended crop/commodity (Applicable for formulated product)	Not required	

S. No.	Data parameters	Proprietary registration	Comments
		Technical gr. AI/Tech conc. of MCPA	
F.2.	**Packaging**		
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Sterile packing condition	Required	
F.3.	**Storage tests (Shelf life) (Temp/RH/Refrigeration)**	Required	

Annex 4B

DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PESTICIDE AGENTS (MCPA)

S. No.	Data parameters	Proprietary registration: Formulated product of MCPA	Comments
Active Agent			
A.1.	**Identity of active agent (MCPA)**	Required*	
	1.1. Chemical abstract services number, if any	Required*	
	1.2 Common name	Required*	
	1.3. Scientific name	Required*	
	1.4. Synonyms	Required*	
	1.5. Taxonomical position (Class/Order/Family/Sub-family)	Required*	
	1.6. Strain/serotype/biotype	Required*	
A.2.	**Identification characteristics of MCPA**	Required*	
	2.1. Morphological characteristics	Required*	
	2.2. Cultural characteristics.	Required*	
	2.3. Biochemical properties	Required*	
	2.4. Serological identification (where appropriate)	Required*	
	2.5. Molecular diagnosis (where appropriate)	Required*	
	2.6. Analytical methods for identification & characterization of MCPA	Required*	
	2.7. Identification of plasmids or other extra chromosomal genetic material responsible for pesticide activity or pathogenicity or toxicity, etc., where appropriate	Required*	
	2.8. Whether wild type or genetically altered organism?	Required*	
	2.9. Natural occurrence of organism and its relation to other related species	Required*	
A.3.	**Biological properties of MCPA**		
A.4.	**Source of active agent of MCPA**		
	4.1. Name & address of supplier(s)	Required*	
	4.2. Suppliers' code number	Required*	
* Required only if technical grade MCPA is not registered in the country and only formulated product is being imported.			
Formulated products of MCPA			
A.5.	**Product identity**		
	5.1. Formulator's name and address	Required	
	5.2. Distinguishing name (proprietary name) of product	Required	
	5.3. Use category (herbicide, insecticide, etc.)	Required	
	5.4. Confidential statement of formula (This statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material	Required	
A.6.	**Composition of product**		
	6.1. Percentage composition (by weight) of each ingredient; the number of units per unit volume or weight is needed for microbial impurities; viability data in terms of PFU, CFU, etc., per unit weight or volume of product	Required	

S. No.	Data parameters	Proprietary registration Formulated product of MCPA	Comments
	6.2. Identity of other ingredients included in the formulation, e.g., stickers, spreaders, etc.)	Required	
	6.3. Certification of Composition limits for each ingredient	Required	
	6.4. Analysis of Contaminants, if any	Required	
	6.5 Specification together with method of analysis	Required	
	6.6. Analytical test report	Required	
	6.7. Shelf life	Required	
	B. Toxicity data		
B.1.	**Acute toxicity tests**	Required	
	1.1. Oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Inhalation toxicity (in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Acute eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
B.4.	**Sub-chronic toxicity tests**	Not required	
B.5.	**Reproduction effects studies**	Not required	
B.6.	**Teratogenicity studies**	Not required	
B.7.	**Neurotoxicity studies in hens (for organophosphorus compounds)**	Not required	
B.8.	**Mutagenicity studies**	Not required	
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies**	Not required	
	C. Bio-efficacy data		
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Required	
	1.2. Dosage/rate of application	Required	
	1.3. No. of applications	Required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume)/Appliances	Required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Required	
C.4.	**Evaluation parameters of MCPA (e.g. tiller counts, yield, percent incidence, etc.)**	Required	
C.5.	**Method of sampling**	Required	
C.6.	**Recording field data**	Required	
C.7.	**Statistical analysis of data and results on lab. and field trials**	Required	

S. No.	Data parameters	Proprietary registration Formulated product of MCPA	Comments
	D. Residue data		
D.1.	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analysed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)		
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	

S. No.	Data parameters	Proprietary registration Formulated product of MCPA	Comments
	4.7. Degradation Studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	
D.5.	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	
E. Human health exposure/environmental fate & effects data			
E.1.	**Human health exposure effects**		
	1.1. Operators Exposure data (dermal exposure/inhalation exposure, biological monitoring)-field application	Required*	
* Required only if the microbial pest control agent proved to have allergic/toxic effects to human beings			
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Required*	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Required*	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Required*	
	2.4. Primary data on phytotoxicity effects	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
* Required if the TGAI of MCPA not registered in the country and only formulated product is required to be imported.			
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence)**	Not required	
F. Labelling/Packaging/Storage test data			
F.1.	**Labelling**		
	1.1. Common name of MCPA	Required	
	1.2. Product name	Required	
	1.3. Formulation/contents of the product	Required	
	1.4. Quantity of the product	Required	
	1.5. Registration number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	

S. No.	Data parameters	Proprietary registration	Comments
		Formulated product of MCPA	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry and or/shelf life (months/year	Required	
	1.10. Manufacturer	Required	
	1.11. Precautions & directions for use	Required	
	1.12. Warning phrases/hazard symbols/pictograms/colour band	Required	
	1.13. Storage conditions	Required	
	1.14. Recommended crop/commodity	Required	
F.2.	**Packaging**		
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Sterile packing condition	Required	
F.3.	**Storage tests (Shelf life) (Temp./RH/Refrigeration)**	Required	

Annex 4C

DATA REQUIREMENTS FOR REGISTRATION OF MICROBIAL PEST CONTROL AGENTS (MCPA)

S. No.	Data parameters	Supplementary registration: Formulated product of MCPA	Comments
Active Agent			
A.1.	**Identity of Microbial Agent (MCPA)**		
	1.1. Chemical abstract number, if any	Required	
	1.2. Chemical name of toxic product, if characterized	Required	
	1.3. Common name of microbial organism/agent, if applicable	Required	
	1.4. Scientific name of microbial organism/agent, if applicable	Required	
	1.5. Synonyms, if any	Required	
	1.6. Taxonomical position (Class/Order/Family/Sub-family) of microbial organism/agent	Required	
	1.7. Strain/serotype/biotype of microbial organism/agent	Required	
A.2.	**Identification characteristics of MCPA**		
	2.1. Morphological characteristics	Required	
	2.2. Cultural characteristics	Required	
	2.3. Biochemical properties	Required	
	2.4. Serological identification (where appropriate)	Required	
	2.5. Molecular diagnosis (where appropriate)	Required	
	2.6. Analytical methods for identification & characterization of MCPA	Required	
	2.7. Identification of plasmids or other extra chromosomal genetic material responsible for pesticide activity or pathogenicity or toxicity, etc., where appropriate	Not required	
	2.8. Whether wild type or genetically altered organism?	Not required	
	2.9. Natural occurrence of organism and its relation to other related species	Not required	
A.3.	**Biological properties of MCPA**	Not required	
A.4.	**Source of Active Agent of MCPA**		
	4.1. Name & address of supplier(s)	Not required	
	4.2. Suppliers' code number	Not required	
Formulated products of MCPA			
A.5.	**Product identity**		
	5.1. Formulator's name and address	Required	
	5.2. Distinguishing name (proprietary name) of product	Required	
	5.3. Use category (herbicide, insecticide, etc.)	Required	
	5.4. Confidential statement of formula (This statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material	Required	
A.6.	**Composition of product**		
	6.1. Percentage composition (by weight) of each ingredient; the number of units per unit volume or weight is needed for microbial impurities; viability data in terms of PFU, CFU, etc., per unit weight or volume of product	Required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product of MCPA	
	6.2. Identity of other ingredients included in the formulation, e.g. stickers, spreaders, etc.)	Required	
	6.3. Certification of composition limits for each ingredient	Required	
	6.4. Analysis of contaminants, if any	Required	
	6.5. Specification together with method of analysis	Required	
	6.6. Analytical test report	Required	
	6.7. Shelf life	Required	
B. Toxicity data			
B.1.	**Acute toxicity tests**		
	1.1. Oral toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.2. Dermal toxicity/infectivity (i.e., LD_{50} expressed as mg/kg of body weight)	Required	
	1.3. Inhalation toxicity (LC_{50} in mg/L)	Required	
B.2.	**Irritation tests**		
	2.1. Primary skin irritation	Required	
	2.2. Acute eye irritation	Required	
B.3.	**Allergy/sensitization test**	Required	
C. Bio-efficacy data			
C.1.	**Pest information**		
	1.1. Pest (Common/Scientific name)	Required	
	1.2. Dosage/rate of application	Required	
	1.3. No. of applications	Required	
	1.4. Application method (e.g. dusting/spraying (high volume/low volume/ ultra low volume)/Appliances	Required	
C.2.	**Crop/Commodity information**		
	2.1. Crop/Commodity (Common/Scientific name)	Required	
	2.2. Stage of crop (e.g. seedling, vegetative growth stage, flowering stage, fruiting stage, etc.)	Required	
C.3.	**Field trials planning/design (location/climatic data/statistical design/ plot size/controls/replications)**	Not required	
C.4.	**Evaluation parameters of MCPA (e.g. tiller counts, yield, percent incidence, etc.)**	Not required	
C.5.	**Method of sampling**	Not required	
C.6.	**Recording field data**	Not required	
C.7.	**Statistical analysis of data and results on lab. and field trials**	Not required	
D. Residue data			
D.1	**Plant metabolism**		
	1.1. Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops)	Not required	
	1.2. Number of studies to be carried out (extrapolation from 3 studies on different groups to all crops)	Not required	
	1.3. Crop groupings	Not required	
	1.4. Use of radio labelled material (C-14, P-32, S-35)	Not required	

S. No.	Data parameters	Supplementary registration Formulated product of MCPA	Comments
	1.5. Dosage rate (at least equal to intended use)	Not required	
	1.6. Identification & characterization of residues	Not required	
	1.7. Residue definition (The "marker compound concept" should be used for enforcement and "toxicological relevant compounds" should be used for risk assessment)	Not required	
D.2.	**Farm animal metabolism**		
	2.1. Species to be used: ruminants (i.e. lactating cows, goats) and poultry chicken	Not required	
	2.2. Duration of dosing (dosed daily for 3 consecutive days)	Not required	
	2.3. Information required (milk, eggs, meat, liver, kidneys and fat should be collected and analysed)	Not required	
	2.4. Dose rate at the level of expected exposure but in practice not normally lower than 10 mg/kg	Not required	
	2.5. Parental compounds should be used	Not required	
D.3.	**Farm animal feeding studies**		
	3.1. Species: ruminants (normally lactating cows) and poultry (chickens)	Not required	
	3.2. Number of animals and duration of dosing (A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs)	Not required	
	3.3. Information required (meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analyzed)	Not required	
	3.4. Dose rate: (use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X) and control group)	Not required	
	3.5. Material used: usually parent compound	Not required	
D.4.	**Processing studies**		
	4.1. Data on transfer of residues into processed commodities	Not required	
	4.2. Minimum of 2 studies/commodity Pome fruits (peel, juice, wet/dried), Stone fruits (jam, dried), Citrus (peel, pulp, juice), Grape (juice/wine), Wheat (flour, bran), Rice (flour, bran), Carrot (peel, juice), Tomato (juice, ketchup) Peas and beans (without pods), Oilseeds (meal, oil) Olive (virgin oil), Tea (brewed)	Not required	
	4.3. Residue trials carried out over different years (At least minimum of 3 trials)	Not required	
	4.4. Glasshouse trials (protected crops)	Not required	
	4.5. Post-harvest treatment studies (wheat, potato)	Not required	
	4.6. Significance of commodities in the diet (currently 5 diets; mean consumption for the whole population)	Not required	
	4.7. Degradation Studies (4 sampling intervals, i.e., five samples) Degradation information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue	Not required	
	4.8. Extrapolation studies ±25% rule could be used when comparing GAPs	Not required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product of MCPA	
D.5	**Analytical methods/standards for residue determination**		
	5.1. Description of analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Not required	
	5.2. Analytical standards/reference chemicals	Not required	
E. Human health exposure/environmental fate & effects data			
E.1.	**Human health exposure effects**		
	1.1. Operators exposure data (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
	1.2. Bystanders exposure (dermal exposure/inhalation exposure, biological monitoring) – field application	Required*	
* Required only if the microbial pest control agent proved to have allergic/toxic effects to human beings			
E.2.	**Evaluation of environmental fate & effects**		
	2.1. Primary data on potential hazards (infectivity) to mammals (including humans)	Not required	
	2.2. Primary data on toxicity to non-targeted organisms (bees, birds, pollinators, etc.)	Not required	
	2.3. Experimental data on Infectivity to crop plant species (e.g. microbial agents used for control of weed species)	Not required	
	2.4. Primary data on phytotoxicity effects	Not required	
	2.5. Primary data on persistence/translocation in plants	Not required	
	2.6. Primary data on treatment of effluents & disposal	Not required	
E.3.	**Monitoring of environmental effects**		
	3.1. Monitoring of substantial change in use/application pattern	Not required	
	3.2. Monitoring biological effect of pesticides (e.g. replacement of keystone species, natural enemies of pests, etc.)	Not required	
	3.3. Monitoring release of toxic residues/fumes into the surrounding air around the manufacturing plant, where appropriate	Not required	
E.4.	**Post-registration data generation (occurrence of toxic residues and/or possible biological effects including pesticide resurgence)**	Not required	
F. Labelling/Packaging/Storage test data			
F.1.	**Labelling**		
	1.1. Common name of MCPA	Required	
	1.2. Product name	Required	
	1.3. Formulation/contents of the product	Required	
	1.4. Quantity of the product	Required	
	1.5. Registration number/date of registration/date of expiry and/or import permit number/date of issue, where applicable	Required	
	1.6. Manufacture licensing number/date of issue	Required	
	1.7. Batch number	Required	
	1.8. Date of manufacturing	Required	
	1.9. Date of expiry and or/shelf life (months/year)	Required	
	1.10. Manufacturer	Required	
	1.11. Precautions & directions for use	Required	
	1.12. Warning phrases/hazard symbols/pictograms, etc.	Required	

S. No.	Data parameters	Supplementary registration	Comments
		Formulated product of MCPA	
	1.13. Storage conditions	Required	
	1.14. Recommended crop/commodity	Required	
F.2.	**Packaging**		
	2.1. Specification of primary package	Required	
	2.2. Specification of secondary package	Required	
	2.3. Sterile packing condition	Required	
F.3.	**Storage tests (Shelf life) (temp./RH/Refrigeration)**	Required	

3 Nov 2011

ATTACHMENT 2

GUIDELINES FOR DATA REQUIREMENTS FOR THE REGISTRATION OF BIOPESTICIDES

ABBREVIATIONS

ASEAN	Association of Southeast Asian Nations
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agriculture Practice
GIFAP	International Group of National Associations of Manufacturers of Agrochemical Products
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
ISO	International Organization for Standardization
TCP	Technical Cooperation Programme
WHO	World Health Organization

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1. INTRODUCTION

These guidelines were developed as part of the FAO Technical Cooperation Programme (TCP) project to assist Southeast Asian countries to achieve biopesticide regulatory harmonization. One of the components of the project was to develop guidelines on harmonized biopesticide labelling requirements to be used as guidance by pesticide regulatory authorities to ensure that pesticide products in their own country will be labelled in accordance to the regional principles. Further, these guidelines are also expected to benefit the registrants, as biopesticide requirements for all Southeast Asian countries would be similar and this would facilitate and expedite the registration of pesticides in the region.

Registration of biopesticides is the process by which authorities (e.g. national governments or designated regional or provincial authorities) approve the sale and use of a biopesticide following the comprehensive evaluation of scientific data whether the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health, or the environment. If, during the assessment or evaluation process, responsible authorities identify products or uses that would result in unacceptable risks, or risks that outweigh benefits of the use, those applications should not be approved.

Governments should introduce the necessary legislation for the registration of biopesticides that follow the general guidelines and procedures for the registration of pesticides, including licensing and inspection schemes. However, governments should design procedures suited to their own specific requirements and needs; registration criteria should take full account of local circumstances, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate and affordable pest control options and protective equipment. Therefore, data requirements for registration should be tailored to the specific conditions of the registering country. If conditions of use, climatic conditions, pests, application methods or possible exposeur are different, then data requirements should be different between two countries or regions.

This guidance document focuses on the scientific data and other information that may be needed to determine which products should be permitted to be used and for what purposes. The annexes provide comprehensive lists of the data requirements themselves.

It is important to note that the data requirements presented in this document are based on data required by advanced regulatory authorities such as the European Union, Canada, and the United States. FAO and WHO recognize that these lists are extensive and that it may not be practical for member countries to require and review all of the data listed in the appendices to this document. However, as described in the 2010 Guidelines for the Registration of Pesticides, FAO and WHO promote transparency and exchange of information between responsible authorities in the pesticide registration process and in the collection and review of data to prevent duplication of efforts and minimize the use of test animals, among other efficiencies. Governments and responsible authorities should faciliate the exchange of information between responsible authorities and should, wherever possible, make use of data that have been released publicly, and that preferably have been peer-reviewed, when considering an application for registration. Further, where possible and appropriate, FAO and WHO also encourage the mutual recognition of registration and mutual acceptance of data. This concept of work and data sharing is discussed further in this document.

This guidance was developed under Article 6 of the *International Code of Conduct on the Distribution and Use of Pesticides* (hereinafter referred to as the Code of Conduct), Regulatory and technical requirements, and the overall *FAO/WHO Guidelines for the Registration of Pesticides* of April 2010.

2. SCOPE AND OBJECTIVES OF THE GUIDELINES

The main objective of these guidelines is to assist countries in Southeast Asia (Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand and Vietnam) to develop (minimum) data requirements for the registration of biopesticides.

The purpose of these guidelines is to facilitate harmonizing biopesticide management among countries in Southeast Asia (SEA), so that the biopesticide data accepted for registration in one country can be considered for registration of the same biopesticide in another SEA country. Such a policy approach would ensure that only those biopesticides are imported which do not compromise on human health and the environment.

This document provides guidance for harmonizing biopesticide registration requirements among Southeast Asian countries.

These guidelines are intended to:

1) provide guidance on the scientific data and information that are needed to evaluate biopesticides for the purpose of registration;
2) facilitate the generation of data and submission of applications for biopesticide registration in developing countries;
3) describe under what circumstances and conditions different types of requirements are appropriate and how countries can make decisions on what data to require; and
4) bring further harmonization into data requirements for pesticide registration.

3. BACKGROUND

The harmonization of registration requirements for biopesticides falls under the overall efforts to harmonize pesticide registration procedures in Southeast Asia. While there are differences between the countries, the following general principles apply on a broader scale:

Legislations of the nations shall be enforceable within their sovereign boundary limits. However, each country that wants to harmonize the legal registration process, may adopt relevant laws, rules or guidelines.

Enforcement system: Adapting a model enforcement system in each country is an ideal way of harmonizing the pesticide regulatory process. Proposals for this may emerge from the TCP project. However, suitable staff needs to be built up that would support the harmonized pesticide registration system.

Sharing of chemical, botanical, microbial, toxicity, bio-efficacy, labelling, packaging, storage test, environmental data, etc.: The countries may finalise these data sets for being harmonized. This needs bilateral agreements between Southeast Asian countries. It is essential to the harmonized registration process to decide upon a data exchange system, preferably in electronic format, through webpages with suitable security platforms. This inter-country platform shall enable pesticide registrants to apply to multiple countries electronically with an agreed and harmonized data package. Except for specific non-harmonized registration requirements of each sovereign country, the remaining data requirements can be distributed to all countries through such a single input system. Such a system has to co-evolve by regulatory agencies in order to seamlessly harmonize the entire process. Analogies to systems in NAFTA, European Union, and OECD are applicable for this purpose.

ASEAN would be good platform for maintaining such a data exchange system. Issues of cost or IPR sharing shall be negotiated by tri-partite agreements between the registration applicant, the host and the guest country. The views of Crop Life International in this matter should be considered.

Minimum data requirement: National pesticide registries need to decide on uniform data requirement for registering biopesticides. To secure high safety standards and to make powerful risk assessment, the minimum data requirements are central to the harmonsiation process.

Test protocols and data generation process: Imperative to harmonization is the data sharing by national pesticide registries. There shall be acceptable international guidelines for this purpose that are generated out of expert consultations and then put up for adoption in all countries.

Data protection: The issue in this regard is how to make data protection effective and to give recognition to those who generated the data, including universities and research institutes. Regulations to protect and safeguard the proprietary rights to the data shall take into account the provisions of WTO-TRIPS Agreement.

The need for harmonization of registration process in Southeast Asian countries

The Code of Conduct provides the foundation for the harmonization of biopesticide regulatory process in the region. Greater cooperation among countries in the region through information exchange and biopesticide harmonization is strongly encouraged by the Code of Conduct. The Code of Conduct calls on the governments to cooperate with each other towards harmonization of pesticides regulations system as mentioned in Article 6.1.5 of the Code:

> "**The Governments should,** promote the advantages of, and cooperate with other governments in, the establishment of harmonized (regionally or by groups of countries) pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards, and where possible incorporate these standards into national or regional legislation".

In Southeast Asia, the first serious efforts of the pesticide regulatory authorities towards harmonization of pesticide regulatory system began at the workshop on pesticides regulatory harmonization for ASEAN countries in 2002 in Thailand. The aim of the workshop was to assess the desire and needs for harmonization of the pesticide regulatory process among the participating countries. Regulators from seven ASEAN that participated expressed strong interest in working towards achieving pesticide regulatory harmonization. At the second workshop in 2003, Kuala Lumpur, the government representatives at that workshop have expressed the need for assistance in the form of FAO-TCP project to realize the harmonization efforts due to lack of resources and expertise in the region. Without this intervention, countries in the region that have expressed the desire to harmonize their pesticide regulatory process would find it very difficult to achieve this objective. This assistance would provide the necessary technical inputs and impetus to countries in the region to work together more closely in the area of pesticide management in support of sustainable agricultural development.

One of the priority areas identified for harmonization in ASEAN countries through FAO-TCP Project is biopesticide regulatory harmonization. Since most of the Southeast Asian countries overwhelmingly depend on the import of various biopesticides, be it of botanical or microbial concentrates and/or formulations, there is a strong necessity to understand the global standards, as provided by FAO or OECD.

The importance of harmonized classification and labelling of pesticides is fundamental for sound pesticide management practice in the region. With the harmonized classification and labelling system, it will not only facilitate the exchange of information between regulators but also it will lower the cost of registration of pesticide as all countries will follow the same classification and labelling system.

4. DEFINITIONS OF TERMS

Active ingredient means the biologically active part of the biopesticide such as microbials or phytochemicals, extracted with solvent chemicals.

Acute dermal LD_{50} means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute inhalation LC_{50} means a statistically derived estimate of the inhaled concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD_{50} means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute toxicity means the toxicity effects of a substance resulted from single and or multiple exposures in a short period of time (usually less than 24 hours).

Antagonist is an organism (usually pathogen) which does no significant damage to the host but its colonisation of the host protects the host from significant subsequent damage by a pest.

Applicant means an individual or company or their authorized representative that makes an application of registration of a biopesticide to the registration authority.

Aquatic toxicity means toxicity to fish and other aquatic animals.

Augmentative releases: Either inundative or seasonal inoculative releases, i.e. those forms of biological control where mass-produced, biological control agents are released to reduce a pest population without necessarily leading to continuing impact or establishment of the IBCAs.

Avian toxicity means toxicity to birds.

Banned biopesticide means a biopesticide for which all uses have been prohibited by final regulatory action, in order to protect human health or the environment. The term includes a biopesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Biological control (biocontrol): Pest management strategy making use of living natural enemies, antagonists or competitors and other self-replicating biotic entities.

Biological control agent: A natural enemy, antagonist or competitor, and other self-replicating biotic entity used for pest management.

Biological pesticide (biopesticide) – BP: A generic term, not specifically definable, but generally applied to a microbial control agent, usually a pathogen, formulated and applied in a manner similar to a chemical pesticide, and normally used for the rapid reduction of a pest population for short-term pest management.

Biopesticide: Pesticides of biological origin with organic solvent extracted phytochemicals or microbials with proven pathogenicity to target pest(s). Generally, biopesticides are safe to non-target organism. However, contaminant microbes or chemicals in their formulations could cause hazard to non-target organisms.

Botanical pesticides: Formulations of pesticides that originate from plants as phytochemicals and eliciting toxic effects on insects and mites. These could be water or organic solvent based or even animal urine extracted from defined plant parts where active principles of insecticide phytochemicals are known to be present in high concentration.

Classical biological control: The intentional introduction and permanent establishment of an exotic biological agent for long-term pest management.

Clearance (of a consignment): Verification of compliance with phytosanitary regulations.

Competitor: An organism which competes with pests for essential resources (e.g. food, shelter) in the environment.

Consignment: A quantity of plants, plant products and/or other regulated articles being moved from one country to another and covered by a single phytosanitary certificate.

Chronic toxicity means toxic effects of a substance resulted from repeated exposures often at lower levels to a substance over a long time period (months or years).

Distribute or sell and other grammatical variations of the term such as "distributed or sold" and "distribution or sale," means the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.

Distributor means one who distribute or sale or resale of the biopesticide product for end use.

Direct effect (from the introduction of an exotic biocontrol agent): This involves physical interaction between the biocontrol agent and target or non-target organisms (effects can be positive, negative or neutral).

Distributor means one who distribute or sale or resale of the biopesticide product for end use.

Eco-area: An area with similar fauna, flora and climate and hence similar concerns about the introduction of biological control agents.

Ecosystem: A complex of organisms and their environment, interacting as a defined ecological unit (natural or modified by human activity, e.g. agro-ecosystem), irrespective of political boundaries.

Efficacy (of a biological control agent): The ability to cause a statistically significant reduction with regard to the number of pest organisms, direct and indirect crop damage, or yield loss.

Eradication: Application of phytosanitary measures to eliminate a pest from an area.

Established species: Successful long-term survival and reproduction of a species after introduction into a new area.

Establishment (of a biological control agent): The perpetuation, for the foreseeable future, of a biological control agent within an area after entry.

Exotic: Not native to a particular country, ecosystem or eco-area.

Equivalence means the determination of the similarity of the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk.

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the biopesticides (ready to use products) as purchased by users (FAO Code of Conduct, 2003).

Good Agricultural Practice (GAP) in the use of biopesticides includes the officially recommended or nationally authorized uses of biopesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of biopesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Hazard means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).

Hazard of adverse effects (from the release of biocontrol agents): Any imaginable adverse effect which can be named and measured (e.g. in biological control: direct and indirect adverse effects on non-target organisms and ecosystem).

Host specificity: A measure of the host range of a biological control agent on a scale ranging from 'extreme specialist' where the IBCA is only able to complete development on a single species or strain of its host (monophagous), to 'generalist', where many hosts ranging over several groups of organisms (polyphagous) can be used.

Inert ingredient means any substance (or group of structurally similar substances if designated by *Generalist*: See 'host specificity' below.

Import permit (for a biological control agent): An official document authorising importation (of a biological control agent) in accordance with specified requirements.

Indirect effect (from the introduction of an exotic biocontrol agent): The effect that the introduction of exotic IBCAs has on other organisms not involving physical interaction with the biocontrol agent (effects can be positive, negative or neutral).

Inoculative release: The introduction of a biological control agent with the aim of obtaining its establishment for long-term pest management, e.g. classical biological control.

Integrated Pest Management (IPM): A pest population management system that utilises all suitable techniques in a compatible manner to reduce pest populations and maintains them at levels below those causing economic injury (Smith and Reynolds, 1966) (definition adopted by FAO).

Intra-guild predation: The killing and eating of species that otherwise use similar resources.

Introduction (of a biological control agent): The release of a biological control agent into an ecosystem where it did not exist previously.

Inundative release: The release of very large numbers of a mass-produced biological control agent with the expectation of achieving a rapid reduction of a pest population without necessarily achieving continuing impact or establishment of the IBCA.

Invertebrate Biological Control Agent (IBCA): An invertebrate natural enemy used for pest management.

Integrated Pest Management (IPM) means the careful consideration of all available pest control techniques in crops and subsequent integration of appropriate measures that discourage the development of pest populations and keep biopesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.

Label or Labelling means the written, printed or graphic matter on, or attached to, the biopesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the biopesticide.

Legislation: Any act, law, regulation, or other administrative order promulgated by a government.

Licensing Authority: means a government agency recognized under the biopesticide regulation for granting license for domestic manufacturing facilities of biopesticides, stockiest/distributors and pest control operators and working under direct supervision and/or in close coordination and cooperation with registration authority.

Management or control of a pest: Suppression, containment or eradication of a pest population.

Manufacturer means one who manufacture the technical grade active ingredient and or/formulated product of biopesticide including repackaging.

Maximum Residue Limit (MRL) means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff.

Misbranded biopesticide means any biopesticide product is manufactured, distributed and sold in the market without confirming to the labelling requirements of registration as to the kind, grade, quality or composition and/or that the biopesticide product of one manufacturer is distributed or sold in the name of another manufacturer illegally.

Microbial control: The use of micro-organisms (including viruses) as biological control agents.

Micro-organism: A protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic entity.

Monophagous: An organism that attacks only one host species and is species specific.

Native: Naturally occurring at area of proposed IBCA releases.

Natural enemy: An organism which lives at the expense of another organism and which may help to limit the population of this other organism. The term 'natural enemy' in this context includes parasitoids, parasites, predators and pathogens.

Naturally occurring: Refers to a component of an ecosystem or a selection from a wild population, not altered by artificial means.

Non-target organism: All organisms except the target organism.

Oligophagous: An organism that attacks a limited group of related hosts (e.g. up to 20 species in the same genus or subfamily.

Organism: Biotic entity capable of reproduction or replication, includes vertebrate and invertebrate animals, plants and micro-organisms.

Polyphagous: An organism that attacks a wide range of hosts from different subfamilies.

Predator: A natural enemy that preys and feeds on other animal organisms, more than one of which are killed during its lifetime.

Probability of adverse effects (from the release of biocontrol agents): The likelihood that an adverse effect will occur (e.g. reduction in the number of a non-target organism); in biological control, the likelihood that an adverse effect will occur is often a matter of space (dispersal) and time (survival and establishment).

Package or Packaging means the immediate container or wrapping, including any attached closure(s), in which the biopesticide is contained for distribution, sale, consumption, use, or storage. The term does not include any shipping or bulk container used for transporting or delivering the biopesticide unless it is the only such package.

Parasite: An organism which lives on or in a larger organism, feeding upon it.

Parasitoid: An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult.

Pathogen: Micro-organism causing disease.

Pest: Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

Pestilence: Process of pest damage.

Pesticide Inspector means technical personnel specifically authorized and or/designated by the registration authority for the purpose of drawing samples of biopesticides for quality testing from the premises of importer/exporter/manufacturer/stockiest/distributors before use.

Pesticide Analyst means technical personnel specifically authorized or designed by the registration authority for the purpose of quality testing of pesticide samples sent by pesticide inspector/authorized person in accredited test laboratories and reporting of the results to the concerned sender of the samples.

Pesticide Regulatory Board means a board or council or committee, which is the legally appointed body that takes final decision on matters of pesticide registration.

Pesticide legislation means any laws or regulations to regulate the manufacture, marketing, distribution, labelling, packaging, use and disposal of biopesticides in their qualitative, quantitative, health and environmental aspects.

Pesticide product means a pesticide in the particular form (including composition, packaging, and labelling) in which the pesticide is, or is intended to be, distributed or sold.

Phytotoxicity means the toxic or harmful effects of the chemical to plants.

Proprietary (original) registration means the registration granted to the product originally owned by a manufacturer after submitting or citing full information and data that are required for registration.

Quarantine (of a biological control agent): Official confinement of biological control agents subject to phytosanitary regulations for observation and research, or for further inspection and/or testing.

Release (into the environment): Intentional liberation of an organism into the environment.

Release (of a consignment): Authorisation for entry after clearance.

Registration means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment.

Re-registration means renewal of registration granted to the product after expiry of original registration or the extension of original registration.

Registration authority means the government agency or agencies responsible for the registration of pesticide for manufacturing, distribution, stock and sale of pesticide within the country.

Repackaging means the authorized transfer of a pesticide from any commercial package into any other, usually smaller, container for subsequent sale.

Residue means any specified substances in or on food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental) as well as known uses of the chemical.

Risk is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.

Risk of adverse effect (from the release of biocontrol agents): Hazard times probability.

Seasonal inoculative releases: The release of mass-produced biological control agents with the expectation of achieving the reduction of a pest population during several generations without necessarily achieving continuing impact or establishment of the IBCA.

Specialist: See 'host specificity' above.

Suppression: The application of phytosanitary measures in an infested area to reduce pest populations.

Stockist means the one, who stocks pesticides and/or biopesticides for retail distribution.

Sub-chronic toxicity means Studies that continue for 90 days or for up to 10 percent of a test subjects' life span.

Substandard biopesticide means a biopesticide product manufactured, distributed and or/sold in the market, which does not confirm with the quality standards established by the responsible authority.

Spurious biopesticide means a biopesticide product, which lack authenticity or validity in essence or origin and/or not genuine or false or fraudulently distributed and sold in the market.

Supplemental (me-to) registration means the registration granted to the similar/identical product manufactured by another manufacturer subsequent to the registration of the product by original manufacturer.

Technical concentrate or technical grade active ingredient means the technical material used to manufacture the biopesticide product.

Toxicity means a physiological or biological property which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means.

5. GUIDELINES

The major aspects of the guidelines are as follows:

They aim to assist the applicants (the pesticide industry/entreprenuers or manufacturers) when preparing the data dossier for biopesticide registration and the concerned department of the countries/governments when evaluating and deciding about the biopesticides registration. Governments may make their own independent decisions, based on suitable modification of these broad guidelines, as needed.

They aim to promote consistency and quality management of processing and evaluating the data dossiers. Governments may issue their own notifications of the information/data required in the data dossiers. It is the purpose of this document to list the desirable information necessary for decision making.

Biololgical pesticides (BP) are either of botanical origin or microbial pathogens of insects and mites. The mode of action of these products is different from that of synthetic chemical pesticides and hence

the data requirement for registration shall be evidently different. Generally, three types of biological pesticides are considered for registration under relevant regulatory laws and rules, namely:

i) phytochemicals toxic to pests and are extracted from plants,
ii) microbial (microorganisms) pesticides (nematodes, algae, protozoa, bacteria, fungi and viruses),
iii) pheromones/semiochemicals,
iv) invertebrate biocontrol agents (macrobials) such as insects/mites.

These pest control methods are major components of Good Agricultural Practices (GAP) and are used in integrated pest management (IPM) for biological pest control of pests. They are the outcome of research studies of natural pest suppression system where many such organisms are part of food chains in agro-ecosystems. Such scientific research led to the development of formulated products that can be applied on crops with standard application methods. In a strict sense, those products that contain biochemical provided from natural origin such as plants, microbes, etc. and **not synthetic chemical moieties** are considered to be biopesticides/biological pesticides.

(i) Phytochemicals normally quickly affect the target life stage of the pest. Neem tree kernels are a rich source of several alkaloids that have useful properties for controlling insects, mites and nematodes. Other effects such as repellency, feeding and oviposition deterrence, growth and reproduction inhibition have been attributed to poly-terpenoid compounds – azadirachtin, salannin, meliantriol, etc. that occur mainly in the seed. However, the complex chemical structure of these compounds precludes their synthesis on a large scale. Therefore, simple formulations of neem derivatives such as leaf or kernel powder or extracts are generally popularized. Since they are considered as safe to non-target organisms, including humans, that makes them an ideal insecticides. Several azadirachtin-rich formulations from neem oil have already been commercialized in various countries for use on non-food and food crops. These are generally formulated as emulsions so that they can be applied through aqueous high volume sprays. The properties of neem formulation show that the azadiractin A (α) content of neem oil is water dispersible. The other important botanical pesticides such as rotenone and saponin are formulated as solid baits for mammalian pest control. Tobacco dicoction is another ready-to-use preparation that farmers of many countries use to suppress pests, especially sap-sucking and certain chewing insects.

(ii) Microbial biopesticides usually flourish and multiply in farms or greenhouses under ambient favourable conditions and thus suppress pests. This reduces the need for synthetic chemical pesticides. Since most nations support this concept, the commercialization of BP has become relevant and many manufacturers promote their formulations to farmers. During the recent decade, government policies promoted integrated pest management (IPM) as part of good agricultural practices (GAP). GAP has been emphasized in World Trade Organization (WTO) as a primary requisite for trade of agricultural commodities.

(iii) Semiochemicals are produced by plants and animals to affect responses in other organisms. Pheromones are semiochemicals that influence the behavior in the same species, while allelochemicals affect other species. Even though the synthesized and formulated products they do not kill pests, they are categorized as biopesticides in this document for regulatory purposes. All these products are environmentally friendly and do not pose risks to humans and domestic animals.

(iv) Invertebrate biocontrol agents – IBCA, (macrobials) such as insects and mites are part of the natural food chain and can be deployed for effective pest suppression in crops.

Regulatory requirements

The regulatory requirements focus on botanical and microbial BPs. Accordingly, specific guidelines for these two groups are are given separately. The regulatory requirements of insect-behavior modifying semiochemicals including pheromones are discussed additionally.

I. Information requirements for botanical BPs

a. Name of plant source; characterisation and identification of the given botanical pesticide (phytochemical principle); target pests and target crops (these two items could be on the registration certificate as well as on the label leaflet).

b. Efficacy of the product – The registration authority may satisfy itself about the efficacy claims against target pest(s) in target crop(s). This would be required to be mentioned on the certificate and label leaflet, once the registration is approved.

c. Information on assessment of safety and effects on human health in manufacturing, market handling, storage in commercial godowns and farms as well as application in farms.

d. Information on assessment of safety to animals and environment.

II. Information requirements for microbial BPs

a. Taxonomic identity (phylum, class, order, family, genus, species), of the organism along with common names, history of any recorded name change; and accession numbers of voucher culture deposited in a recognized culture collection. Furthermore, the morphological, biochemical and molecular characteristics should be described.

b. Efficacy of the product – The registration authority may assure itself about the efficacy claims against target pest(s) in target crop(s). This needs to be mentioned on the registration certificate and label leaflet.

c. Biological information

- Culture methods of the microbial strain
- Host plant and host organism for rearing the microbial strain
- Native range and global distribution of the organism and information on any known variability including countries where the agent has been used for biological control.
- longevity; and special characteristics, e.g. toxicity, ability to induce allergic reaction, aggressive behaviour or feeding changes, offensive odour, damage to plants, etc. If there is a known problem, it should be reported. If the microbial strain is known to cause an adverse effect, instructions should be given on how to mitigate this effect.
- climatic tolerance, habitat preferences, phenology, natural enemies, voltinism (number of generations per year), dispersal mechanism, means of overcoming unfavourable periods (e.g. diapause, resting stage, migration), etc.
- affinities of the agent with other organisms to form associations, its ability to produce hybrids; competitors and natural enemies in managed and natural environments.
- specific habitat requirements, for example, terrestrial, aquatic, pasture, forest, scrub, mountain, arable land, waste land, etc.

  Note: A country may seek information about the nature and origin of the microbial isolates and whether the organism is genetically engineered or modified.

d. Information for assessment of safety and effects on human health

- Information on assessment of safety and effects on human health during manufacturing and handling, storage in commercial warehouses and farms as well as its application in farms.

- Any environmental risk assessment should be tailored to a specific country, climate or eco-area

e. Information for assessment of efficacy, quality control and benefits of use

f. Methods for quality control (OECD guidelines)
   - Provide information on methods for evaluation of quality and purity, (for reference on some evaluation methods see for example: Van Lenteren and Tommasini, 1999)

III. Information on biocontrol agents (BCAs) such as predators/parasioids (regulation on this may be at the discretion of individual country)

The required information for obtaining permits to introduce a biological control agent must meet the regulatory requirement for its handling, release and monitoring of the outcome.

a. Taxonomic identity along with classification (e.g. phylum, class, order, family, genus, species), including common names and history of any recorded name change; with accession number of voucher specimen deposited in recognized museum or culture collection.

b. Information on physical characteristics: morphology, appearance, sexual dimorphism, height, length, weight and size, winged/wingless.

c. Bionomics and lifecycle of the organism, including behavioural characteristics such as predator/prey relationships, life history and life cycle information; for example, mode of reproduction, seasonal pattern of reproduction; reproductive potential (number of eggs, young, generations), and longevity.

d. Information on the efficacy is important to prevent the introduction and release of ineffective IBCAs. A biological control agent is considered effective if it can cause a statistically significant reduction of at least 10 percent in the number of pest organisms, of direct and indirect crop damage, or of yield loss. All relevant information to judge the efficacy of an IBCA should be provided. Summarise information on what crop, against what pest, and under what conditions the agent is shown to be effective, and what the role and strength of the agent would be in IPM programmes.

e. Host range. Available information on host/prey range of BCAs must be provided. Monophagous and oligophagous BCAs are expected to pose no or very limited potential risks to non-target organisms, whereas polyphagous BCAs may affect them directly and indirectly.

f. Intra-guild predation. Provide available information on negative intraguild predation effects for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely. Conclusions concerning the risk should be provided.

g. Competition and displacement. Check literature to see if competition and displacement effects are indicated for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely.

h. Potential for hybridisation with indigenous strains or biotypes. Provide available information on hybridisation of the natural enemy with indigenous strains or biotypes of the same or very closely related natural enemy species.

i. Effects on plants. Effects of natural enemy on plants should be provided if the biological control agent is potentially a facultative herbivore and if there is a potential for phytotoxic effects. Check literature to see if negative effects on the target crop and non-target plants are indicated for specific or related natural enemy species, or determine from the biology of the natural enemy whether such effects are likely.

j. Available information on the potential for establishment and dispersal

- Potential for establishment. In case of movement of BCAs from one area to another, it is important to know if the agent can be established. If the agent cannot be established, less information may be required.

  Key factors that need to be considered include:

  – abiotic factors: do the climates of the area of origin and area of release match?

  – biotic factors: availability of non-target species suitable for reproduction, temporal and/or spatial matching of non-target organisms and biocontrol agent, diapause capabilities, winter survival; and combined biotic and abiotic factors: availability of other resources for survival and reproduction.

- Potential for dispersal. In order to answer the question 'what is the probability of a temporal and spatial encounter between the biological control agent and non-target species?' it is important to determine the potential for dispersal of the BCA. This is based on the mechanism of dispersal and lifespan of the IBCA, and the local climate and habitat conditions in the area of release. Any information on the possibility for secondary dispersal, e.g. mechanical or with crops, should be provided.

k. Available information on possible indirect effects – report any known indirect effects or discuss potential indirect effects on individual species and/or ecosystem.

l. Available information on environmental benefits – information on the benefical effects of release of IBCAs compared to current or alternative pest management methods.

m. Information for assessment of environmental risks

Identify any potential hazard posed by BCAs, including:

(i) available information on the role of the agent in original ecosystem, the type of natural enemy (parasitoid, predator, pathogen), type of organisms it attacks, effect of attack on target and nontargets, intraguild effects, higher up trophic level effects, and effects on ecosystem;

(ii) available information on existing natural enemies of the target organism in the area of release;

(iii) available information on non-target effects from previous use of IBCAs in biological control.

n. Host range testing

(i) Available information and/or data on possible direct effects:

– on non-target host/prey related to target host (phylogenetically or ecologically related);

– on non-related non-target hosts, such as threatened and endangered species;

– concerning competition or displacement of organisms;

– concerning potential for interbreeding with indigenous natural enemy strains or biotypes;

– on plants (target crop and non-target plants)

(ii) Available information and/or data on potential of establishment and dispersal of biological control agent.

(iii) Available information on and/or data on possible indirect effects.

(iv) Available information (from rearing facility or from the field) on the ability of the IBCA to carry viruses or micro-organisms that can negatively affect non-target organisms.

Provide a summary of information for assessment of environmental risks.

Any environmental risk assessment should be tailored to a specific country, climate or eco-area. (Please note recent references regarding the assessment of risks, for example in Van Lenteren *et al*., 2003).

o. Information for assessment of efficacy

- Information relevant for determining the efficacy of an BCA should be provided.
- Information on methods for the evaluation of quality and purity (quality control) of IBCAs.
- Information on benefits of use of BCAs.
- Summary of information for assessment of efficacy.

p. Available information, and/or data on potential host/prey range in areas of release and potential distribution of the BCA.

q. Available information on environmental benefits (e.g. beneficial effects of release of IBCAs compared to current or alternative control methods).

r. Assessment of environmental risks, safety and effects on human and farm animal health, especially for Biocontrol agents (BCA – insects/mites/nematodes) for weed management.

s. For native or established natural enemies and on BCAs long use, substantially reduced information requirements may be appropriate (this is left to the discretion of the countries, based on appropriate guidelines).

t. Assessment of safety and effects on human health

- Information on assessment of safety and effects on human health in manufacturing, market handling, and storage in commercial warehouses and farms as well as application in farms. (Workers at manufacture sites may suffer from attacks of asthma and rhinitis after long term exposure to large quantities of IBCAs or by the laboratory rearing hosts may cause likely skin irritation and sensitisation so as to evoke an immune response in humans. Farmers have a lower level chance of exposure to IBCAs and their laboratory host(s) than those who work in facilities where mass-rearing occurs. If there is a known problem, it should be reported. If the organism is known to cause an adverse effect, instructions should be given on how to mitigate this effect.
- BCAs present no health risk to users and consumers. However, health problems are known for people involved in mass-rearing of some IBCAs.

Provide available information on relevant hazards to human and animal health that may be posed by the use of BCAs during and following introduction (for example, allergy, skin irritation, disease vectors).

Provide a summary of information for assessment of safety and effects on human health.

IV. Behaviour modifying chemicals – Pheromones

Pheromones are semiochemicals that are deployed by insects and other organisms for communicating to members of their community for propagation, aggregation or dispersal. These substances can also be used for alternative pest suppression and to reduce the need for chemical pesticides. Each chemical is specific to a certain insect, and thus insect pests can be specifically targeted. Synthetic pheomones have been commercially produced and they are formulated in such ways that they simulate natural.

So far, regulatory systems in EU, OECD and NAFTA have not issued specific guidelines for these compounds. However, it is significant to note that these are less harmful toxicologically and to agro-ecosystems due to their highly labile nature of chemistry and reduced hazard to non-target organisms. Both sex and alarm/aggregating pheromones could be usefully deployed in alternate pest control strategies. Generally, they are used to trap the insects and thus the trap design is important for their effective deployment.

Regulating such chemicals would involve identifying the various isomers and their purity. Formulations from the technical material may involve solvents that enable the effective delivery of the desirable isomer blends for eliciting adequate response in adult pests.

The increase in use of these chemicals in pest management has started a global discussion on the regulatory requirements of such behavior modifying chemicals and their formulations. Iain Weatherston and Albert K. Minks (Integrated Pest Management Reviews, 1995, vol. 1(1), p. 1-13 Regulation of semio-chemicals-global aspects) described suitable regulatory aspects of this new class of agro-chemicals discussed at EU, OECD and NAFTA India's registration process requires limited data on toxicology and residues while large data sets on the bio-efficacy in various agro-ecosystems. Pheromones used for trapping male moths for both monitoring and mass-trapping in rice, pulses, oilseeds, cotton, etc. have been registered along with their use against tertiary stored-grain pests in commodities warehouses. No field trial data is required by the Environmental Protection Agency (EPA), although field demonstrations and the approval from government bodies is important for ensuring recommendations for their use. Experimental use permits are granted by waiver if the pheromone is already known and has been used before (even if only for pest monitoring). There are special waivers applied to most data submission requirements.

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Annexes

The following annexes provide lists and tables of recommended data requirements:

Please note that inclusion in these tables does not mean the recommended study must always be conducted. These annexes provide comprehensive lists that need to be critically reviewed by responsible authorities to determine whether the specific data requirements apply in their country or apply to the proposed use pattern or registration situation. In addition, see the information in each table and footnotes to determine the test substance, applicable uses, and whether the data are always recommended to be required or only recommended for certain use patterns or situations.

The contents of the annexes are as follows:

Annex A
LISTS OF RECOMMENDED DATA REQUIREMENTS

Annex B
DATA REQUIRMENTS FOR HARMONIZED REGISTRATION OF BIOPESTICIDES
Information sheets for different biopesticides

Annex C

ISSUES INVOLVED IN HARMONIZATION

Page

Annex A

LISTS OF RECOMMENDED DATA REQUIREMENTS

Types of phytochemicals/botanical

a) Herbal extract (Mixture of diallyl disulphide, allyl propyl disulphide and allyl isothiocyanate)
b) Neem products (Neem leaves, Neem oil, Neem seed kernel, Neem cake)
c) Karanjin (isolated from *Ponqamia glabra*)
d) Extract of *Cymbopogan* Species
e) Oxymatrine (plant derived pesticide – *Sophora flavescens*)
f) *Triptericium wilferdii* Hook GTW – Plant extact
g) Bitterbarkomycin (Plant extract of *Apocynum venetum*)
h) Squamocin (Seed extract of Plant *Annona squamosa* Linn)
i) *Eucalyptus* leaf extract

Formulations in markets of Southeast Asia

Azadirachtin 0.1% W/V SL, 3% W/V SL, control of thrips, leafminer, cowpea weavil, leaf hopper, etc.

Rotenone 8% W/V EC

Saponin 10% DP

Bacillus subtilis 1×10^9 cfu/gm WP for foot rot of Durian, sheath blight of rice

Bacillus thuringiensis aizawai

8 500 IU/mg SC, 15 000 IU/mg WP, 1 × 109 cfu/ml (12% W/V SC), 24 000 IU/mg WP,

25 000 IU/mg WP, 32 000 IU/mg (4% WP), 35,000 DBMU/mg WG, 7 000 DBMU/mg SL

Bacillus thuringiensis kurstaki

10 600 IU/mg SC, 16 000 IU/mg WP, 53 000 SU/mg (6.4% WG), 1×10^9 cfu/g. WP, 32 000 IU/mg WP, 36 000 IU/mg Oil Flowable, 36 000 IU/mg WG, 5 500 IU/mg WP, 64 000 IU/mg (15% WG)

Beauveria bassiana

1×10^9 cfu/gm. WP, 2.3 × 107 conidia/ml SC

Chaetomium cupreum

1.5 × 106 cfu/g WP

Metarhizium anisopliae

1×10^9 cfu/gm WP

Sarcocystis singaporensis 200 000 spore/lump RB

Steinernema carpocapsae 400 000 units/bag

Steinernema siamkayai 1×10^7 units/bag

Trichoderma harzianum

Virus NPV 0.64% W/V SL & 2×10^9 cyrstals/ml

1. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF BOTANICALS (plant, plant extracts)

Active substances of plant protection products made from one or several plants and mixed with water and plant protection products possibly with formulants added.

Plant Nomenclature:

Latin name of the plant and its author

Common names

Geographic origin

Natural state: cultivated or wild

Growth stage

Organ or part of the plant sampled

If the plant protection product is not obtained directly from the plant itself, specify, the processing used

Origin of the plant

Name and address of grower (where relevant) and/or region of origin

Growing conditions

Place, time and conditions of harvest of plant part (s) that provide the active principle

Length of storage and storage conditions

Any change of origin must be considered in advance before being accepted.

Identity of the plant protection product

Name and address and detailed particulars relating to the plant protection product manufacturer

Name and address of applicant

Name of contact person

Place of manufacture

Name of contact person

Plant protection products specifications:

Establish a chemical profile: Description of the known active plant protection substances. Provide the active substances' concentration range

For the other substances, provide a percentage of the total weight (or a percentage range).If any active substance has been identified the following information are required: Chemical name according to IUPAC, and other information about identity (CAS No, structural formula, ISO name)

Physico-chemical properties: vapour pressure, partition coefficient, hydrolysis, photolysis

For any toxic substances that are relevant for human, animal health and environment provide a maximum content limit

If the active substance(s) is (are) not identified, define a representative marker: i.e., a chemical naturally present in a known proportion in the plant in order to identify the plant protection product

Analysis report of 5 batches of different manufacture, collected over several periods

Manufacture of the plant protection product

Precise description of the manufacturing process: methods, stages, operating conditions

Detection and identification of possible contaminants such as heavy metals, toxins, pesticides

Assessment of microbiological quality: detection and quantification of the plant and animal and human pathogens (depending on the type and origin of the plant, and the plant protection product's manufacture and storage)

Full list of ingredients

The plant protection product's trade name, physical state and function; Example: plant protection product manufactured directly from a plant

A precise quantity of the plant, or an upper and lower limit must be submitted

Plant (whole or part): [-] g/kg or g/l (express as fresh weight and dry weight or as a weight interval)

Other ingredient (Include CAS No.) [ ] g/kg or g/l Water [ ] g/l

Physical and chemical properties of the plant protection product

Type of formulation

Appearance (physical state, colour, and odour)

pH

Oxidising properties

Hygroscopic property

Relative density

Suspensibility

Persistent foaming

Particle size distribution for powders

Compatibility with the packaging

Plant protection product's stability in storage:

With monitoring in all cases of its physical, chemical and micro-biological properties and of the active substances that have been identified

The wrapping and packaging must be specified. The stability trials are to be carried out under normal conditions on 3 batches of the same formula, using the dose and wrapping that will be used when the product is marketed

Data on application of the formulation

Field of use

Effect on harmful organisms, expected mode of action

Details of intended use (crops, parasites)

Application rate

Method of application

Number and timing of applications and the protection period where relevant

Further information on the plant protection product

Packaging (description, type, capacity, size, materials, seal)

Methods for cleaning the equipment used to apply the product

Re-entry periods, required waiting periods or other precautions for protecting man, animals andthe environment

Recommended procedures and precautions for product handling, storing and transporting, or in the event of a fire

Emergency procedures in the event of an accident

Destruction or decontamination procedures (depending on the kind of ingredients in the plant protection product)

Analytical methods

If the substances are identified: Validated method for analysing the identified active substance in the plant protection product.

If the active substances are not identified, validated method of analysis of the marker in the plant protection product should be available.

Validated method for analysing the active substance in water, soil and air can be judged necessary if exposure of the concerning compartment is likely and the contribution compared to natural background levels is substantial.

If any toxic substances that are relevant for human or animal health and the environment are detected in the plant protection product, validated methods of analysis must be provided.

Toxicological studies

Provide all toxicological information available, including studies, publications, evaluations done, other uses than pesticides, etc. The information provided must be of sufficient quality to enable an evaluation of the plant protection product, taking into account the endpoints relevant for the intended use of the product (i.e. acute oral, dermal, inhalation toxicity, cutaneous and eye irritation and skin sensitization). In case the plant used in the plant protection product is also used in food and feed, information on oral toxicity may be waived.

Depending on the outcome of the evaluation, additional information can be required on a case by case basis.

In the case where formulant(s) are added in the plant protection product, the safety data sheets of the formulant(s) must be provided.

Based on available information on the formulant(s) and the amount added in the plant protection product, further toxicological data may be required based on expert judgment.

Risk assessment for the operator and worker must be addressed and personal protective equipment where relevant indicated.

Residues in or on treated products food and feed

The extent of exposure due to the use as plant protection product, must be compared to the exposure due to consumption of the plant itself. In cases where relevant residues of the active substance or other components of toxicological relevance occur in/on the treated plants used as a food or feed item, supervised field trials must be carried out.

Depending on the results, further studies (e.g. processing, feeding) might be necessary.

When relevant a dietary risk assessment for the consumer is required.

Fate and behavior in the environment

If exposure of water, soil or air is likely to occur available information from literature on natural background levels should be provided. If there is a substantial increase more information may be required based on expert judgment.

Ecotoxicological studies

Provide all ecotoxicological information available, including studies, publications, evaluations done.

Based on the evaluation of the available information, further ecotoxicological data on the plant protection product may be required based on expert judgment.

In the case where formulant(s) are added in the plant protection product, the safety data sheets of the formulant(s) must be provided.

Based on available information on the formulant(s) and the amount added in the plant protection product, further ecotoxicological data may be required based on expert judgment.

Classification and labelling

If applicable, proposals for the classification and labelling are mandatory.

2. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF PHYTOCHEMICAL FORMULATED PEST CONTROL PRODUCTS

Active formulated substances of plant protection products prepared with one or several organic solvent or water-based extracts made of plants and plant protection products possibly with formulants added.

Plant nomenclature

Latin name of the plant and its author

Common names

Genus, species, sub-species, variety or chemotype, if necessary

Geographic origin

Natural state: cultivated or wild

Growth stage

Organ or part of the plant sampled

If the plant is not used in its natural state, specify the processing used and the characteristics of the resulting product

Origin of the plant

Name and address of grower (where relevant) and/or region of origin

Growing conditions

Place, time and conditions of harvest

Length of storage and storage conditions

Any change of origin must be considered in advance before being accepted

Identity of the plant protection product

Particulars relating to the plant protection product manufacturer

Name and address of applicant

Name of contact person

Name and address of the manufacturer

Place of manufacture

Name of contact person

Extract specifications

Chemical profile of the formulation may be given: Description of known active plant protection substances. Provide a concentration range for the active substances

For the identified active substance(s) the following information are required: Chemical name according to IUPAC, and other information about identity (CAS No, structural formula, ISO name)

Physico-chemical properties such as vapour pressure, partition coefficient, hydrolysis and photolysis including pH-effect

For other substances, provide a percentage of the total weight

For any toxic substances that are relevant for human, animal health and environment, provide a maximum content limit

Analysis report of 5 batches of different manufacture, collected over several periods

Manufacture of the extract

Precise description of the manufacturing method: methods, stages, operating conditions, type and quantity of the solvents used

Plant protection product specifications

Precise description of the manufacturing process of the plant protection product: methods, stages, operating conditions

Detection and identification of possible contaminants such as heavy metals, toxins, pesticides

Assessment of microbiological quality: detection and quantification of the plant and animal and human pathogens (depending on the type and origin of the plant, and the plant protection product 's manufacture and storage)

Full list of ingredients

The plant protection product's trade name, physical state and function must be specified. Example: A precise quantity or an upper and lower limit corresponding to a defined quantity of plant-protection substances must be submitted

Extract of [-] prepared from [-] g/kg or g/l of extract corresponding to Plant(s) [-] g/kg = [-] g/kg or g/l of active substance solvent (specified solvent composition) indicating content in g/l or g/kg (include CAS No.)

Other ingredients: [-] g/kg or g/l

Physical and chemical properties of the water/organic solvent extract

Type of formulation

Appearance (physical state, colour, and odour)

pH

Explosiveness, flash point, self-combustibility

Oxidising properties

Volatility

Viscosity

Surface tension

Relative and overall densities

Suspensibility

Persistent foaming

Compatibility with the packaging

Plant protection product's stability in storage:

With monitoring in all cases of its physical, chemical and micro-biological properties and content of the identified active substances

The wrapping and packaging must be specified. The stability trials are to be carried out under normal conditions on 3 batches of the same formula, using the dose and wrapping that will be used when the product is marketed

Data on field crop application

Field of use

Effect on harmful organisms, expected mode of action

Details of intended use (crop(s), pest(s)

Application rate

Method of application

Number and timing of applications and the protection period where relevant

Further information on the plant protection product

Packaging (description, type, capacity, size, materials, seal)

Methods for cleaning the equipment used to apply the product

Re-entry periods, required waiting periods or other precautions for protecting man, animals and the environment

Recommended procedures and precautions for product handling, storing and transporting, or in the event of a fire

Emergency procedures in the event of an accident

Destruction or decontamination procedures (depending on the kind of ingredients in the plant protection product)

Analytical methods

If the active substances are identified, validated method for analysing the identified active substance in the plant protection product must be provided.

If the active substances are not identified, validated method of analysis of the marker in the plant protection product should be available.

Validated method for analysing the active substance in water, soil and air can be judged necessary if exposure of the concerning compartment is likely and the contribution compared to natural background levels is substantial.

If any toxic substances that are relevant for human or animal health and the environment are detected in the plant protection product, validated methods of analysis must be provided.

Toxicological studies

Provide all toxicological information available, including studies, publications, evaluations done in OECD countries, other uses than pesticides, etc.

The information provided must be of sufficient quality to enable an evaluation of the plant protection, taking into account the endpoints relevant for the intended use of the product (i.e. acute oral, dermal, inhalation toxicity, cutaneous and eye irritation and skin sensitization). In case the plant used in the plant protection product is also used in food and feed, information on oral toxicity may be waived.

Depending on the outcome of the evaluation, additional information can be required on a case by case basis.

In the case where formulant(s) are added in the plant protection product, the safety data sheets of the formulant(s) must be provided.

Based on available information on the formulant(s) and the amount added in the plant protection product, further toxicological data may be required based on expert judgment

Risk assessment for the operator and worker must be addressed and personal protective equipment where relevant indicated.

Residues in or on treated products food and feed

The extent of exposure due to the use as plant protection product, must be compared to the exposure due to consumption of the plant itself. In cases where relevant residues of the active substance or other components of toxicological relevance occur in/on the treated plants used as a food or feed item, supervised field trials must be carried out.

Depending on the results, further studies (e.g. processing, feeding) might be necessary. When relevant a dietary risk assessment for the consumer is required.

Fate and behavior in the environment

If exposure of water, soil or air is likely to occur available information from literature on natural background levels should be provided. If there is a substantial increase more information may be required based on expert judgment.

Ecotoxicological studies

Provide all ecotoxicological information available, including studies, publications, evaluations done in OECD countries, other uses than pesticides, etc.

Data available on the extract could be used in a case by case approach.

Based on the evaluation of the available information, further ecotoxicological data on the plant protection product may be required based on expert judgment.

In the case where formulant(s) are added in the plant protection product, the safety data sheets of the formulant(s) must be provided.

Based on available information on the formulant(s) and the amount added in the plant protection product, further ecotoxicological data may be required based on expert judgment.

Classification and labelling of the water/ethanol extract; if applicable, proposals for the classification and labelling are mandatory.

Plant parts or plant extract to be produced or imported for export to foreign countries, which is the same kind as the plant part or plant extract already been registered in Southeast Asia nations; but in different formulation and concentration, need not submit data in items below:

For parts or extract of neem, which has technical information supports that it is safe to human, plant, animal and the environment, is not required to submit data in item below.

Toxicological data of plant parts or plant extract shall be generated by GLP laboratories and followed OECD guidelines or other standardized laboratories.

3. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF PHEROMONES (semi-chemicals)

Information on finished/formulated product

Common name proposed/accepted by ISO or othersstandard, (if any)

Trade name or manufacturer's code number

Content (%) and nature of components included in the formulation and appearance

Analytical method for active ingredient

4. RECOMMENDED DATA REQUIREMENTS FOR THE REGISTRATION OF MICROBIAL PEST CONTOL AGENTS

Identity of the Microbial Pest Control Product (MPCA)

Applicant (name, address)

Manufacturer(s) of the concentrate preparation and/or formulation (name, address)

Trade name or proposed trade name and manufacturer's code number(s)

Physical state of MPCP (GIFAP formulation type)

Biological function category and field of use category, e.g. "control of weeds"

Scientific name and strain/serotype of MPCA, its accession number in a recognized culture collection

Composition of each ingredient in MPCP, including

Technical Grade of MPCA

Each additive includes chemical name and structure; CAS numbers of components of additive if they exist or an appropriate specification; trade name; function in MPCP

Microbial impurities: taxonomic identification as required by quality criteria to support the hygienic state of the production process; express content of microbial impurities in appropriate units, e.g. cfu/ml

Non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues)

Quality criteria for the production and storage of the MPCP, including

Acceptable range for content of MPCA as cfu/g of product

Presence of human or non-target animal pathogens

Presence or maximum accepted level of known mammalian toxins, if their presence is suspected at any stage in process, or if MPCA is closely related to a toxigenic human pathogen

Maximum accepted level for microbial impurities

Quality control data (measures of quality criteria) from 3-5 production batches, including product stored for duration of shelf life if it is metabolically active. If the Technical Grade concentarte of MPCA is a stage in a continuous production process of an end use product, this information should be provided for the entire production process

Physical, chemical and technical Properties of the Microbial Pest Control Product

Appearance (colour, odour, physical state)

Technical characteristics as appropriate: wetability, persistent foaming, suspensibility, suspension stability, dry/wet sieve test, particle size distribution, content of dust/fines, emulsifiability, emulsion stability, lowability, pourability, dustability

Application instructions and precautions of the Microbial Pest Control Product

Pest organism(s) taht could be controlled, crop(s) that could be protected, available information on mode of action (site of uptake, toxic/competitive effect), is microorganism transmitted or translocated to another part of plant?

Application rate in terms of mass/vol of MPCP per unit area/volume (e.g. kg/ha). Content of micro-organism in material used (diluted spray, bait, treated seed)

Application rate in terms of units of micro-organism per unit area/volume

Method of application (incl. type of equipment and volume of diluent)

Number and timing of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval

Proposed instructions for use as printed, or to be printed, on labels (*Specimen label*)

Packaging: description (Packaging should be checked for safety and protection of MPCP)

Label instructions regarding safe handling and storage

Procedures for destruction/disposal of MPCP and its packaging (e.g. detailed instructions for controlled incineration)

Methods of analysis, manufacturing, quality control and post-registration, monitoring of the Microbial Pest Control Product

Quality control and post-registration monitoring method to define content of microorganism in appropriate terms (see below), including standardization, sensitivity, reproducibility, statistical validity, and representative data to validate the bio-assay. Concentration of microorganism (and metabolite, if appropriate) in terms of g/kg, or g/L, and cfu/ml or appropriate potency units;

Storage stability test and determination of shelf life

Production process for MPCP, describing techniques used to ensure a uniform product and procedures when hazardous contamination is detected in a batch. List stating intermediate materials, with source and purity of each

Toxicological studies and exposure data and information for the Microbial Pest Control Product

Acute oral toxicity

Acute percutaneous (dermal) toxicity

Acute inhalation toxicity to rats

Skin irritation

Eye irritation

Safety data sheet for each additive

Residues in/on food and feed products, and fate and behavior in the environment for the Microbial Pest Control Product

Provide the rationale to waive residue studies on MPCP

Residues in/on food and feed products, and fate and behavior in the environment for the Microbial Pest Control Product

Provide the rationale to waive testing, based on adequacy of information provided for MPCA, to permit an assessment of the fate and behaviour of MPCA in the environment

Environmental fate: (for exotic organisms, for MPCPs where evidence (e.g. overdosing) suggests that uncontrolled spread could occur or negative impacts on ecosystem can not be excluded)

Effects of the Microbial Pest Control Product on Non-Target Organisms

Effects on non-target organisms

Whether or not testing of non-target organisms decided on a case by case basis, under consideration of native or exotic organism the general biology of a.i. of MPCP – scientific information available

Toxicological data of microbial pest control product shall be generated by GLP laboratories, other accredited, empowered and standardized laboratories that follow OECD guidelines for this purpoe

Registration for the manufacture for export to Southeast Asian countries:

Export microbial pest control product to be produced or imported for export to foreign countries, if are the same kind as the microbial pest control product already been registered in Southeast Asian countries, but different formulation and oncentration in accordqance with importing country's demand, need not have to submit data in item [5.1-5.9?].

For *Bacillus thuringiensis aizawai, Bacillus thuringiensis kurstaki,* Nuclear Polydrosis Virus (NPV), *Steinernema* spp. (*Neoaplectana* spp.) and *Heterorhabditis* spp., which has technical information supports that it is safe to human, plant, animal and the environment, is not required to submit data in item [5.1-5.9?].

Annex B

DATA REQUIREMENTS FOR HARMONIZED REGISTRATION OF BIOPESTICIDES

Information sheet for different biopesticides

I. GUIDELINES/DATA REQUIRMENTS FOR REGISTRATION OF BOTANICAL PESTICIDES

Sl. No.	Particulars	Technical concentrate	Formulation
		Provisional registration	Regular registration
A. BIOLOGICIAL CHARACTERISTICS AND CHEMISTRY			
1.	Systemic name (genus and species)	R	R
	1.1. Strain name	NR	NR
2.	Common name	R	R
3.	Source of origin	R	R
4.	Specification of the product	R	R
5.	Composition of the product	R	R
6.	Manufacturing process	R	R
7.	Test procedures and criteria for identification of DNA test	NR	NR
8	Method of analysis/biological assay	R	R
9.	Contaminants	NR	NR
10.	Shelf life claim	R	R
11.	A sample for verification	R	R
B. BIO-EFFICACY			
12.	Field studies	R	R
13.	Lab. studies	R	R
C. TOXICITY*			
14.	For mother culture	NR	NR
15.	For formulation	NR	NR
16.	For formulated products to be directly manufactured (mammalian toxicity)	NR	NR
17.	Environment safety testing	NR	NR
D. PROCESSING, PACKAGING AND LABELLING			
18.	Manufacturing process/process of formulation	R	R
20.	Labels and leaflets	R	R

Abbreviations: R = required; NR = Not required

Please mention, any other data required/not required besides above in your country.

* Except parts or extract of neem including azadiractin

PROPOSED GUIDELINES FOR MINIMUM INFRASTRUCTURE FACILITIES TO BE CREATED BY THE MANUFACTURERS OF BOTANICAL BIOPESTICIDES
(Pyrethrum, Azadirachtin, Cymbopogon, etc.)

MANPOWER REQUIRMENT	
1.	Quality control botanist
2.	Sufficient personnel to supervise production, maintenance, stores, etc.
GENERAL REQUIREMENT	
1.	Extraction room
2.	Production room
3.	Formulation unit
4.	Packing and storage room
5.	Quality control laboratory
6.	Protective clothing
7.	Respiratory devices
8.	First aid measures
9.	Waste disposal arrangement in compliance with pollution control norms
PLANT EQUIPMENT/INSTRUMENT REQUIREMENT	
1.	Phase separation vessels
2.	Decanter
3.	Mixing vessels with stirrer
4.	Centrifuge
5.	Soxhlet apparatus
6.	Electric oven with thermometer
7.	Chemical measuring cylinders
8.	Chemical transfer pumps
9.	Filter pressure pump
10.	Measuring cans
11.	Electric weighing machine
12.	Counter scales
13.	Filtration assembly
14.	Water distillation unit
15.	Wrist action shaker
16.	Blender
17.	Vortex
18.	Large air tight containers
19.	Material filling trays
20.	Storage tank
21.	Filling machine
22.	Sealing machine
23.	Packing accessories
LABORATORY EQUIPMENT/INSTRUMENT REQUIREMENT	
1.	HPLC System
2.	pH meter
3.	Spectrophotometer
4.	Refrigerator
5.	Thermometer

6.	Microscope
7.	Autoclave
8.	U.V. Lamp
9.	Abel flash point apparatus
10.	Incubator
11.	Glassware (conical flasks, test tubes, beaker, separating funnel, funnels, glass tubes, etc.)
12.	Pipette fillers
13.	Pipette
14.	Burette
15.	TLC apparatus and accessories
16.	Micro-syringes

Note: These are the general requirements of minimum infrastructure to be created by the manufacturers. However, for specific botanical biopesticides formulation(s) and their quantum of production, specific requirement of manpower, space, equipment/ instrument may be needed.

II. GUIDELINES/DATA REQUIRMENTS FOR REGISTRATION OF MICROBIAL PESTICIDES

Sl. No.	Particulars	Provisional registration	Regular registration
A. BIOLOGICIAL CHARACTERISTICS AND CHEMISTRY			
1.	Systemic name (genus and species)	R	R
	1.1. Strain name	NR	R
2.	Common name	R	R
3.	Source of origin	R	NR
4.	Specification of the product	R	R
5.	Composition of the product	R	R
6.	Manufacturing process	R	R
7.	Test procedures and criteria for identification of DNA test	NR	NR
8	Method of analysis/Biological assay	R	R
9.	Contaminants	NR	R
10.	Shelf life claim	R	R
11.	A sample for verification	R	R
B. BIO-EFFICACY			
12.	Field studies	R	R
13.	Lab. studies	R	R
C. TOXICITY*			
14.	For mother culture	NR	NR
15.	For formulation	NR	R
16.	For formulated products to be directly manufactured (mammalian toxicity)	NR	
17.	Environment safety testing	NR	R
D. PROCESSING , PACKAGING AND LABELLING			
18.	Manufacturing process/process of formulation	R	R
20.	Labels and leaflets	R	R

Abbreviations: R = required; NR = Not required

Please mention, any other data required/not required besides above in your country.

* Except *Bacillus thuringiensis aizawai, Bacillus thuringiensis kurstaki,* Nuclear Polyhedrosis Virus (NPV), Nematode of *Steinernema* spp. (*Neoaplectana* spp.) and *Heterorhabditis* spp.

PROPOSED GUIDELINES FOR MINIMUM INFRASTRUCTURE FACILITIES TO BE CREATED BY THE MANUFACTURERS OF MICROBIAL BIOPESTICIDES
(Antagonistic fungi, Entomopathogenic fungi, Antagonistic bacteria, Entomotoxic bacteria)

MANPOWER REQUIREMENT	
1.	Quality control biologist
2.	Sufficient personnel to supervise production, maintenance, stores, etc.
GENERAL REQUIREMENT	
1.	Production, mixing & drying room and formulation unit for antagonistic fungi/entomopathogenic fungi
2.	Inoculation, fermentor & sterilization room and formulation unit for antagonistic bacteria/entomotoxic bacteria
3.	Packaging and storage room
4.	Quality control laboratory
5.	Protective clothing
6.	Respiratory devices
7	First aid measure
8.	Waste disposal arrangement in compliance with Pollution Control norms
PLANT EQUIPMENT REQUIREMENT	
1.	Plant fermentor with all accessories
2.	Steam boiler
3.	Chilling plant
4.	Air compressor
5.	RO/Softner (water treatment plant)
6.	Distillation unit
7.	Micro centrifuge
8.	Magnetic stirrer
9.	300 __and 160 _ Sieves
10.	Electronic weighing balance
11.	Blender/homogenizer
12.	Vortex
13.	Vibro-screen
14.	Autoclavable bag
15.	Large air tight container
16.	Pouch sealing machine
17.	Box strapping machine
18.	Racks and cabinet
LABORATORY EQUIPMENT/INSTRUMENT REQUIREMENT	
1.	Autoclave
2.	Water bath
3.	Shaking incubator
4.	Refrigerator
5.	Thermo hygrometer
6.	U.V. light
7.	BOD Incubator
8.	Hot Air oven
9.	Laminar flow

10.	pH meter
11.	Balance (2-3 decimal places)
12.	Vacuum pump
13.	Hot plate
14.	Deep freezer
15.	Spirit
16.	Microscope and all accessories
17.	Glassware *such as* conical flasks, test tubes, beaker, etc.
18.	Petri dishes
19.	Titanium inoculating needles
20.	Pipette fillers
21.	Pipettes (0.1 ml to 20 ml)
22.	Haemocytometer
23.	Colony counter

Note: These are the general requirements of minimum infrastructure to be created by the manufacturers. However, for specific microbial biopesticides formulation(s) and their quantum of production, requirement of manpower, space, equipment/instrument may be needed.

III. GUIDELINES/DATA REQUIRMENTS FOR REGISTRATION OF ENTOMOTOXIC BACTERIA

Sl. No.	Parameter	Technical concentrate		Formulation	
		Provisional registration	Regular registration	Provisional registration	Regular registration
1. BIOLOGICAL CHARACTERSTICS AND CHEMISTRY					
1.1.	Common name	R	R	R	R
1.2.	Systematic name: (Genus, species, serotype and strain)*	R	R	R	R
	1.2.1. Cry toxin classification (delta endotoxin)	R*	R*	R*	R*
R* If H-Serotype is not known, it is mandatory to provide the details of Cry toxin to confirm that it is *Bacillus thuringiensis*.					
1.3.	Physical specification	R	R	R	R
	1.3.1. Form and appearance	R	R	R	R
	1.3.2. pH, particle size, suspensibility, miscibility	R	R	R	R
1.4.	Composition	R	R	R	R
	1.4.1. Delta endotoxin content – through housefly bio-assay test	R	R	R	R
	1.4.2. Beta exotoxin content – to be ruled out through bio-efficacy test (housefly bio-assay method)	R	R	R	R
	1.4.3. Adjuvants	R	R	R	R
	1.4.4. Moisture content	R	R	R	R
	1.4.5. Human pathogens (culture method)	R	R	R	R
	1.4.6. Other microorganisms (not more than 10^4)	R	R	R	R
	1.4.7. Chemical and botanical pesticide contaminants g)	R	R	R	R
1.5.	Natural occurrence of the organism	R	R	R	R
1.6.	Test procedure and criteria used for identification – morphology, biochemistry, serology/ immunology	R	R	R	R
	1.6.1. Morphology description, particle size	R	R	R	R
	1.6.2. Immunology assays: Elisa/Dot Blot assay test	R	R	R	R
	1.6.3. Potency of product by bio-assay method (LC_{50} on target larvae and potency against a reference using artificial diet or leaf disc method or in the water for mosquito larvae	R	R	R	R
	1.6.4. Separation and purification of crystals required (R) if antisera is to be developed for the strains delta endoxin	R/NR	R/NR	R/NR	R/NR
1.7.	**Shelf life**				
	1.7.1. Shelf life claim (not less than 6 months)	R	R	R	R
	1.7.2. Shelf life data in support of shelf life claim as detailed in **Note 2**	R	R	R	R
1.8.	A sample for test (100 g)	R	R	R	R
2. BIO-EFFICACY					
2.1.	**Laboratory Test**: LC_{50} values for each insect species under laboratory conditions should be generated at least at two approved institutions	R	R	R	R

Sl. No.	Parameter	Technical concentrate		Formulation	
		Provisional registration	Regular registration	Provisional registration	Regular registration
2.2.	**Field test**				
	2.2.1. Data on bioeffectiveness and phytotoxicity generated at approved institutes	NR	R***	R**	R***
R** Two seasons/years data on bioeffectiveness from minimum two agro-climatic conditions R*** Two seasons/years data on bioeffectiveness from minimum three agro climatic conditions					
	2.2.2. Data on non-target organisms: One season/ one year data on the effect of the product on natural predators/parasites	NR	R	R	R
3. TOXICITY					
3.1.	**Single exposure studies**	R	R	R	R
	3.1.1. Oral toxicity/pathogenicity	R	R	R	R
	3.1.2. Dermal toxicity/pathogenicity	R	R	R	R
	3.1.3. Inhalation toxicity/pathogenicity	R	R	R	R
	3.1.4. Primary skin irritation	R	R	R	R
	3.1.4. Mucous membrane irritation	R	R	R	R
	3.1.6. Allergy/sensitization/immuno supression	R	R	R	R
3.2.	**Eco-toxicity**				
	3.2.1. Toxicity to birds[a]	NR	NR	NR	R
	3.2.2. Toxicity to fish[b]	NR	NR	NR	R
	3.2.3. Toxicity to honeybees	NR	NR	NR	R
	3.2.4. Toxicity to silkworm	NR	NR	NR	R
[a] Information on infection and pathogenicity: suggested test: single-dose, oral test. suggested test species: pigeon and chicken. [b] Information on infection and pathogenicity: suggested test species: *Tilapia mossambica* or other appropriate species.					
4. PACKAGING AND LABELLING					
4.1.	Packaging requirements as per ISI or as per the approval of RC	R	R	R	R
	4.1.2. New Packaging system approved by FAO/ ASPM/other global standards (relevant)	R	R	R	R
4.2.	**Manner of packing**	R	R	R	R
	4.2.1. Specification of primary packing	R	R	R	R
	4.2.2. Specification of secondary packing	R	R	R	R
	4.2.3. Specification of transport packing	R	R	R	R
	4.2.4. Detailed information for completely filled transport packing containing quantity of primary and secondary packing				
4.3.	**Manner of labelling**				
	4.3.1. Specification of primary packing	R	R	R	R
	4.3.2. Specification of secondary packing	R	R	R	R
	4.3.3. Specification of transport packing	R	R	R	R
4.4.	**Container content compatibility**				
	As per approved national protocols				
4.5.	**Labels and leaflets**				
	4.5.1. 7 copies of L/Ls upto 250 ml	R	R	R	R
	4.5.2. 7 copies of L/Ls upto 500 ml	R	R	R	R

Abbreviations: R = Required; NR = Not required

Notes:

1. Applicants are required to submit an undertaking that strain is indigenous, naturally occurring, not exotic in origin, and not genetically modified.
2. Additional two months data for six months shelf life claim/three months additional data for one year shelf-life claim at two different agro climatic locations at ambient temperature along with meteorological data should be submitted.
3. If same microbial strain is used for making formulation by different entrepreneurs that the information submitted once on the said strain will be sufficient. All entrepreneurs need not submit relevant data.
4. If same microbial strain, same method and same adjutants, stabilizers, etc. are used for making the given formulation, data once submitted for validitating these claims will be sufficient for subsequent registrants, as substantiated by the relevant supportive documents.

(c) The packaging material should also be ensured to be free from contamination from handling, storage and transportation and is as per prescribed standards, as the case may be.

(d) The percentage of ingredient relative to total material is required to be stated and may vary from 2-7 percent, the balance being inert ingredients. In addition, the labels will have to contain a measurement of toxin protein as percent protein, referring to the Lepidopteran-active toxin(s) present in the crystal.

(e) Bt products should be labelled with biopotency and (or) toxin content.

(f) The presently used Bt var. kurstaki standard is HD-1-S-1980 and its potency was calculated at 16 000 Ius per milligram of powder (Beegle *et al*. 1986. Standardization of HD-1-S-1980: US Standard for Lepidopterous-active *Bacillus thuringiensis*. Bulletin Ent. Soc. America 32: 44-45.). This standard strain is now available with PDBC, Bangalore and DOR, Hyderabad.

(g) Defined potency and toxin concentration – Bio-assay would require the use of an insect species. Normally manufacturers could select *Trichoplusia ni*/*Helicoverpa armigera* for Lepidopteran specific Bt formulations. *Spodoptera* Units (SPU), *Leptinotarsa* Units (LTUs) or International Toxin Units (ITUs) are to be used for denoting a specific insect.

(h) No test for beta exotoxin is required for *Bacillus sphaericus*, because this species is not known to produce exotoxins.

(i) The biopotency of products based on *B. thuringiensis* subsp. *israelensis* (*Bti*) is compared against a reference strain IPS82, 1884 using early fourth-instar larvae of Aedes aegypti (strain Bora Bora). The toxicity of IPS82 has an arbitrarily assigned toxicity of 15 000 ITU/mg powder.

(j) The bio-efficacy of products based on *B. sphaericus* (*Bsh*) is determined against a reference standard SPH88, strain 2362 using early fourth-instar larvae of Culex pipiens pipiens (strain Montpellier). The toxicity of SPH88 has an arbitrarily assigned toxicity of 1 700 ITU/mg of the powder (Guidelines for laboratory and field testing of mosquito larvicides, WHO 2005 pp 45).

(k) The use of alternative bacterial reference powders and/or strains must be approached cautiously. Such alternatives must be the subject of careful cross-calibraation against the reference powders and should be conducted by recognized laboratories. The alternative powders/strains and the cross-calibration data which support them, should be made available to anyone who wishes to use, or check, the test with the alternative powders/strains.

(l) Water content should not exceed 5 percent, to preclude premature degradation of the product.

PROPOSED STANDARDS FOR ENTOMOTOXIC BACTERIA TECHNICAL/FORMULATION SPECIFICATIONS

Sl. No.	Details
1. SCOPE	
1.1	This Indian Standard prescribes the requirements and the method of sampling and test for entomotoxic bacteria technical and formulation. The product is a biopesticide active against target insects. The product is not for human consumption.
2. REQUIREMENTS	
2.1.	Common name: i.e., *Bacillus thuringiensis or B. sphaericus, etc*.
2.2.	Systematic name (genus, species, serotype, strain and Cry-toxin* along with cry gene)
* If H-Serotype is not known, it is mandatory to provide the details of Cry toxin to confirm that it is *Bacillus thuringiensis*.	
2.3.	Physical specification
	2.3.1. Form and appearance
	2.3.2. pH
2.4.	**Composition**
	2.4.1. Delta endotoxin content (Minimum 2.0%) – estimation as per Annex V
	2.4.2. Adjuvants
	2.4.3. Moisture content
	2.4.4. Beta Exotoin content – Negative through housefly bio-assay test
	2.4.5. Human pathogens (gram negative bacateria Salmonella, shigella & vibrio, etc.) – Absent
	2.4.6. Other microorganisms (not more than 10^4/g)
	2.4.7. Chemical/botanical pesticide contamination – Absent
2.5.	Natural occurrence of the organism
	2.5.1. Its relationship of the organisms
	2.5.2. History (exotic or indigenous strain)
	2.5.3. The isolate should not be genetically modified organism (GMO)
3. SAMPLING	
3.1.	Representative samples of the material shall be drawn in accordance with IS 10946:1984
4. TESTS	
4.1.	An appropriate test procedure and criteria used for identification, such as morphology, biochemistry and/or serology/immunology
	4.1.1. Morphology description, particle size
	4.1.2. Immunology assays: ELISA/Dot blot assay test or any other sensitive standard immunology test
	4.1.3. Method of analysis
	4.1.4. Level of beta exotoxins to be identified if expressed by Housefly bio-assay method.
	4.1.5. Potency of product by bio-assay method
	4.1.5.1. Bio-assay method
	a) LC_{50} on target larvae and potency against a reference using artificial diet or leaf disc method or in the water for mosquito larvae
	b) Housefly Bio-assay method for Beta-exotoxin content
	c) Determination of toxin content by ELISA/Dot Blot Assay Method
	4.1.5.2. A technique for the separation and purification of the crystals (Annex III) is to be used by the manufacturer and the antisera to be raised using solublized toxin. Toxin content (3.5%) to be standardized in the formulation using this antisera (ELISA/Dot blot assay)

Bio-assay method

Diet incorporation

The following protocol is used for diet incorporation of oral toxicants to test their toxicity on target insects. The example presented here is to bio-assay Cry I Ac on *H. armigera* (first instar larva of other test insects are used for similar bio-assay).

1. Pipette out 3 ml of the solution into a 40 ml plastic cup.
2. Pour lukewarm diet, approx 60 ºC, into the cup to a total volume of 30 ml. Place the lid and shake the cup vigorously for a minute to mix properly.
3. Pour the diet to 0.5 cm height, into wells of a 24-cell insect-rearing tray. Allow the diet to cool in laminar airflow under UV lamps for I h to surface sterilize the diet.
4. If concentration of the toxicant in the stock solution was 2 µg/ml, the final concentration in the diet would now be 0.2 µg/ml diet. Thus the final concentration of toxin in diet was diluted 10-fold.
5. Release first instars into the diet rearing trays at the rate of one per well. Cover the diet tray with semi-permeable wrap and close the lid.
6. It is recommended that the lid be tightly secured to the tray with rubber bands, to prevent the larvae from escaping. Because the diet is unsuitable, larvae try constantly to escape from the diet rearing trays.
7. Keep controls with larvae released on untreated diet, for all the experiments.
8. The unused rearing trays with diet can be stored in a refrigerator for a week.
9. Change the diet for the larvae every two or three days.
10. Record mortality observations at 8 hourly intervals until the end of seven days, for median lethal time LT_{50} calculations. LT_{50} is the time at which 50 percent of' the test population is killed with the specific dose tested. A simple linear regression equation can be worked out to calculate the LT_{50}.
11. Otherwise, record mortality at alternate days until the end of seven days, for median lethal concentralion LC_{50} calculations. LC_{50} is the concentration that kills half the test population.
12. Record weights of surviving larvae at the end of seven days, for median effective concentration EC_{50} and LC_{50} is the concentration that prevents half the test population from reaching 50 percent of the weight attained by control larvae. For example, if the average weight of larvae on the control diet (without toxin) was 80 mg, EC_{50} represents the concentration at which 50 percent of the test population is unable to gain a weight more than 40 mg. LC_{50} is the concentration that inhibits half the test population from reaching the third instar.

Diet incorporation for filter paper bioassays

1. For bioassays with bollworms, 10 ml toxin incorporated diet is poured over a 16 sq cm piece of filter paper. The filter papers layered with diet are cooled and cut into smaller squares of 2 × 2 cm, and 10 first instar larvae are released in small plastic cups 3 × 3 cm (d × h) cups containing a square. Change the strips every alternate day.
2. Record mortality observations until the seventh day.

Surface coating of semi-synthetic diet

1. Prepare the diet and pour it into the trays or the rearing plastic cups. Generally 10 µl of the toxin can be used to coal 1 sq cm surface area. Gently swirl the diet surface to ensure uniform and complete spread of the solution over the diet surface.

2. Allow the surface to dry in a laminar airflow under UV light for 2-3 hours to surface sterlize.
3. Release one first instar H. armigera larva per well. Always maintain proper controls with untreated diet.
4. Change the diet on alternate days and record mortality until the seventh day. Then, weight of surviving larvae should be recorded on the final day of the bio-assay.

The method has the advantage of obtaining constantly reliable results because the toxin is unlikely to be affected by either improper mixing or heat as can occur in the diet-incorporation method. Moreover, less amount of the toxin is required for the assay, compared to the diet-incorporation method.

Calculation of results

The potency of the sample (International Units – IUs)

$$\textbf{IU/mg sample} = \frac{LC_{50}\ \text{Standard}}{LC_{50}\ \text{Sample}} \times \text{IU/mg Standard}$$

(IU/mg Standard, i.e., HD-1-S-1980 is 16 000 IUs/mg; the US standard is available with PDBC, Bangalore; each registrant should prepare a "self reference" and should deposit it with the Registering Authority. Each self reference will be expressed as IU/mg using International standard)

Dot Blot assay of *Bacillus thuringiencis* (Bt) toxin protein as alternate of bio-assay.

1) B.t. grown till sporulation in shake flask or in fermenter vessel and let the cells lyse and release spore/crystals into the medium
2) Cells are harvested by centrifugation at 10 k for 15 mins
3) Wash the pellet with 1 M NaCl to remove the B.t. associated seine/metallo proteases and washd twice with sterile distilled water
4) Pellet resuspended in 50 MM NaOH to solublize the toxin protein for 2 hours at R.T. with slow shaking and centrifuged again at 10 K for 15 mins
5) Supernatent was adjusted to pH 8.0 with Tris HCL pH 8.8
6) Protein contents estimated by Lowry's protocol
7) Two fold serial dillutions of test protein were made in PBS and known amount at protein applied on NCP using S&S or Biorad Dot Blot manifold apparatus and applying water vaccum for 30 mins
8) NCP was carefully removed from Dot Blot set and soaked in excess of 3 percent Skim milk in PBS for blocking the remaining acetic sites on NCP for 2-3 hours at R.T/O/N at 4 ^{o}C
9) Wash the NCP with excess PBS with 0.01 percent Tween 20, 3-4 times and then finally with PBS
10) Polyclonal antiserum raised against total crystal protein was suitably diluted in PBS and added to the 'seal a meal' containing NCP and incubated for 1-2 hours with shaking.
11) Remove the NCP from the bag and was several times (as mentioned in step. No. 9)
12) Antirabbit antibodies conjugated with HRPO/alkaline Phosphate was diluted as per the suppliers instruction and incubated NCP (as in step 10)
13) Was as in step 11
14) For HRPO:
    a) Diaminobenzeden (4 mg/10 ml PBS)/4-Chloro-1-Napthol (4 mg/10 ml 20% Alcohol) were dissolved and 10 ml of 30 percent of H2O2 per 10 ul substrate soluion was added and

colour reaction developed in dark for 5-10 mins (DAB gives brick red colour. 40N gives blue colour).

b) For alkaline Phosphatase:

Alkaline Phosphatase Buffer:

1 M Tris pH 8.8 – 10 ml/

4 M NaCI – 2.5 ml/make up to 100 ml

1 M Mgc12 – 0.5 ml/

For 10 ml of above buffer add NBT-66 ul and BCIP-33 ul and developed and colour reaction

15. Stop the reaction by removing the substrate and washing with PBS
16. Keep on filter paper and dry

DIFFERENT PROTEIN CONCENTRATION

10 ug 5 ug 2.5 ug 1.25 ug 512.5 ng 256.25 ng 128 ng 64 ng 32 ng 16 ng 8 ng 4 ng

Different samples

Determination if cell dry weight

Take a known volume of the bacterial culture spin down at 4R for min
Wash the pellet in minimal distilled water
Transfer to a pre weighed container
Incubate at 80 ºC for 16-18 hours till become dry and weight becomes constant

Purification of crystals by gelatin method

Centrifuge the sporulated material and wash pallet twice with 1 M Nacl. Add 200 ml of 0.5 percent Gelatin, stir and remove all froth completely. Dilute with sterile water and centrifuge. Take debris and stir with 20 ml of 1.5 M sucrose. Further add 50 ml of 1.5 M sucrose, stir and centrifuge at 3 000 RPM for 2 hours. Remove supernatant and purified crystals are harvested.

Beta-exotoxin determination by House Fly Bio-assay Method

Fly Assay Diet Condition		Laboratory	
Agar	16 g	Temp	25 ºC + 2 ºC
Milk powder	100 g	R.H.	70%
Yeast	100 g	Test insect	-2 days old Hot fly larvae
Methyl Paraben	2.1 g	No. of replications	2
Water	1 000 ml		

Procedure

i) 1 g sample thoroughly mixed with 9 ml of sterile saline. This solution is heat treated at 65 ºC (Water bath) for 45 minutes and incubate at rotary shaker for 2 hrs at room temp.
ii) Then centrifuge this sample at 12 000 RPM for 10 minutes.
iii) This suspension is serially diluted (1:10) to 10^{-6} dilutions.
iv) Liquid diet 200 g for each replicate is placed in trays/beakers.
v) 5 ml of heat treated culture supernatant (10^{-6}) is poured on diet. Let it solidify at room temp. For control, use 5 ml of sterile water.

vi) 2 days old House fly larvae (50) in each replicate i.e. two replicate each for sample and control and cover with wire mesh/clot.

vii) Incubate the trays at 25 ºC + 2 ºC till emergence.

viii) After 24 hours, just put 5 g wheat bran in each tray on the top (on 8^{th} to 10^{th} day). On adult emergence freeze the trays for 2 hours to count the adults and % mortality may be calculated as:

% Mortality = (100 – Number of Normal Adults).

Quantification of Bt endotoxin using ELISA Technique

The Cry1Ac Bt-Quant is an ELISA kit, which facilitates a precise quantification of Cry1Ab or Cry1Ac, present in Bt based biopesticides. The kit is simple, cost effective and very reliable. It takes about 2 hrs for completion of one set of ELISA assay. Each ELISA plate can be used for 96 samples (including four wells for standards and two for blank). Depending on the capabilities of a laboratory hundreds of samples can be processed in a single day. ELISA plate reader is a requirement for use of the kit.

Materials

1. 96 well ELISA plate coated with antibody (Store refrigerated)
2. Calibrated standards
3. Substrate (Store refrigerated)
4. PBST (10x) Dilute it before use
5. IgG-conjugate (Store refrigerated)
6. Stop Solution (ready to use)

Procedure

1. Grind the sample into a fine solution with 0.5 ml sample extraction buffer
2. Centrifuge the sample at 10 000 RPM (optional)
3. Prepare serial dilutions of the standards provided, for a range between 0.01 to 0.5 ppm
4. Pipette out 50 µl of antibody-conjugate into each well
5. Add 50 µl (microliter) of the sample into each well of the ELISA plate
6. Pipette 50 µl of each of the standard solutions into the wells of a particular column. Pipette out buffer only in one or two wells of the ELISA plate to maintain blanks
7. Incubate for 1 hour at room temperature, preferably in a humid chamber
8. Wash the plate with wash buffer (PBST) 3 times and empty wells
9. Add 50 µl substrate to each well. Incubate for 20-30 minutes. Blue color develops in positive samples
10. Add 40 µl stop solution to each of the wells. Positive samples turn yellow
11. Read absorbance at 450 nm

Calculations for ELISA to quantify Cry1Ac

Example

Weight of sample	= 68 mg
Buffer quantity	= 500 µl
Crush the sample thoroughly	
50 µl was pipetted into each well	

Standards

1 ppm (1 µg Cry1Ac per 1 000 µl)
0.2 ppm (200 ng Cry1Ac per 1 000 µl)
0.04 ppm (40 ng Cry1Ac per 1 000 µl)
0.008 ppm (8 ng Cry1Ac per 1 000 µl)

Standards	Cry1Ac quantity		
	1 ml (1 000 µl)	100 µl	50 µl
1 ppm	1 000 ng	100 ng	50 ng
0.2 ppm	200 ng	20 ng	10 ng
0.04 ppm	40 ng	4 ng	2 ng
0.008 ppm	8 ng	0.8 ng	0.4 ng

50 µl was pipetted into each well, hence each well contains the following amount of Cry1Ac

Results

	Standards	O.D			
	Cry1Ac ng/well				
	50	1.6			
	10	0.44			
	2	0.22			
	0.4	0.17			
	0	0.11			
Steps Samples	**Sample weight in mg**	**O.D**	**1**	**2**	**3**
			ng/well	**ng/sample**	**ng/gm**
1	68	0.67	18.1	180.7	2 657
2	72	0.12	-0.8	-8.3	0
3	54	0.98	28.7	287.2	5 319
4	48	1.12	33.5	335.3	6 986
5	77	0.88	25.3	252.9	3 284
6	82	0.76	21.2	211.6	2 581
7	59	0.65	17.4	173.8	2 946
8	49	0.11	-1.2	-11.8	0
9	55	0.74	20.5	204.7	3 723
10	62	0.82	23.2	232.2	3 746

To construct the standard curve, use INSERT – CHART – XY (SCATTER) – trendline – options to obtain regression equation. (Please see EXCEL spread sheet)

Regression equation with standard

$y = bx + a$

$y = 0.0291x + 0.1442$

y represents O.D (optical density or absorbance)

x represents amount of Cry1Ac

b represents slope

a represents constant

Step 1. Use formula to derive x = (O.D-a)/b to get ng/well

Step 2. Multiply the value of ng/well with 10 (because $1/10^{th}$ of the sample was pipetted into each well)

Step 3. Calculate ng/gm using the following formula = (ng/sample × 1 000)/weight of sample

Notes:

1 g (gram) = 1 000 mg (milligram)

1 mg (milligram) = 1 000 µg (microgram)

1 µg (microgram) = 1 000 ng (nanogram)

1 l (litre) = 1 000 ml (millilitre)

1 ml (millilitre) = 1 000 µl (microlitre)

1 µl (microlitre) = 1 000 nl (nanolitre)

ppm = parts per million (1 000 000)

1 mg in 1 litre = 1 ppm

1 mg in 1 kg = 1 ppm

1 µl in 1 litre = 1 ppm

(The Bt quant kit available with Head, Divn of Plant Protection, Central Institute for Cotton Research, PB No. 2, Shankar Nagar PO, Nagpur 440 010)

STATEMENT BY MANUFACTURERS OF ENTOMOTOXIC BACTERIA

I, _____ , aged _____ years, s/o _____ , R/o _____ _____ and _____ of M/s _____ _____ Registered Office at _____ do hereby undertake as follows:

(a) That the product _____ based on _____ , Strain _____ _____ , manufactured by M/s _____ and/or imported by M/s _____ does not contains any genetically modified organism (GMO).

(b) That I/We shall abide by the provisions contained in the International Plant Protection Convention with regard to the import of this product.

(c) That I/We shall abide by the provisions in context of International Standards for Phyto-Sanitary Measures-Code of Conduct for the import and release of exotic biological control agents of the International Plant Protection Convention (IPPC), FAO, Rome.

(d) That I/We shall provide the samples of our _____ product as and when desired by the competent authorities of Government of India for verification.

(e) That I/We further undertake that in the event of the above product having proved otherwise by any competent authority and resulting in environmental damage, I/We shall inform the Central Insecticides Board and Registration Committee, the relevant authorities for Manufacturing Licensing, Pollution Control and of appropriate District/State/National Level and shall comply with the directions/decisions from them.

(f) That my/our above undertaking is true, and no portion is false and I have concealed nothing relevant to the above matter.

Signature

Date: _____

Place: _____

Name: _____

Designation: _____

Seal of the Company: _____

IV. GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF BACULOVIRUSES – NUCLEAR POLYHEDROSIS VIRUS (NPV) & GRANULOSIS VIRUS (GV)

Since these cannot have typical pesticide formulations and have only local preparations, arising out of larval crushing, sieving and suspensions, registration process of NPVs/GVs may not be put in place. However, the undermentioned componenets of information might be useful to enable complete identity and mode of action of the particular insect pathogenic virus.

Sl. No.	Parameters	Provisional registration	Permanent registration
PRODUCT CHARACTERISTICS			
FORMULATION			
A. BIOLOGICAL CHARACTERISTICS AND CHEMISTRY			
1.	**Systematic name (Genus and species)**	R	R
1.1.	Strain name	R	R
2.	**Common name, if any**	R	R
3.	**Source of origin**	R	R
4.	**Specification of the product**	R	R
5.	**Composition of the product**	R	R
5.1.	Viral unit: POB/Capsule count pr ml/g of the product	R	R
5.2.	Percent content of the bio-control organism in the formulation and nature of biomass	R	R
5.3.	Percent of carrier/filler, wetting/dispersing agent, stabilizers/emulsifiers, containments/impurities, etc.	R	R
5.4.	Moisture content	R	R
6.	**Manufacturing process**	R	R
7.	**Test procedure and criteria used for identification by DNA test** (Restriction enzymes analysis test)	R	R
8.	**Method of analysis**		
8.1.	Viral unit: NPVs 1×10^9 POB/ml or g minimum GVs: 5×10^9 capsules/ml or g minimum (For NPV/GV, POB/Capsule Count will be taken with Haemocyto meter as detailed in Annex I)	R	R
8.2.	**Biological assays** for determining the LC_{50}/LD_{50} of the formulation Bio-assay for NPV by the Diet Surface Contamination Method Bio-assay for GV against *Chilo infuscatellus* Bio-assay for GV against *Plutella xylostella* Bio-assay for GV against *Acheae janta*	R	R
9.	**Contaminants**	R	R
9.1.	Pathogenic contaminants (*Salmonella, Shigella, Vibrio*, etc.)	R	R
9.2.	Other microbial contaminants	R	R
9.3.	Chemicals and botanical pesticide contaminants	R	R
10.	**Shelf life claim: Not less than 6 months**	R	R
10.1.	Data on storage stability as detailed in Note 2	R	R
11.	**A sample for verification (100 ml or g)**	R	R
B. BIO-EFFICACY			
12.	**Field studies: data from approved Institution**	R**	R***
13.	**Laboratory studies data on LC_{50} values for each target insect species should be generated at the approved laboratory**	R	R

Sl. No.	Parameters	Provisional registration	Permanent registration
C. TOXICITY			
14.	**For mother culture**		
14.1.	Single dose oral (rat and mouse)	R	R
14.2.	Single dose pulmonary	R	R
14.3.	Single dose intravenous	R	R
14.4.	Cell culture	R	R
14.5.	Human safety records	R	R
15.	**For formulation**		
15.1.	Data on mother culture as in 14 above	R	R
15.2.	Single dose oral (rat and mouse)	R	R
15.3.	Single dose pulmonary	R	R
15.4.	Primary skin irritation	R	R
15.5.	Primary eye irritation	R	R
15.6.	Human safety records	R	R
16.	**For formulated product to be directly manufactured** (Mammalian toxicity testing of formulations)		
16.1.	Single dose oral (rat and mouse) Toxicity/Infectivity/Pathogenicity	R	R
16.2.	Single dose pulmonary Toxicity/Infectivity/Pathogenicity (Intratracheal preferred)	R	R
16.3.	Single dose intravenous Toxicity/Infectivity/Pathogenicity	R	R
16.4.	Human safety records (Effect/lack of effects)	R	R
16.5.	Primary skin irritation	R	R
16.6.	Cell culture	R	R
17.	**Environmental safety testing: Core Information requirements** (For formulation only)		
17.1.	**Non-target vertebrates**		
	17.1.1. Mammals[a]	NR	R
	17.1.2. Birds (two species)[b]	NR	R
	17.1.3. Fresh water fish[c]	NR	R
17.2.	**Non-target invertebrates**		
	17.2.1. Terrestrial invertebrates[d]	NR	R
	17.2.2. Soil invertebrates[e]	NR	R

[a] Information on infection and pathogencity in mammals will be available from mammalian safety testing.
[b] Information on infection and pathogenicity, suggested test: single-dose, oral test. Suggested test species: pigeon and chicken.
[c] Information on infection and pathogencity. Suggested test species; *Tilapia mossambica* or other appropriate spp.
[d] Information on morality effects. It is recommended that information be obtained for honey bee and *Bombyx mori* (silk worm).
[e] Information on morality effects. It is recommended that test species include an earthworm (*Lumbricus terrestris*) or other appropriate macro invertebrates of ecological significance.

D. PROCESSING, PACKAGING AND LABELLING			
Formulation			
18.	**Manufacturing process/process of formulation**		
18.1.	Raw material	R	R
18.2.	Plant and machinery	R	R
18.3.	Unit process operation/Unit process	R	R
18.4.	Out-put (Finished product and generation of waste)	R	R

Sl. No.	Parameters	Provisional registration	Permanent registration
19.	**Packaging**		
19.1.	Classification-solid, liquid or other types of product	R	R
19.2.	Unit pack size – In metric system	R	R
19.3.	Specification – Details of primary, secondary and transport pack	R	R
19.4.	Compatibility of primary pack with the product	NR	R
20.	**Labels and leaflets** Indicating the common name, composition, antidote, storage, statements, etc.	R	R

Abbreviations: R = Required; NR = Not required

R** Two seasons/years data on bioeffectiveness from minimum two agro climatic conditions

R*** Two seasons/years data on bioeffectiveness from minimum three agro climatic conditions

Notes:

1. Applicants are required to submit an undertaking that strain is indigenous, naturally occurring, not exotic in origin, and not genetically modified as certified at 1.4.

2. Additional three months data for up to one year shelf-life claim and additional six months data for more than one year claim at two different agro climatic locations at ambient temperature along with meteorological data should be submitted.

3. Considering the fact that many small entrepreneurs are engaged in the business of cultivation of NPV/GV, the following mentioned simplification has been suggested.

   3.1. If same mother culture is used for making formulation by different entrepreneurs then the information submitted once on mother culture will be sufficient. All entrepreneurs need not to submit data.

   3.2. If same mother culture, same method and same adjutants, stabilizers, etc. are used for making formulation, then data once submitted will be sufficient for subsequent registrants.

4. The packaging material should also be ensured free from contamination from handling, storage and transportation.

STANDARDS PROPOSED BACULORIVUS SPECIFICATIONS

1. Form and composition of the product
   - 1.1. Viral Unit: POB/Capsule count pr ml/g of the product
   - 1.2. Percent content of the bio-control organism in the formulation and nature of biomass
   - 1.3. Percent of carrier/filler, wetting/dispersing agent, stabilizers/emulsifiers, containments/ impurities, etc.
   - 1.4. Moisture content

2. pH

3. Viral Unit:
   NPVs (*Helicoverpa & Spodeptera*) – 1×10^9 POB/ml or gm (minimum)
   (POB – Polyhedral Occlusion Body)
   GV (Chilo, Plutella & Acheae) – 5×10^9 Capsules/ml or g (minimum)

4. Contaminants:
   - 4.1. Biological contaminants:
     - 4.1.1. Pathogenic contaminants: Pathogenic contaminants such as gram negative bacteria *Salmonella, Shigella, Vibrio*, etc. should be **absent**.
     - 4.1.2. Other microbial contaminants: Other microbial contaminants should not exceed 1×10^4/ml or g
   - 4.2. Chemical/botanical pesticides contaminants should be **absent**.

5. Identification of Baculovirus by DNA test (Restriction enzyme analysis test)

6. Method of analysis: Viral Unit:
   NPVs (Helicoverpa and Spodeptera) = 1×10^9 POB/ml or g minimum; GVs = 5×10^9 Capsules/ml or gm minimum
   In case of NPVs/POB/Capsule count should be taken with Haemocytometer using shallow depth counting chamber as detailed in Annex I
   Biological assay for determining the LC_{50} or LD_{50} of the formulation:
   Bio-assay for NPV by the Diet Surface Contamination
   Method as detailed in Annex II OR
   Bio-assay for GV against *Chilo infuscatellus* as detailed in Annex III OR
   Bio-assay for GV against *Plutella xylostella* as detailed in Annex IV
   Bio-assay for GV against Acheae janta as detailed in Annex V
   Plating for contaminants on specified media

A statement should be submitted that the strain is indigenous, naturally occurring and not exotic and not genetically modified.

Counting of NPV/GV (POB/capsule) using improved Neubauer Haemocytometer counting chamber

A haemocytometer is used for estimating of NPVs/GVs in a unit volume of the product. The Improved Neubauer Haemocytometer comprised a thick glass slide with a shallow depression in the central section divided into two halves. Each side, the base of the depression has a fine ruled grid of squares which is visible under a microscope. The dimensions of this grid are defined. Place a standard cover slip placed over the depression and a one half halves of the slide chamber using a micro pipette. The particles require 2-5 minutes to sediment to the chamber floor.

Either dark field or a phase contrast microscope is used to identify and count polyhedral occlusion bodies (POB) or capsule. With the counting chamber under the microscope, the number of Polyhedra/capsule in a given number of grid squares can be counted. Each count consists of a tally of the number of polyhedra completely contained within a big square plus the number of touching the top and left sides. Polyhedra touching the bottom and right sides are not counted. Since both the depth of the chamber and the grid dimensions are known. It is then a straight forward calculation to determine the number of polyhedra/ capsule per ml of test suspension.

$$\text{Number of NPV (POB) per ml/gm} = \frac{D \times X}{N \times K}$$

Where:

D = Dilution factor
X = Total number of polyhedra counted
N = Number of squares counted
K = Volume above one small square in $cm^3 = (2.5 \times 10^{-7}\ cm^3)$

Area of each small square is 1/400 $mm^2 = 0.0025\ mm^2$. Depth of chamber is 0.1 mm. Volume of liquid above a single small square is $0.0025\ mm^2 \times 0.1\ mm = 0.00025\ mm^3$. To covert to cm^3 multiply by 1/1 000 to get a volume of $2.5 \times 10^{-7}\ cm^3$ above 1 small square. Hence, $K = 2.5 \times 10^{-7} cm^3$.

Example:
Suppose in a sample diluted by a factor of 1 000 we count 535 polyhedra in 160 small squares then:

D = 1 000
X = 535
N = 160
$K = 2.5 \times 10^{-7}\ cm^3$

$$\text{Thus, POB count} = \frac{1\,000 \times 535}{160 \times 2.5 \times 10^{-7}} = 1.34 \times 10^{10}\ \text{POB/ml of test sample}$$

Note:

(i) Usually, this procedure is repeated 3 times and an average taken to get a more accurate estimate.
(ii) Same procedure will be used for GV also for counting the number of capsule per unit volume of the product.

Proposed procedure for estimation of LC_{50} of NPV by the diet surface contamination method

i) Diet to be used: The standard chickpea-based diet without formaline
ii) Bio-assay bottles: 5 ml vials with a diameter of 18 mm (255 mm^2 surface area)
iii) Doses of NPV to be tested:

Helicoverpa armigera		*Spodoptera litura*	
POB/ml	POB/mm^2	POB/ml	POB/mm^2
a) 5×10^4	1.96	1×10^6	39.21
b) 1×10^4	0.39	2×10^5	7.84
c) 2×10^3	0.078	4×10^4	1.57
d) 4×10^2	0.016	8×10^3	0.31
e) 0.8×10^2	0.003	16×10^2	0.062
f) 1.6×10	0.0006	3.2×10^2	0.013

iv) Method of dosing: Dispense 10 Microlitre aliquots into each vial and spread uniformly over the entire diet surface using a polished rounded lip of 4 mm glass rod and allow to dry off under flow laminar hood for 10 minutes.

v) No. of larvae/dose: 50 (Maintain 50 healthy larvae without virus inoculation for control)

vi) Stages of larvae: II instar larvae (Preferably 4 days old)

Release one larva/vial and plug mouth with sterile absorbent cotton.

Incubate at 25 ± 1 ºC for 7 days.

vii) Record mortality in different doses on the 7th day.

viii) Apply Abott's formula for correction of mortality in control treatment.

ix) Subject the dose – mortality response to probit analysis using relevant statistical soft ware.

x) Express LC_{50} as POB/mm^2 of diet surface.

Expected standards for NPV for II instar larvae	
Species	LC_{50} POB//mm^2
1. *Heliocoverpa armigera*	<0.5
2. *Spodoptera litura*	<20.0

Proposed bio-assay for GV against *Chilo infuscatellus*

Determination of LD_{50}:

To determine the LD_{50} of the GVs, third instar larvae should be used. The larvae are to be microfed (one micro litre per larva) with six different doses, namely 1.1×10^1, 10^2, 10^3, 10^4, 10^5, and 10^6 IBs/larva. One hundred freshly moulted larvae have to be used for each treatment. Larvae fed with equal quantity of distilled water serve as control. The mortality has to be recorded daily. The LD_{50} of the virus is determined following the probit analysis method (Finney, 1962).

$LD_{50} = <1 \times 10^3$ OB for third instar larvae by micro-feeding.

Proposed laboratory bio-assay procedures for estimation of LC_{50} of *Plutella xylostella* (P × GV) by leaf disc method:

1. Cut leaf discs of cauliflower (3.2 cm). Soak it in 0.1 NaOCI for 5 min and wash thoroughly in distilled water. Air dry these leaf discs for 2-3 minutes. (Fifth leaf from top to be used)
2. P × GV (containing 0.01 percent Triton × 100) of different concentrations 28 000, 2 800, 280, 28, 2.8 OB/mm^2 on the leaf disc) is prepared
3. Aliquots of 12 ul of each concentrating of GV is dispensed on the upper surface of the leaf disc and spread uniformly with a blunt end glass rod (use separate tips and glass rods for each treatment)
4. Air dry these leaf discs for 2-3 minutes
5. Repeat the same on the lower surface of the leaf disc
6. Control discs were treated with distilled water containing 0.01 percent Triton × 100 only
7. The leaf discs are placed in Petri dishes lined with wet filter paper discs and 35-second instar larvae of *P. xylostella* (starved for 6 hours) are released on each leaf disc starting from control treatment to highest concentration. This is replicated three times
8. Incubate these larvae at 25 ºC
9. After 24 hours remove the treated leaves (partially eaten) and provide the larvae with fresh cauliflower leaves

10. The leaves are changed daily and mortality data recorded every day
11. The dosage and time mortality responses are subjected to probit analysis
12. If the mortality in the control excess 10 percent repeat the experiment

LC_{50} = < 0.15 OB/mm^2 for second instar larvae by disc method.

Proposed laboratory bio-assay procedures for estimation of LC_{50} of *Achaea janata* Granulosis virus (AjGV) by leaf disc method:

1. Cut leaf discs of castor (8 cm dia) and wash in distilled water. Air dry these leaf discs for 5 minutes
2. Treat the leaf disc on both the upper and lower surfaces with 200 µl suspension of AjGV (containing 0.02% Tween-80) of different concentrations (5×10^8, 5×10^7, 5×10^6, 5×10^5, 5×10^4 corresponding to 19 884, 1 988, 198, 19, 1.9 OB per mm^2 on the leaf disc)
3. Aliquots of 100 µl of each concentration of GV is first dispensed on the upper surface of the leaf disc and spread uniformly with a blunt end of glass rod (use separate tips and glass rods for each treatment)
4. Air dry these leaf discs for 5 minutes
5. Repeat the same on the lower surface of leaf disc
6. Control leaf discs were treated with distilled water containing 0.02% Tween-80 only
7. The leaf discs are placed in Petri dishes (9.0 cm diameter) line on wet filter paper discs and 35 second instar larvae (third day after hatching) of *A. janata* are released on each leaf disc starting from control treatment to highest concentration. This is replicated three times
8. Incubate these larvae at 25 ºC
9. After 24-48 hours remove the treated leaves (partially eaten) and provide the larvae with fresh castor leaves
10. The leaves are change daily and mortality data recorded every day
11. The dosage and time mortality responses are subjected to probit analysis
12. If the mortality in the control exceeds 10 percent repeat the experiment

Recommended LC_{50} GV (*Achaea janata) – LC_{50}* <4 OB/mm^2 for second instar larvae by the leaf disc method.

PROPOSED GUIDELINES FOR MINIMUM INFRASTRUCTURE FACILITIES TO BE CREATED BY THE MANUFACTURERS OF BACULOVIRUSES (NPV, GV)

MANPOWER REQUIREMENT	
1.	Quality Control Biologist
2.	Sufficient personnel to supervise production, maintenance, stores, etc.
GENERAL REQUIREMENT	
1.	Post culture production room with temperature and humidity control
2.	Moth ovi-position room with temperature and humidity control
3.	Production room with temperature and humidity control
4.	Diet preparation room
5.	Virus processing lab.
6.	Quality control lab.
7.	Formulation unit
8.	Cold storage
9.	Washing and sterilization facility
10.	Stores room
11.	Protective clothing
12.	Respiratory devices
13.	First aid measures
14.	Waste disposal arrangement in compliance with Pollution Control norms
EQUIPMENT/INSTRUMENT REQUIREMENT	
1.	Diet preparation machine (mixer)
2.	Diet dispenser
3.	Multi channel pipette
4.	Vacuum pump with an aspirator
5.	Blenders
6.	Multipurpose centrifuges
7.	B.O.D. incubator or an incubator room or an environmental chamber
8.	Scale balance
9.	Digital balance
10.	Haemocytometer shallow depth counting chamber
11.	Hot air oven
12.	Compound research microscope
13.	Zoom microscope
14.	Vortex mixers
15.	Tally counters
16.	Electric stove
17.	Autoclave
18.	Shaker
19.	Water distillation unit
20.	Air conditioners
21.	Humidifiers
22.	Oviposition iron cage
23.	Washing machine
24.	Racks and cabinet
25.	Refrigerators

Note: These are the general requirements of minimum infrastructure to be created by the manufacturers. However, for specific baculovirus formulation(s) and their quantum of production, requirement of manpower, space, equipment/instrument may be needed.

STATEMENT BY MANUFACTURERS OF NPV/GV PESTICIDES

I, _____ , aged _____ years, s/o _____ , R/o _____ _____ and _____ of M/s _____ _____ Registered Office at _____ do hereby undertake as follows:

(a) That the product _____ based on _____ , Strain _____ _____ , manufactured by M/s _____ and/or imported by M/s _____ does not contains any genetically modified organism (GMO).

(b) That I/We shall abide by the provisions contained in the International Plant Protection Convention with regard to the import of this product.

(c) That I/We shall abide by the provisions in context of International Standards for Phyto-Sanitary Measures-Code of Conduct for the import and release of exotic biological control agents of the International Plant Protection Convention (IPPC), FAO, Rome.

(d) That I/We shall provide the samples of our _____ product as and when desired by the competent authorities of Government of India for verification.

(e) That I/We further undertake that in the event of the above product having proved otherwise by any competent authority and resulting in environmental damage, I/We shall inform the Central Insecticides Board and Registration Committee, the relevant authorities for Manufacturing Licensing, Pollution Control and of appropriate District/State/National Level and shall comply with the directions/decisions from them.

(f) That my/our above undertaking is true, and no portion is false and I have concealed nothing relevant to the above matter.

Signature

Date: _____

Place: _____

Name: _____

Designation: _____

Seal of the Company: _____

V. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ENTOMOPATHOGENIC FUNGI

STANDARD FOR FORMULATIONS:

1. Colony Forming Unit (CFU) count on selective medium should be minimum of 1×10^8 per ml or g for Entomopathogenic fungi.

2. Contaminants:
   - 2.1. Biological contaminants
   - 2.2. Pathogenic contaminants such as gram negative bacteria *Salmonella*, *Shigella,* Vibrio and such other microbials should not be present
   - 2.3. Other microbial contaminants should not exceed 1×10^4 count per ml or per g of formulation.
   - 2.4. Chemical/botanical pesticide contaminants should not be present
   - 2.5. Stability of CFU counts at 30 ºC and 65% RH

REGISTRATION REQUIREMENTS

Sl. No.	Requirements	Provisional registration	Regular registration
A. BIOLOGICAL CHARACTERISTICS AND CHEMISTRY			
1.	**Systematic name (Genus, species and strain)**	R	R
2.	**Common name, if any**	R	R
3.	**Source of origin**	R	R
4.	**Natural occurrence of the organism and morphological description**	R	R
5.	**Composition of the product**	R	R
5.1.	CFU/g of the product	R	R
5.2.	Percent content of the biocontrol organism in the formulation & nature of biomass	R	R
5.3.	Percentage of carrier/filler, wetting/dispending agent, stabilizers/emulsifiers, contaminants/impurities, etc.	R	R
5.4.	Moisture content	R	R
6.	**Specification of the product as per Annex I**	R	R
7.	**Manufacturing process including type of fermentation and biological end products: The microbial cultures are multiplied by liquid solid fermentation. Information pertaining to use of entire mycelia mats with spores separated must be provided in terms of biomass.**	R	R
8.	**Test method**		
8.1.	Pathogencity test on insect	R	R
8.2.	Bio-assay procedure for *Plutella xylostella* as detailed in **Annex II**	R	R
9.	**Qualitative analysis**	R	R
9.1.	CFU on selective medium	R	R
9.2.	**Contaminants**		
	9.2.1. Pathogenic contaminants such as *Salmonella, Shigella, Vibrio* and such other microbials	R	R
	9.2.2. Other microbial contaminants	R	R
	9.2.3. Chemical and botanical pesticide contaminants	R	R
9.3.	Shelf life claims (Not less than 6 months)	R	R
	9.3.1. Data on storage stability as per shelf life claims as detailed in **Note 2**	R	R
10.	**A sample for verification (100 g)**	R	R

Sl. No.	Requirements	Provisional registration	Regular registration
B. BIO-EFFICACY			
11.	**Field tests**		
11.1.	Data on bioeffectiveness from approved Institution	R**	R***
11.2.	Data on non-target organism: One season/one year on effect on product against natural parasites/predators	R	R
12.	**Laboratory tests** The product should be tested at approved laboratory	R	R
C. TOXICITY			
13.	**For mother culture**		
13.1.	Single dose oral (rat and mouse)	R	R
13.2.	Single dose pulmonary	R	R
13.3.	Single dose dermal	R	R
13.4.	Single dose intra-peritoneal	R	R
13.5.	Human safety records	R	R
14.	**For formulation**		
14.1.	Data on mother culture as in (13) above	R	R
14.2.	Single dose oral (rat and mouse)	R	R
14.3.	Single dose pulmonary	R	R
14.4.	Primary skin irritation	R	R
14.5.	Primary eye irritation	R	R
14.6.	Human safety records	R	R
15.	**For formulated product to be directly manufactured** (Mammalian toxicity testing of formulations)		
15.1.	Single dose oral (rat and mouse) Toxicity/Infectivity/Pathogenicity	R	R
15.2.	Single dose pulmonary Toxicity/Infectivity/Pathogenicity (Intratracheal preferred)	R	R
15.3.	Single dose dermal Infectivity	R	R
15.4.	Single dose intraperitoneal (Infectivity)	R	R
15.5.	Primary skin irritation	R	R
15.6.	Primary eye irritation	R	R
15.7.	Human safety records (Effect/Lack of effects)	R	R
16.	**Environmental safety testing: Core Information requirements** (For formulation only)		
16.1.	**Non-target vertebrates**	NR	R
	16.1.1. Mammals[a]	NR	R
	16.1.2. Birds (two species)[b]	NR	R
	16.1.3. Fresh water fish[c]		
16.2.	**Non-target invertebrates**		
	16.2.1. Soil invertebrates[d]	NR	R

[a] Information on infection and pathogenicity in mammals will be available from mammalian safety testing.
[b] Information on infection and pathogenicity: suggested test: single-dose, oral test. Suggested test species: pigeon and chicken.
[c] Information on infection and pathogenicity: suggested test species: *Tilapia mossambica* or other appropriate spp.
[d] Information on morality effects. It is recommended that test species include an earthworm (*Lumbricus terrestris*) or other appropriate macro invertebrates of ecological significance.

Sl. No.	Requirements	Provisional registration	Regular registration
D. PACKAGING AND LABELLING			
Formulation			
17.	**Manufacturing process/process of formulation**		
17.1.	Raw material	R	R
17.2.	Plant and Machinery	R	R
17.3.	Unit Process operation/Unit process	R	R
17.4.	Out-put (Finished product and generation of waste)	R	R
18.	**Packaging**		
18.1.	Classification-solid, liquid or other types of product	R	R
18.2.	Unit pack size – In metric system	R	R
18.3.	Specification – Details of primary, secondary and transport pack	R	R
18.4.	Compatibility of primary pack with the product (Glass bottles are not recommended)	NR	R
19.	**Labels and leaflets** Indicating the common name, composition, antidote/storage, statements, etc.	R	R

Abbreviations: R = Required; NR = Not required

R** Two seasons/years data on bioeffectiveness from minimum two agro-climatic conditions

R*** Two seasons/years data on bioeffectiveness from minimum three agro climatic conditions

Notes:

1. Applicants are required to submit an undertaking that strain is indigenous, naturally occurring, not exotic in origin, and not genetically modified as per Annex 1.1.

2. Additional two months data for six months claim/three months additional data for one year shelf-life claim at two different agro climatic locations at ambient temperature along with meteorological data should be submitted.

3. Considering the fact that many small entrepreneurs are engaged in the business of cultivation of entomopathogenic fungi the following simplification has been considered.

   3.1. If same microbial strain is used for making formulation by different entrepreneurs that the information submitted once on the said strain will be sufficient. All entrepreneurs need not submit relevant data.

   3.2. If same microbial strain, same method and same adjutants, stabilizers, etc. are used for making the given formulation, data once submitted for validitating these claims will be sufficient for subsequent registrants, as substantiated by the relevant supportive documents.

4. The packaging material should also be ensured to be free from contamination from handling, storage and transportation and is as per prescribed standards, as the case may be.

STANDARDS FOR ENTOMOPATHOGENIC FUNGI SPECIFICATIONS

1. Form and appearance

2. pH

3. Composition
   - 3.1. CFU/g of the product
   - 3.2. Percent content of the biocontrol organism in the formulation and nature of biomass
   - 3.3. Percentage of carrier/filler, wetting/dispending agent, stabilizers/emulsifiers, contaminants/ impurities, etc.
   - 3.4. Moisture content

4. CFU counts: Minimum 1×10^8 CFU/ml or g (Stability at 30 ºC and 65% RH)

5. Contaminants:
   - 5.1. Biological Contaminants:
     - 5.1.1. Pathogenic Contaminants: such as gram negative bacteria Salmonella, Shigella, *Vibrio,* etc.: absent.
     - 5.1.2. Other contaminants should not exceed 1×10^4/ml or g
   - 5.2. Chemical/botanical pesticides contaminants: absent.

6. Method of analysis:
   - 6.1. CFU counts by serial dilution and examination under regular compound research microscope with bright field optics
   - 6.2. Plating for contaminants on specific media
   - 6.3. Entomopathogenic capability on target insects by bio-assay

7. A statement should be submitted that strain is indigenous, naturally occurring, not exotic in origin and not genetically modified (example given below)

Proposed laboratory bio-assay procedures for screening fungal pathogens on *Spodoptera litura* and *Helicoverpa armigera*

Insect pathogens:

Beauveria bassiana, Metarhizium anisopliae, Nomuraea rileyi

Preparation of fungal inoculum for bioassays:

The fungus is grown on SDAY/SMAY medium for 10 days in slants and aqueous spore suspensions of various concentrations are prepared using sterile water. The spore count is estimated by Haemocytometer. (10^4 – 10^{10} spores/ml). Tween-80 is added @ 0.01% to get uniform spore suspension.

Rearing insects:

H. armigera, S. litura – Artificial diet (Semi-synthetic diet)

Stage of insect for bio-assay

H. armigera, S. litura – II instar larvae to be used for bio-assay protocols for lepidopteron pests

Method of inoculation

S. litura

1. Cut castor leaf discs of 3.0 cm diameter, rinse in sterile distilled water and place each leaf disc in a sterile Petri plate and allow it air dry in a laminar flow system
2. Apply ten micro liters of the spore suspension of each concentration on the leaf disc and spread it uniformly on the leaf surface and allow it air dry in a laminar flow system. Treat the other side of the disc similarly.
3. Release ten numbers of second instar larvae of *S. litura* on the leaf surface and incubate the discs in an incubator at 25 ºC and 90% RH
4. After 24 hours, shift the larvae to the polypots containing the semi-synthetic diet and incubate in an incubator at 25 ºC and 90% RH
5. After 5 days of incubation, mortality of the larvae are recorded in each concentration tested
6. Lc-50 can be calculated using SPSS package

   Standard for $LC-_{50:}$ Not more than 2.00×10^6 spores/ml (3.0×10^3 spores/mm^2)

H. amigera:

Instead of castor leaves, soybean leaves can be used for *H. amigera* and the procedure is same as above.

Standard for $LC_{50:}$ Not more than 4.00×10^6 spores/ml (6.0×10^3 spores/mm^2)

Proposed bio-assay procedure for *Plutella xylostella*

Various concentrations of *Beauveria bassiana* formulation ranging from 6×10^8 to 2×10^{10} are to be screened to assess the mortality.

Fresh undamaged radish leaves free from pesticide application are to be collected and washed thoroughly in sterile distilled water and air-dried. Individual leaves are dipped in respective concentrations for 30 seconds. After complete drying of leaves ten late 2^{nd} instar larvae of *Plutella xylostella* are released per treatment. A water dipped radish leaf is maintained simultaneously as control.

To prevent desiccation of leaves, the petiole is covered with a moist cotton swab. Each treated leaves are placed in a plastic container of dimension 12.5 × 10 cm containing moist filter paper, Whatman No. 41 to provide humidity.

Each treatment has to be replicated thrice. Fresh radish leaves were provided as feed at 24 hours interval. This set up has to be maintained at 25 + 1 ºC and 70-80% RH for 7 days. Observations on larval mortality are to be made at 3, 5 and 7 days after treatment.

Standard for LC_{50} = Not more than 3×10^9 CFU/g

STATEMENT BY MANUFACTURERS OF ENTOMOPATHOGENIC FUNGI

I, _____ , aged _____ years, s/o _____ , R/o _____ _____ and _____ of M/s _____ _____ Registered Office at _____ do hereby undertake as follows:

(a) That the product _____ based on _____ , Strain _____ _____ , manufactured by M/s _____ and/or imported by M/s _____ does not contains any genetically modified organism (GMO).

(b) That I/We shall abide by the provisions contained in the International Plant Protection Convention with regard to the import of this product.

(c) That I/We shall abide by the provisions in context of International Standards for Phyto-Sanitary Measures-Code of Conduct for the import and release of exotic biological control agents of the International Plant Protection Convention (IPPC), FAO, Rome.

(d) That I/We shall provide the samples of our _____ product as and when desired by the competent authorities of Government of India for verification.

(e) That I/We further undertake that in the event of the above product having proved otherwise by any competent authority and resulting in environmental damage, I/We shall inform the Central Insecticides Board and Registration Committee, the relevant authorities for Manufacturing Licensing, Pollution Control and of appropriate District/State/National Level and shall comply with the directions/decisions from them.

(f) That my/our above undertaking is true, and no portion is false and I have concealed nothing relevant to the above matter.

Signature

Date: _____

Place: _____

Name: _____

Designation: _____

Seal of the Company: _____

VI. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC FUNGI

STANDARD FOR FORMULATIONS:

1. Colony Forming Unit (CFU) count on selective medium should be minimum of 2×10^6 per ml or g for *Trichoderma* spp.

2. Contaminants:
   - 2.1. Biological contaminants:
     - 2.1.1. Pathogenic contaminants such as gram negative bacteria Salmonella, Shigella, Vibrio and such other microbials should not be present.
     - 2.1.2. Other microbial contaminants should not exceed 1×10^4 count per ml or per g of formulation.
   - 2.2. Chemical/botanical pesticide contaminants should not be present.

3. Stability of CFU counts at 30 ºC and 65% RH

REGISTRATION REQUIREMENTS:

Sl. No.	Requirements	Provisional registration	Regular registration
A. BIOLOGICAL CHARACTERISTICS AND CHEMISTRY			
1.	**Systematic name (Genus and species)**	R	R
1.1	Strain name	R	R
2.	**Common name, if any**	R	R
3.	**Source of origin**	R	R
4.	**Habitat and morphological description**	R	R
5.	**Composition of the product**	R	R
5.1.	CFU/g of the product	R	R
5.2.	Percent content of the biocontrol organism in the formulation & nature of biomass	R	R
5.3.	Percentage of carrier/filler, wetting/dispending agent, stabilizers/emulsifiers, contaminants/impurities, etc.	R	R
5.4.	Moisture content		
9.	**Qualitative analysis**	R	R
9.1	CFU on selective medium	R	R
9.2.	**Contaminants**		
	9.2.1. Pathogenic contaminants such as *Salmonella, Shigella,* Vibrio and such other microbials	R	R
	9.2.2. Other microbial contaminants	R	R
	9.2.3. Chemical and botanical pesticide contaminants	R	R
9.3.	Moisture content	R	R
9.4.	Shelf life claims: Not less than 6 months	R	R
	9.4.1. Data on storage stability as per shelf life claims as detailed in **Note 2**	R	R
10.	**A sample for verification (100 g)**	R	R
B. BIO-EFFICACY			
11.	**Field studies** Data from approved Institution	R**	*R***

Sl. No.	Requirements	Provisional registration	Regular registration
12.	**Laboratory studies** The product should be tested at approved laboratory	R	R
C. TOXICITY			
13.	**For mother culture**		
13.1.	Single dose oral (rat and mouse)	R	R
13.2.	Single dose pulmonary	R	R
13.3.	Single dose dermal	R	R
13.4.	Single dose intraperitoneal	R	R
13.5.	Human safety records	R	R
14.	**For formulation**		
14.1.	Data on mother culture as in (13) above	R	R
14.2.	Single dose oral (rat and mouse)	R	R
14.3.	Single dose pulmonary	R	R
14.4.	Primary skin irritation	R	R
14.5.	Primary eye irritation	R	R
14.6.	Human safety records	R	R
15.	**For formulated product to be directly manufactured** (Mammalian toxicity testing of formulations)		
15.1.	Single dose oral (rat and mouse) Toxicity/Infectivity/Pathogenicity	R	R
15.2.	Single dose pulmonary Toxicity/Infectivity/Pathogenicity (Intratracheal preferred)	R	R
15.3.	Single dose dermal Infectivity	R	R
15.4.	Single dose intraperitoneal (Infectivity)	R	R
15.5.	Primary skin irritation	R	R
15.6.	Primary eye irritation	R	R
15.7.	Human safety records (Effect/Lack of effects)	R	R
16.	**Environmental safety testing: Core Information requirements** (For formulation only)		
16.1.	**Non-target vertebrates**	NR	R
	16.1.1. Mammals[a]	NR	R
	16.1.2. Birds (two species)[b]	NR	R
	16.1.3. Fresh water fish[c]	NR	R
16.2.	**Non-target invertebrates**		
	16.2.1. Soil invertebrates[d]	NR	R

[a] Information on infection and pathogencity in mammals will be available from mammalian safety testing.
[b] Information on infection and pathogenicity: suggested test: single-dose, oral test. Suggested test species: pigeon and chicken.
[c] Information on infection and pathogenicity: suggested test species: *Tilapia mossambica* or other appropriate spp.
[d] Information on morality effects. It is recommended that test species include an earthworm (*Lumbricus terrestris*) or other appropriate macro invertebrates of ecological significance.

D. PACKAGING AND LABELLING			
Formulation			
17.	**Manufacturing process/process of formulation**		
17.1.	Raw material	R	R
17.2.	Plant and Machinery	R	R
17.3.	Unit Process operation/Unit process	R	R

Sl. No.	Requirements	Provisional registration	Regular registration
17.4.	Out-put (Finished product and generation of waste)	R	R
18.	**Packaging**		
18.1.	Classification-solid, liquid or other types of product	R	R
18.2.	Unit pack size – In metric system	R	R
18.3.	Specification – Details of primary, secondary and transport pack	R	R
18.4.	Compatibility of primary pack with the product (Glass bottles are not recommended)	NR	R
19.	**Labels and leaflets** Indicating the common name, composition, antidote, storage, statements, etc.	R	R

Abbreviations: R = Required; NR = Not required

R** Two seasons/years data on bioeffectiveness from minimum two agro-climatic conditions

R*** Two seasons/years data on bioeffectiveness from minimum three agro climatic conditions

Notes:

1. Applicants are required to submit an undertaking that strain is indigenous, naturally occurring, not exotic in origin, and not genetically modified as per Annex 1.

2. Additional two months data for six months shelf-life claim, three months additional data for one year shelf-life claim at two different agro climatic locations at ambient temperature along with meteorological data should be submitted.

3. Considering the fact that many small entrepreneurs are engaged in the business of cultivation of antagonistic fungi the following simplification has been considered.

   3.1. If same microbial strain is used for making formulation by different entrepreneurs that the information submitted once on the said strain will be sufficient. All entrepreneurs need not submit relevant data.

   3.2. If same microbial strain, same method and same adjutants, stabilizers, etc. are used for making the given formulation, data once submitted for validitating these claims will be sufficient for subsequent registrants, as substantiated by the relevant supportive documents.

4. The packaging material should also be ensured to be free from contamination from handling, storage and transportation and is as per prescribed standards, as the case may be.

STANDARDS FOR ANTAGONISTIC FUNGI SPECIFICATIONS

1. Form and appearance

2. pH

3. CFU counts: Trichoderma 2 × 106 CFU/ml or gm. (Stability at 30 ºC and 65% RH)

4. Percent content of the Biocontrol organism in the formulation & nature of biomass

5. Percentage of carrier/filler, wetting/dispending agent, stabilizers/emulsifiers, contaminants/ impurities, etc.

6. Moisture content

7. Contaminants:
   - 7.1 Biological Contaminants:
     - 7.1.1. Pathogenic Contaminants: such as gram negative bacteria *Salmonella, Shigella, Vibrio,* etc.: **absent**.
     - 7.1.2. Other contaminants should not exceed 1×10^4/ml or g
   - 7.2 Chemical/botanical pesticides contaminants: **absent**.

8. Method of analysis:
   - 8.1. CFU counts by serial dilution and examination under regular compound research microscope with bright field optics.
   - 8.2. Plating for contaminants on specific media.
   - 8.3. Antagonistic mycolytic capability on target organism by bio-assay on plants (Laboratory test).
   - 8.4. Bio-assay procedure based on diseased severity and root colonization as detailed below.

9. A statement should be submitted that strain is indigenous, naturally occurring, not exotic in origin and not genetically modified (example given below).

Proposed bio-assay for plant disease antagonists based on disease severity and root colonization

The target pathogen to be tested against has to be grown in Sand maize medium. The Sand-maize medium is prepared by adding sand 90 g, maize 10 g and water 10 ml in a saline or any glass bottle of 300 ml capacity and then autoclaved twice. Then 5 mycelial discs of the test pathogen are transferred into the bottle and left for incubation for 15 days. Once the culture has grown well, the sand maize medium is mixed along with the fungal growth and 1 g from this preparation is used as the inoculum after adjusting the CFU to 1 × 10/g by addition of sand. The plastic cups (5-6 cm diameter) filled with soil and FYM (3:1) have to be used. In each cup the filling should be done upto $^3/_4$th level. The pathogen inoculum is mixed with sand has to be applied upto 2 cm depth in the plastic cups.

The bio-efficacy of the bioagent shall be tested by both seed treatment and soil application. For seed treatment, the recommended dose of the formulation has to be used (5 to 10 g). For soil application, the bioagent is added at the rate of 1 g of formulation (minimum CFU should be the 2×10^6). The germination percentage, disease intensity and seedling vigour are to be recorded.

Another set of plastic cups filled with sterile soil and sterile FYM has to be used to confirm whether the bio-efficacy was due to the isolate of the bioagent tested or due to the native isolates of the bioagent present in the soil.

The keys for grading the efficacy mentioned below shall be used. However, for the registration purpose, the bioagents that are Highly Efficient, Efficient or Moderately Efficient in the plastic cup test under glass house condition (in the presence of pathogen) can be allowed (i.e.) germination percentage of 70 percent or above, disease incidence of 30 percent or less can be considered for registration.

Disease grading key

Disease incidence (%)	Description	Rating of bio-efficacy of bioagents
0	Germination >90%, no seed rotting, seedling healthy, root and shoot portions well developed	Highly Efficient (HE)
1-15	Germination 80-90%, infection on main as well as lateral roots, seedlings are well developed	Efficient (E)
16-30	Germination 70-80%, development of roots restricted and growth is less compared to Score 1. Infection occurred on roots. Shoot portions developed but growth retarded compared to Score 1	Moderately Efficient (ME)
31-45	Germination 60-70%, length of roots and shoots short compared to Score 1. Germination of seeds inhibited. 50% of root area infected. Shoot portions also showed infection	Moderately Inefficient (MI)
46-60	Seed germination 50-60%. Development of roots and shoots greatly retarded. Shoot portions also showed infection	Efficient (E)
Above 60	Less than 50% germination and seed rotting	Highly Inefficient (HI)

For the root colonization assay, the rhizosphere region of the plants tested above have to be collected and the soil adhering to the root surface has to be removed by gently tapping the roots. The root bits have to be cut into 1 cm bits and randomly 25 bits should be selected for each treatment. They have to be plated on (TSM) and the percentage of root bits colonized has to be recorded. This has to be performed in the sterile soil and non sterile soil. One control treatment without the Biocontrol agent, being tested, should be kept for both the sterile and non-sterile soil to rule out of the possibility of interference of native micro flora in the bio-efficacy assay.

STATEMENT BY MANUFACTURERS OF ANTAGONIST PESTICIDES

I, _____ , aged _____ years, s/o _____ , R/o _____ _____ and _____ of M/s _____ _____ Registered Office at _____ do hereby undertake as follows:

(a) That the product _____ based on _____ , Strain _____ _____ , manufactured by M/s _____ and/or imported by M/s _____ does not contains any genetically modified organism (GMO).

(b) That I/We shall abide by the provisions contained in the International Plant Protection Convention with regard to the import of this product.

(c) That I/We shall abide by the provisions in context of International Standards for Phyto-Sanitary Measures-Code of Conduct for the import and release of exotic biological control agents of the International Plant Protection Convention (IPPC), FAO, Rome.

(d) That I/We shall provide the samples of our _____ product as and when desired by the competent authorities of Government of India for verification.

(e) That I/We further undertake that in the event of the above product having proved otherwise by any competent authority and resulting in environmental damage, I/We shall inform the Central Insecticides Board and Registration Committee, the relevant authorities for Manufacturing Licensing, Pollution Control and of appropriate District/State/National Level and shall comply with the directions/decisions from them.

(f) That my/our above undertaking is true, and no portion is false and I have concealed nothing relevant to the above matter.

Signature

Date: _____

Place: _____

Name: _____

Designation: _____

Seal of the Company: _____

VII. PROPOSED GUIDELINES/DATA REQUIREMENTS FOR REGISTRATION OF ANTAGONISTIC BACTERIA

STANDARD FOR FORMULATIONS**:**

1. Colony Forming Unit (CFU) count on selective medium should be minimum of 1×10^8 per ml or g for Entomopathogenic bacteria.

2. Contaminants:
   - 2.1. Biological contaminants:
     - 2.1.1. Pathogenic contaminants such as gram negative bacteria *Salmonella*, Shigella, Vibrio and such other microbials should not be present.
     - 2.1.2. Other microbial contaminants should not exceed 1×10^4 count per ml or per g of formulation.
   - 2.2. Chemical/botanical pesticide contaminants should not be present.

3. Stability of CFU counts at 30 ºC and 65% RH

REGISTRATION REQUIREMENTS:

Sl. No.	Requirements	Provisional registration	Regular registration
A. BIOLOGICAL CHARACTERISTICS AND CHEMISTRY			
1.	**Systematic name (genus, species and strain)**	R	R
2	**Common name, if any**	R	R
3.	**Source of origin as per Annex 1.1**	R	R
4.	**Natural occurrence of the organism and morphological description**	R	R
5.	**Composition of the product**	R	R
5.1.	Percent content of the biocontrol organism in the formulation & nature of biomass	R	R
5.2.	CFU/g or ml of the product	R	R
5.3.	Percentage of other components: carrier/filler, wetting/dispersing agent, stabilizers/emulsifiers, contaminants/impurities, etc.	R	R
5.4.	Moisture content	R	R
6.	**Specification of the product as per Annex I**	R	R
7.	**Manufacturing process including type of fermentation and biological end products: The microbial cultures are multiplied by liquid solid fermentation. Information pertaining to use of entire mats with spores separated must be provided in terms of biomass.**	R	R
8.	**Test method**		
8.1.	Dual culture for antagonistic bacteria to attain at least 35% reduction in target organism	R	R
8.2.	Bio-assay: based on disease severity and root colonization	R	R
9.	**Qualitative analysis**	R	R
9.1.	CFU on selective medium	R	R
9.2.	Contaminants		
	9.2.1. Pathogenic contaminants such as *Salmonella, Shigella,* Vibrio and such other microbials	R	R
	9.2.2. Other microbial contaminants	R	R
	9.2.3. Chemical and botanical pesticide contaminants	R	R

Sl. No.	Requirements	Provisional registration	Regular registration
9.3.	Shelf life claims (Not less than 6 months)	R	R
	9.3.1. Data on storage stability as per shelf life claims as detailed in **Note 2**	R	R
10.	**A sample for verification (100 g)**	R	R
B. BIO-EFFICACY			
11.	**Field tests**		
11.1.	Data from approved Institution	R**	R***
11.2.	Data on non-target organism: One season/one year on effect on product against natural parasites/predators	R	R
12.	**Laboratory tests** The product should be tested at approved laboratory	R	R
C. TOXICITY			
13.	**For mother culture**		
13.1.	Single dose oral (rat and mouse)	R	R
13.2.	Single dose pulmonary	R	R
13.3.	Single dose Dermal	R	R
13.4.	Single dose intra-peritoneal	R	R
13.5.	Human safety records	R	R
14.	**For formulation**		
14.1.	Data on mother culture as in (13) above	R	R
14.2.	Single dose oral (rat and mouse)	R	R
14.3.	Single dose pulmonary	R	R
14.4.	Primary skin irritation	R	R
14.5.	Primary eye irritation	R	R
14.6.	Human safety records	R	R
15.	**For formulated product to be directly manufactured** (Mammalian toxicity testing of formulations)		
15.1.	Single dose oral (rat and mouse) Toxicity/Infectivity/Pathogenicity	R	R
15.2.	Single dose pulmonary Toxicity/Infectivity/Pathogenicity (Intratracheal preferred)	R	R
15.3.	Single dose dermal Infectivity	R	R
15.4.	Single dose intra-peritoneal (Infectivity)	R	R
15.5.	Primary skin irritation	R	R
15.6.	Primary eye irritation	R	R
15.7.	Human safety records (Effect/Lack of effects)	R	R
16.	**Environmental safety testing: Core Information requirements** (For formulation only)		
16.1.	**Non-target vertebrates**		
	16.1.1. Mammals[a]	NR	R
	16.1.2. Birds (two species)[b]	NR	R
	16.1.3. Fresh water fish[c]	NR	R
16.2.	**Non-target invertebrates**		
	16.2.1. Soil invertebrates[d]	NR	R

[a] Information on infection and pathogenicity in mammals will be available from mammalian safety testing.
[b] Information on infection and pathogenicity: suggested test: single-dose, oral test. Suggested test species: pigeon and chicken.

Sl. No.	Requirements	Provisional registration	Regular registration
[c] Information on infection and pathogenicity: suggested test species: *Tilapia mossambica* or other appropriate spp. [d] Information on morality effects. It is recommended that test species include an earthworm (Lumbricus terrestris) or other appropriate macro invertebrates of ecological significance.			
D. PACKAGING AND LABELLING			
17.	**Manufacturing process/process of formulation**		
17.1.	Raw material	R	R
17.2.	Plant and machinery	R	R
17.3.	Unit Process operation/Unit process	R	R
17.4.	Out-put (Finished product and generation of waste)	R	R
18.	**Packaging**		
18.1.	Classification-solid, liquid or other types of product	R	R
18.2.	Unit pack size – In metric system	R	R
18.3.	Specification – Details of primary, secondary and transport pack	R	R
18.4.	Compatibility of primary pack with the product (Glass bottles are not recommended)	NR	R
19.	**Labels and leaflets** Indicating the common name, composition, antidote, storage, statements, etc.	R	R

Abbreviations: R = Required; NR = Not required

R** Two seasons/years data on bioeffectiveness from minimum two agro-climatic conditions

R*** Two seasons/years data on bioeffectiveness from minimum three agro-climatic conditions

Notes:

1. Applicants are required to submit an undertaking that strain is indigenous, naturally occurring, not exotic in origin, and not genetically modified as per Annex 1.1.

2. Additional two months data for six months shelf-life claim/three months data for one year shelf-life claim at two different agro climatic locations at ambient temperature along with meteorological data should be submitted.

3. Considering the fact that many small entrepreneurs are engaged in the business of cultivation of antagonistic bacteria the following simplification has been considered.

   3.1. If same microbial strain is used for making formulation by different entrepreneurs that the information submitted once on the said strain will be sufficient. All entrepreneurs need not submit relevant data.

   3.2. If same microbial strain, same method and same adjutants, stabilizers, etc. are used for making the given formulation, data once submitted for validating these claims will be sufficient for subsequent registrants, as substantiated by the relevant supportive documents.

4. The packaging material should also be ensured to be free from contamination from handling, storage and transportation and is as per prescribed standards, as the case may be.

STANDARDS FOR ANTAGONISTIC BACTERIA SPECIFICATIONS

1. Form and appearance

2. pH

3. Composition
   - 3.1. Percent content of the Biocontrol organism in the formulation & nature of biomass
   - 3.2. CFU/g or ml of the product
   - 3.3. Percentage of other components: carrier/filler, wetting/dispersing agent, stabilizers/ emulsifiers, contaminants/impurities, etc.
   - 3.4. Moisture content

4. CFU counts: Minimum 1×10^8 CFU/ml or gm (Stability at 30 ºC and 65% RH)

5. Contaminants:
   - 5.1. Biological Contaminants:
     - 5.1.1. Pathogenic Contaminants: such as gram negative bacteria *Salmonella, Shigella, Vibrio,* etc.: **absent**.
     - 5.1.2. Other contaminants should not exceed 1×10^4/ml or g
   - 5.2. Chemical/botanical pesticides contaminants: **absent**.

6. Method of analysis:
   - 6.1. CFU counts on specific medium
   - 6.2. Plating for contaminants on specific media
   - 6.3. Antagonistic capability on target organism by bio-assay
   - 6.4. Bio-assay procedure based on diseased severity and root colonization as detailed below

7. A statement should be submitted that strain is indigenous, naturally occurring, not exotic in origin and not genetically modified (example given below).

Proposed bio-efficacy assay for plant disease antagonists based on disease severity and root colonization

The pathogen to be tested against has to be grown in sand maize medium. The sand-maize medium is prepared by adding sand 90 g, maize 10 g and water 10 ml in a saline or any glass bottle of 300 ml capacity and then autoclaved twice. Then 5 mycelial discs of the test pathogen are transferred into the bottle and left for incubation for 15 days. Once the culture has grown well, the sand maize medium is mixed along with the fungal growth and 1 g from this preparation is used as the inoculum after adjusting the cfu to 1×10/g by addition of sand.

The plastic cups (5-6 cm diameter) filled with soil and FYM (3:1) have to be used. In each cup the filling should be done upto $^3/_4$th level. The pathogen inoculum is mixed with sand has to be applied upto 2 cm depth in the plastic cups.

The bio-efficacy of the bioagent can be tested by both seed treatment and soil application. For seed treatment, the recommended dose of the formulation has to be used (5 to 10 g). For soil application, the bioagent is added at the rate of 1 g of formulation (minimum cfu should be the 2×10^6, the CIB recommended dose). The germination percentage, disease intensity and seedling vigour are to be recorded.

Another set of plastic cups filled with sterile soil and sterile FYM has to be used to confirm whether the bio-efficacy was due to the isolate of the bioagent tested or due to the native isolates of the bioagent present in the soil.

The keys for grading the efficiency mentioned below can be used here (Srivastava *et al.,* 2002). However, for the registration purpose, the bioagents that are Highly Efficient, Efficient or Moderately Efficient in the plastic cup test under glass house condition (in the presence of pathogen) can be allowed (i.e.) germination percentage of 70 percent or above, disease incidence of 30 percent or less can be considered for registration.

Disease grading key

Disease incidence (%)	Description	Rating of bio-efficacy of bioagents
0	Germination >90%, no seed rotting, seedling healthy, root and shoot portions well developed	Highly Efficient (HE)
1-15	Germination 80-90%, infection on main as well as lateral roots, seedlings are well developed	Efficient (E)
16-30	Germination 70-80%, development of roots restricted and growth is less compared to Score I. Infection occurred on roots. Shoot portions developed but growth retarded compared to Score I	Moderately Efficient (ME)
31-45	Germination 60-70%, length of roots and shoots short compared to Score I. Germination of seeds inhibited. 50% of root area infected. Shoot portions also showed infection	Moderately Inefficient (MI)
46-60	Seed germination 50-60%. Development of roots and shoots greatly retarded. Shoot portions also showed infection	Inefficient (I)
Above 60	Less than 50% germination and seed rotting	Highly Inefficient (HI)

For the root colonization assay, the rhizosphere region of the plants tested above have to be collected and the soil adhering to the root surface has to be removed by gently tapping the roots. The root bits have to be cut into 1 cm bits and randomly 25 bits should be selected for each treatment. They have to be plated on TSM and the percentage of root bits colonized has to be recorded. This has to be performed in the sterile soil and not sterile soil. One control treatment without the biocontrol agent being tested should be kept for both the sterile and non-sterile soil to rule of the possibility of interference of native microflora in the bio-efficacy assay.

For the bacterial antagonists, the above bio-assay procedure has to be followed where only the % root colonization will be considered and other parameters are not required. The % root colonization required is 80 percent.

STATEMENT BY MANUFACTURERS OF MICROBIAL PESTICIDES

I, _____ , aged _____ years, s/o _____ , R/o _____ _____ and _____ of M/s _____ _____ Registered Office at _____ do hereby undertake as follows:

(a) That the product _____ based on _____ , Strain _____ _____ , manufactured by M/s _____ and/or imported by M/s _____ does not contains any genetically modified organism (GMO).

(b) That I/We shall abide by the provisions contained in the International Plant Protection Convention with regard to the import of this product.

(c) That I/We shall abide by the provisions in context of International Standards for Phyto-sanitary Measures-Code of Conduct for the import and release of exotic biological control agents of the International Plant Protection Convention (IPPC), FAO, Rome.

(d) That I/We shall provide the samples of our _____ product as and when desired by the competent authorities of Government of India for verification.

(e) That I/We further undertake that in the event of the above product having proved otherwise by any competent authority and resulting in environmental damage, I/We shall inform the Central Insecticides Board and Registration Committee, the relevant authorities for Manufacturing Licensing, Pollution Control and of appropriate District/State/National Level and shall comply with the directions/decisions from them.

(f) That my/our above undertaking is true, and no portion is false and I have concealed nothing relevant to the above matter.

Signature

Date: _____

Place: _____

Name: _____

Designation: _____

Seal of the Company: _____

Annex C

ISSUES INVOLVED IN HARMONIZATION

1. Items that are crucial to an effective regional harmonization

Proprietary (original) biopesticide registration:

Where any biopesticide product is registered for use for first time or an applicant who wishes to register to manufacture any biopesticide product for the first time is responsible for submitting or citing all of the information and data that are required to support the original registration. The duration of such registration may be fixed in the regulations for this purpose. The registration authority will be responsible for protection of data submitted by the original applicant and maintain confidentiality of information provided in accordance with provisions of WTO-TRIPS Agreement, 1994.

Supplemental (me-too) biopesticide registration:

An applicant, who wishes to register a similar/identical product that was previously registered by a company, will become a supplemental registrant for the company that has originally registered a product. This supplemental registration allows the new registrant to market the product under its own company and brand name. To use the supplemental registration process, both parties (the original registrant and the supplemental registrant) must a) enter into bilateral agreement b) file a notice of supplemental registration of a registered biopesticide product with registration authority and c) ensure that the supplemental product bears the identical label language apart from the exceptions, which may include the supplemental label utilizing a different product name and the supplemental registrant's name and address instead of the original registrant's name and address.

Minimum data requirements:

The registration authority will establish harmonized minimum data requirements for different kinds of registration for proprietary (original) biopesticide registration; provisional registration, supplemental (me-too) registration and or/re-registration. An agreed format of minimum data requirement for registration of biopesticides may be developed and executed in all countries. The components for this purpose shall be botanical, chemistry or microbial data, toxicity data, efficacy data, labelling/packaging/storage test data, environmental data and residues data.

Another area for consideration shall be the exemption of data sets to certain types of biopesticides, whose well-known lack of impact to environment is clear.

2. Items that are desirable to be harmonized, but not essential

Unconditional registration:

The registration authority will lay down appropriate criteria for an unconditional registration, which include

- data compensation requirements;
- no additional data were necessary to make the determinations required under biopesticide regulation with respect to the subject product;
- the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data were required;
- the product will perform its intended function without adverse effects on the environment, and that when used in accordance with widespread and commonly recognized practice, the product will not cause adverse effects on the environment; and

- if the proposed labelling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the biopesticide results or may reasonably be expected to result, directly or indirectly, in biopesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances or exemptions from the requirement of a tolerance, and food additive regulations.

3. Items that may vary according to local conditions and which do not need to be harmonized, but other countries could be kept informed through information exchange

Review of biopesticide labelling, review of registration, appeal by the applicant, monitoring status of registration, and conditional registration.

Amendments to previous registration, re-registration, denial of registration, supplemental registration, licensing of manufacturing or repacking facility, licensing of stockiest or distributors, licensing of pest control operators, etc. could be also in this category.

4. Which items are already harmonized and which items still differ substantially?

Already harmonized items

No specific items have been identifjed

Items for which there is substantial difference

Data protection:

The provisions of WTO-TRIPS Agreement should be taken into account. However the registration authority may give public access to health and safety data in support of biopesticide registrations as long as this public access does not include the right to copy that proprietary data. (The registration authority should issue appropriate regulation to safeguard the proprietary rights to the data).

Biopesticide risk assessment:

The assessment of risk associated with biopesticides, particularly in regard to the microbial pesticides for harmful microbial contaminants to human and animal health should be carried out as per the harmonized standards and guidelines established by the registration authority after taking into account the detailed toxicological data and the data on long-term dietary exposure to very low levels of biopesticides.

TARGETS AND INDICATORS OF DEGREE OF HARMONIZATION

Targets	Indicators of degree harmonization
Broad issues	
Legislation	National legislations shall be enforceable within the sovereign boundary limits. However, each country which joined the harmonization process of registration may appropriately adopt or legalize relevant laws, rules or guidance documents to attain harmonization of registration.
Enforcement systems of the relevant legislations including suitable staffing	Adaptation of a model enforcement system in each country is the ideal way of implementing the harmonized pesticide regulatory process. Proposals for this may emerge from the TCP project. Suitable staff cadre needs to be built up that would support the harmonized guidance pesticide registration system.
Implementation status of international conventions and agreements	Central to the harmonization of pesticide registration process is the adoption of international conventions and agreements in each country.
Intellectual property rights of the phytochemical active ingredients, biocontrol agents and their formulations	Bilateral or multilateral agreements may be essential for safeguarding the commercial interests of the registrants. International notions and norms need to be invoked for this purpose.
Commonality of registration process for unified procedures of registration in the region	The ASEAN platform could be used for this with FAO as the facilitator.
Specific issues	
Sharing of chemical, botanical, microbial, toxicity, bio-efficacy, labelling, packaging, storage test, environmental data, etc. The countries may finalise these data sets for being harmonized	This needs bilateral agreements between Southeast Asian countries. It is essential to the harmonized registration process to decide upon a data exchange system, preferably in electronic format, through webpages with suitable security platforms. This inter-country platform shall enable pesticide registrants to apply to multiple countries electronically with an agreed and harmonized data package. Except for specific non-harmonized registration requirements of each sovereign country, the remaining data requirements can be distributed to all countries through such a single input system. Such a system has to co-evolve by regulatory agencies in order to seamlessly harmonise the entire process. Analogies to systems in NAFTA, European Union, and OECD are applicable for this purpose. ASEAN would be good platform for maintaining such a data exchange system. Issues of cost or IPR sharing shall be negotiated by tri-partite agreements between the registration applicant, the host and the guest country. The views of Crop Life International in this matter should be considered. The degree of harmonization depends on the necessity felt by each country and the willingness to share such information for the public good.
Biopesticide risk assessment	The assessment of biopesticides risk to human and animal health (including farm animals) needs to include the hazards of harmful microbial contaminants in microbial pesticides. The assessment of risk should be carried out as per harmonized standards and guidelines established by the registration authorities after taking into account the detailed toxicological and data long-term exposure data to very low levels of biopesticides. International platforms such as CCPR/JMPR system may also be used for guidance for this purpose.
Minimum data requirements	National pesticide registries need to decide on uniform data requirement for registering biopesticides. To secure high safety standards and to make powerful risk assessment, the minimum data requirements are central to the harmonsiation process.
Test protocols and data generation process	Imperative to harmonization is the data sharing by national pesticide registries. There shall be acceptable international guidelines for this purpose that are generated out of expert consultations and then put up for adoption in all countries.

ATTACHMENT 3

GUIDELINES FOR THE PREPARATION OF EFFICACY TEST PROTOCOLS

TABLE OF CONTENTS

GUIDELNES FOR THE PREPARATION OF EFFICACY TEST PROTOCOLS

1. INTRODUCTION

To harmonize bio-efficacy test protocols, a modality for their preparation and a procedure for their usage was recommended. The proposed modality was discussed and recommended for adoption in a 3-day workshop on bio-efficacy test protocols held in Myanmar in January, 2011 which was attended by 25 participants from Cambodia, Lao PDR, Myanmar, Malaysia, Philippines, Thailand and Vietnam.

2. OBJECTIVES OF THE MODALITY

The main objective of recommending a modality for the preparation of efficacy test protocols is to provide guidance on evaluating the efficacy of pesticides against pests, diseases and weeds species on particular crops. This is done to ensure that the proposed claims and use recommendations on the product label are supported by trial data and reflect the actual performance of the product and the benefit to the user. The modality guideline gives guidance on the type of information to be recorded during efficacy trials and the contents of the trial report.

3. BACKGROUND INFORMATION

The standard texts for efficacy test protocols for insecticides, fungicides and herbicides were developed by FAO during 1990-92 and are thus 20 years old. They require updating in the light of developments in the field of bio-efficacy testing and new standards such as the 2006 FAO Guidelines on efficacy evaluation for the registration of plant protection products and the 2009-10 EPPO standards for efficacy evaluation of plant protection products. Other guidelines referred to were from Malaysia and Thailand on efficacy evaluation of pesticides used in agriculture.

The proposed modality guidelines give more detailed guidance for the preparation of efficacy test protocols, specifically giving the number of efficacy trials to be conducted for a major pest on a major crop and for minor uses, number of replications and plot size to be taken, doses of pesticides to be considered, type, time and frequency of assessment, and guidance on phytotoxicity assessment. It is essential that all applications follow good experimental practices and the trials are conducted in a scientific manner as per international guidelines. In the absence of such guidance, variable parameters are being used for the evaluation of pesticides efficacy, resulting in inconclusive data for the registration of pesticides.

The provisions in this guidance shall enable the preparation of efficacy evaluations of pesticides in a more harmonized manner. As a result, registration authorities will be able to evaluate an application for registration without much difficulty thus improving efficiency and cost effectiveness of the registration process.

4. A PROCEDURE THAT WOULD ENSURE THE GREATER USAGE OF THE MODALITY/TEST PROTOCOLS IN THE HARMONIZATION PROCESS

- Adoption of the draft modality for the preparation of new efficacy test protocols.
- Modifications of the existing FAO bio-efficacy test protocols following the draft modality guidelines.
- Adoption of the draft modality guidelines for reviewing the existing efficacy test protocols within the ASEAN region.
- Updating available efficacy guidelines in line with the new modality for harmonizing them.

5. GUIDELINES AND REPORTS REFERRED

1. FAO Report of experts working group meeting on efficacy test protocols, July, 1990.
2. FAO Guidelines on efficacy evaluation for the registration of plant protection products, June, 2006.
3. EPPO Standards: efficacy evaluation of plant protection products (PP1), 2009-10.
4. International code of conduct on distribution and use of pesticides-guidelines for the registration of pesticides, 2010.
5. Guidelines of Malaysia for efficacy evaluation of insecticides, fungicides and herbicides used in agriculture.
6. Guidelines of Thailand on principle, procedure and conditions for efficacy trials of agricultural hazardous substances.

6. MODALITY FOR THE PREPARATION OF EFFICACY TEST PROTOCOLS

A. Chemical insecticides, fungicides and acaricides

EFFICACY TEST PROTOCOLS

(Pest, Plant Pathogen on/of crop)

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of (chemical insecticides, fungicides, acaricides) for the control of (common name/scientific name of insect-pest/plant pathogen) in (common name/scientific name of crop).

The selection of crop, cultivar and test insects/plant pathogen must be relevant to the (proposed) label/ leaflet claims. (Specify objective of the trial and basic information on the trial site like scientific name of the pest and crop, type of trial, environment of trial like field, glasshouse, etc. Any other relevant information).

1.2. Trial conditions

Trials should be conducted only on crops with a known history of uniform high infestation/infection of the target insect-pest(s)/disease(s). Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8 for major pests and on a major crop and 2-6 for minor uses) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

(The relevant conditions of the plot and crop should be adequately described like sowing or planting date, row spacing, cultivation measures, crop condition, etc.)

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design. (Describe design and layout of the plots like type of experimental design, number, size and shape of plots. Any additional remarks).

1.3.2. Plot size and replication

Net plot size: Use an optimum plot size (15-20 sq m); however this will depend on the type of crop/pest and disease/product under study and location of trial.

For perennial trees: Net plot size: 2 trees/plot for big trees and 4 trees/plot for small trees.

Depending on type of the plants/cultivar used; mobility of the test organism, technique of application, type of formulation or application equipment; it may be necessary to take a larger plot size than net plot size or guard or buffer rows/strips are needed to take in to account pest dispersal and possible drift of pesticides.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of insect-pest(s)/disease(s) under investigation. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All Applications should comply with good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast, soil application etc.) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots where relevant by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. (Additional general information on factors influencing time and frequency of application like growth stage of the crop, threshold levels or development stage of pest or infestation level).

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given. The spray volume (lit/ha) will be appropriate to the stage of the crop.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect-pest(s)/diseases like plant growth regulators, stimulants etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period. The exact parameters and frequency of recording will depend on the type of crop/pest/product under study.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Type of assessment depends on the type of the insect-pest(s)/disease(s) under investigation but normally by number of insects on selected plants in the trial/percent infection per unit area of plant parts on selected plants in the trial. A practical scale for assessment is to be used for fungicide evaluation.

3.2.2. Time and frequency

For insecticides and acaricides evaluation preliminary assessment is done immediately before treatment, first assessment 1-3 days after treatment, second assessment 7-14 days after treatment. If long term effects are claimed, further assessments should be carried out at weekly intervals.

For fungicides evaluation preliminary assessment is done immediately before treatment;

First assessment is to be done, 1-3 days after treatment;

Second assessment is to be done, 7-14 days after treatment; and if long term effects are claimed, further assessments should be done at weekly intervals.

For diseases which are of long term in nature, such as root diseases, the symptoms of infection such as wilting, crown collapse etc. can be noted on the whole plant/tree.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects. The type and extent of these effects should be recorded like (include major symptoms of pesticides phytotoxicity on crops as defined in FAO Guidelines for phytotoxicity assessment in protocol FAO/AP/027). In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pests

Any effects, positive (effectiveness) or negative (development of resistance and resurgence), on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Quantitative and/or qualitative yield should be recorded where relevant in each treatment and should preferably be converted in to kg/ha for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

B. Herbicides used in agriculture

EFFICACY TEST PROTOCOL

Weeds in Crop

The biological evaluation of a herbicide involves a programme of trials for assessing its efficacy in weed control and its selectivity to the crop (crop safety). Trials may be used for evaluating weed control or crop safety according to weed occurrence, provided the conditions specified in the test protocol are satisfied. This protocol gives detailed instructions for the conduct of single trials and general recommendations for the whole evaluation programme which may include agronomic sustainability trials (practical use trials, succeeding crop trials, varietals trials, etc. Appendix).

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop, cultivar and weeds

This test protocol is concerned with the efficacy evaluation of herbicides for the control of weeds in (common name and scientific name of the crop). (Specify weed spectrum to be controlled: if possible, common names and scientific names). The selection of crop, cultivar and weeds must be relevant to the (proposed) label/leaflet claims. Consideration with regards to crop safety may also be given to cover crops, where applicable which may be sown together with the primary crop. If crop safety on several cultivars needs to be tested, special varietals trials should be carried out.

(Specify objective of the trial and basic information on the trial site like scientific names of the weeds and crop, type of trial, environment of trial like field, glasshouse, etc. Any other relevant information).

1.2. Weed situation

1.2.1. Evaluation of efficacy in weed control

The plots should be known to carry a varied but uniform weed population typical for the crop. The weed population should correspond to the specific action spectrum of the herbicide to be tested (e.g. monocots and/or dicots, annuals and/or perennials).

1.2.2. Evaluation of crop safety

The plots should preferably be as free from weeds as possible. Remaining weeds may be removed by hand or mechanically. Other herbicides should not be used.

1.3. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8 for major weeds and on major crops and 2-6 for minor uses) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

Record the preceding crop and any herbicide used on or after it. Avoid sites treated with herbicides known to have toxic effects on the succeeding crop.

(The relevant conditions of the plot and crop should be adequately described like sowing or planting date, row spacing, cultivation measures, crop condition, etc.).

1.4. Design and layout of the trial

1.4.1. Treatments

Test product(s), reference standard product(s) at individual doses and/or application times and untreated control are to be arranged in a randomized block design or any other statistically suitable design. (Describe design and layout of the plots like type of experimental design, number, size and shape of plots. Any additional remarks).

1.4.2. Plot size and replication

Net plot size: Use an optimum plot size (15-20 sq m); however this will depend on the type of crop/ weeds/product under study and location of trial.

Depending on type of the plants/cultivar used; technique of application, type of formulation or application equipment; it may be necessary to take a larger plot size than net plot size or guard or buffer rows/strips are needed to take in to account of possible drift of herbicides.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of weed types under investigation. In general, formulation type and mode of action should be close to those of the test product(s).

2.3. Mode of application

All Application should comply with good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast, soil incorporation, etc.) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy and/or duration of weed control and/or crop safety (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots where relevant by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application should normally correspond to that specified on the (proposed) label/leaflet. Application times should be related to emergence of the crop and of the weeds (for weed control testing) and will be:

(a) before sowing or transplanting of the crop (with or without incorporation): and/or

(b) before emergence of the crop (with or without incorporation); and/or

(c) after emergence of the crop or in an established crop (overall or directed).

The state (emergence, growth stage) of both weeds and crop at application should be recorded. The date of application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

In selectivity testing, at least one higher dose (normally the double dose) should be included.

2.3.5. Data on chemicals used against non-target weeds

If other chemicals have to be used (chemicals for the control of other than the target weeds like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period. The exact parameters and frequency of recording will depend on the type of crop/weed/product under study.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

3.2.1.1. Observations on weeds

The weed population of a plot can be recorded in terms of numbers, cover or mass (normally dry weight). These may be assessed in absolute terms and/or estimated.

(a) Absolute assessment

Individual plants may be counted for each weed species or the mass of each species may be determined by weighing (normally dry weight). These assessments can be made on whole plots or on randomly selected marked quadrates (up to 1 sq m) in each plot. In certain cases, it may be preferable to count or measure particular plant organs (e.g. flowering or fruiting tillers in monocot weeds).

(b) Estimation

Each treated plot is compared with adjacent untreated plot or control strip, and the relative weed population is estimated. The assessment involves a general estimation of the total weed population or of individual weed species, combining in one figure an estimate of number, cover, height and vigour (i.e. virtually weed volume). It is in principle rapid and simple. The results may be expressed simply as a percentage (i.e. on a linear scale from 0 = no weeds to 100 = same weed infestation as untreated). An equivalent inverted scale may be used to express percent weed control (0 = no weed control, 100 = full weed control) such as the following:

% Weed control

0	–	No weed control
10-30	–	Poor weed control
40-60	–	Moderate weed control
70-90	–	Satisfactory to very good weed control
100	–	Complete weed destruction

Information should also be provided on absolute level of weed infestation in the untreated plots or strips (absolute assessment of weed cover).

If it is difficult to estimate percentage accurately, a scale such as the following may be used:

1	=	no weeds
2	=	0-2.5% of untreated plot
3	=	2.5-5%
4	=	5-10%
5	=	10-15%
6	=	15-25%
7	=	25-35%
8	=	35-67.5%
9	=	67.5-100%

In order to describe exactly the mode of action of the product, symptoms of damage to the weeds should be accurately described (stunting, chlorosis, deformation, etc.).

Effects on weeds can usefully be noted over 2 seasons. This is essential for deep rooted or difficult weeds (such as *Cyperus rotundus, Imperata cylindrical*) as they may not be killed and might reappear the following year.

3.2.1.2. Observations on the crop

Phytotoxicity is evaluated primarily on crop safety plots which are also harvested. However, the type and extent of damage to the crop should be recorded on efficacy plots and may provide useful additional information.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The % of crop damage (phytotoxicity) may be observed as 0 = no crop injury, 100 = complete destruction as per following rating scale:

Rating (% of crop damage)	*Description of main categories*
0	No crop injury
10-30	Slight crop injury
40-60	Moderate crop injury
70-90	Heavy crop injury
100	Complete crop destruction

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

If the trial site can remain marked out until the following year, effects on succeeding crop can usefully be noted. If clear indications of such effects are obtained, it may be useful to set up agronomic sustainability trials (Appendix).

3.2.1.3. Observation on side-effects

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.2.2. Time and frequency

The times given apply to weed control and crop safety assessment, unless other wise indicated. Frequency of assessment should cover possibility of re-growth.

(a) Pre-emergence applications:

- 1st assessment – when approximately 90 percent of the crop has emerged in the untreated plot.
- 2nd assessment – 20-30 days after treatment.
- 3rd assessment – 60 days after treatment.
- 4th assessment – before harvest.

(b) Post-emergence applications:

1st assessment (preliminary)	–	on the day of treatment, the weed and crop cover in each plot should be recorded.
2nd assessment (weed control only)	–	3-5 days after treatment.
3rd assessment	–	10 -20 days after treatment.
4th assessment	–	30-50 days after treatment.
5th assessment	–	before harvest.

3.3. Quantitative and/or qualitative recording of yield

For crop safety testing, trials should be harvested, but this is optional for weed control testing.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

AGRONOMIC SUSTAINABILITY TRIALS

SUCCEEDING CROP TRIALS

Such trials are useful if indications of persistence have been obtained in weed control or selectivity trials. They are used to determine which crops can safely be planted following the application of a herbicide to the preceding crop. They may be set up as follows:

(a) In "persistence" trials, the plots of a former trial are subjected to a variety of husbandry treatments (ploughing, minimum tillage, direct drilling) and are then sown with a variety of crops that might be used in a rotation. Phytotoxicity is assessed as in 3.2.1.2;

(b) In "crop failure" trials, a herbicide trial has been applied to a crop which fails at an early stage (this may be simulated). The land may then be subjected to a variety of husbandry treatments (as above) and is sown with a variety of crops which could in practice be used to replace the failed crop. Phytotoxicity is assessed as before.

VARIETAL SENSITIVITY TRIALS

In order to obtain a better knowledge of the selectivity of herbicide for a sown or planted annual or biennial crop, varietals sensitivity trials may be carried out. These trials are set up with a large number of cultivars, with limited replication, at several locations with distinct environmental conditions.

They are carried out as follows:

1. Plot size of the same order as for efficacy trials, or smaller if the crop is homogenous and the treatments are applied with care.
2. Cultivars in parallel rows, with a sufficient number of rows to avoid edge effects.
3. Homogenous land as free from weeds as possible.
4. Herbicide treatments applied perpendicularly to the cultivar rows.
5. At least one control strip per product, but it is preferable to have a control strip adjacent to each product/dose combination.
6. For the reference product, use a registered product which has proved satisfactory in practice. In general, formulation type and mode of action should be close to those of the test product. If possible, it is useful to include two reference products: one known to give varietals effects and the other not.
7. Recommended dose and double dose, and sometimes triple dose, in order to assess precisely the relative sensitivity of the cultivars.
8. Phytotoxicity assessed as in 3.2.1.2 at the times in 3.2.2. Visual scoring is used to decide whether a herbicide which can be used selectively on the species as a whole can also be used selectively on each cultivar.

These trials do not include as assessment of yield. If one or more cultivars do show phytotoxicity, further trials may be set up to assess the yield loss due to the herbicide on the sensitive cultivar(s) by comparison with tolerant cultivars.

Annex

NEW EFFICACY TEST PROTOCOLS (041-069)

FAO/AP/041

EFFICACY TEST PROTOCOL

Armyworms on Rice

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of armyworms, *Mythimna separata and Spodoptera mauritia* on rice.

1.2. Trial conditions

Armyworm populations are highly localized. They occur in all rice environments, but are less prevalent in irrigated wetland rice. They are more abundant in the rainy season because of the increased availability of hosts, the grassy weeds and as such the trial should be planned accordingly in the high population season.

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, water depth, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 15 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of armyworms on rice. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Larvae defoliate the plants and can also cut off young seedlings at the plant or panicle base. They may also feed on the panicle rachis near the developing kernels causing these kernels to dry before filling. As such, the timing of application is normally dependent on the growth stage of the plants.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Select 10 hills at random from each plot excluding border rows/hills. Examine for infestation by insect larvae. The damage is assessed based on the percentage of leaves infested as below:

$$\% \text{ leaves damaged} = \frac{\text{Number of damaged leaves/10 hills}}{\text{Total number of leaves/10 hills}} \times 100$$

Record pre and post treatment population of armyworms on the selected hills in each plot for assessing reduction in the population of the army worms larvae. The data collected will be subjected to statistical analysis.

3.2.2. Time and frequency

First assessment is to be made immediately prior to first application.

Further assessments are to be made after 7 and 14 days of each application or prior to subsequent application. If long term effects are claimed, further observations may be taken.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. discoloration, necrosis or deformation of leaves, stems or the inflorescences; delay in emergence of inflorescences or in ripening of grain, reduction in number of tillers, thinning in number of seedlings and inflorescences and any observed adverse effects on grain yield. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

For each plot record yield in kg and express as kg/ha adjusted to 14 percent moisture content.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Mealy bugs on Cassava

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of mealy bugs, *Ferrisia virgata, Pseudoccus jackbeardleyi, Phenacoocus madeirensis* and *P. manihoti* on cassava.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of mealy bugs on cassava. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

Time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. In general, 2-3 applications are to be made and the first application begins when pest infestation crosses a threshold level (10 mealy bugs per stem). Further applications may be required at 10-15 days. The growth stage of the crop should be recorded at the time of each application.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Select 10 plants at random from each plot leaving border rows/plants. Examine leaves for mealy bugs population on each of these selected plants (from the top, middle and bottom of the plant). Count for the number of adults and nymphs mealy bugs. The data collected will be subjected to statistical analysis.

3.2.2. Time and frequency

First assessment: Intermediately prior to first application.

Later assessments: 1, 3, 7, 10, 15 and 21 days after each application. If second application is given, again the pre-count observation will be recorded prior to application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted**.**

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Yield may be recorded in kg/plot for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Flea beetle on Cabbage

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with efficacy evaluation of chemical insecticides for the control flea beetle, *Phyllotreta striolata* on cabbage.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 15 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s)

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of flea beetle on cabbage. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of spray. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factor which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally the first application is made when sufficient population of cabbage flea beetle is observed on plants. Further applications may be required at 15 days intervals depending upon flea beetle population.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For spray, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise on the application should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1 Meteorological data

Weather condition should be measured at the trial site or may be obtained from nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Record pre and post treatment population count of flea beetles on 10 plants selected at random from each plot tagged for the purpose excluding border rows/plants.

The data collected will be subjected to statistical analysis for finding reduction in flea beetles population and interpretation of results.

3.2.2. Time and frequency

First assessment: Immediately prior to first application.

Later assessments: after one and two weeks of each application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. discoloration, necrosis or deformation of seedlings or of established plants and any observed effects on yield and quality of produce. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be one in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 90; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effect on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effect on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effect on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Any effect on the quality of the product (marketability) should be noted. Percent yield loss is to be calculated by weighting the marketable (undamaged) and non-marketable (damaged) product/plot.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual trail reports or their summaries and record keeping and reporting of individual trial (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the registration of Plant Protection Products; Jane 2006.

EFFICACY TEST PROTOCOL

Tirathaba sp. on Corn

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with efficacy evaluation of chemical insecticides for the control of *Tirathaba* sp. on corn. Ensure that plant population will be sufficient in each plot.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all plots of the trial and should conform to local agriculture practices. A series of trials (6-8) should be carried out in different locations with distinct environment conditions over a period of at least 2 growing season. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of *Tirathaba* sp. on corn. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of spray. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factor which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally the first application is to be made when sufficient population of *Tirathaba* sp. is observed on plants. Further applications may be required at 10-15 days intervals depending upon *Tirathaba* larval population.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For spray, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise on the application should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather condition should be measured at the trial site or may be obtained from nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Select 10 plants at random from each plot tagged for larval population observations excluding border rows/plants. The observations on larval population will be taken prior to first application and 7 days after each application.

At harvest, ten plans are selected randomly from each plot and cobs from these plants will be assessed for insect damage. The percentage of infested cobs will be calculated from total number of cobs and that of infested cobs per plant (number of damaged cobs versus healthy cobs).

Percent reduction of cobs damage will be calculated using Henderson and Tilton formula given below:

$$\text{Percent reduction of cob damage} = \left(1 - \frac{\text{Ta Cb}}{\text{Ca Tb}}\right) \times 100$$

Where,

Ta = % cob damage in the treatment plot after application (post treatment count).
Tb = % cob damage in the treatment plot before application (1 day before 1st application).
Ca = % cob damage in untreated check plot after application.
Cb = % cob damage in untreated check plot before application.

3.2.2. Time and frequency

First assessment for larval population is required immediately prior to first application. Further assessments are to be made after 7 days of each application or prior to subsequent application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects i.e. thinning, discoloration, necrosis or deformation of plants, delay in reaching various growth stages and any observed adverse effects on grain yield. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be one in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 90; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effect on non-target organisms

3.4.1. Effects on other pests

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effect on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effect on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Yield is recorded in kg/plot and converted in to kg/ha for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual trail reports or their summaries and record keeping and reporting of individual trial (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Pomacea in Rice

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of molluscicides for the control of golden apple snail, *Pomacea canaliculata* in rice.

1.2. Trial conditions

Field trial should be set up in lowland rice areas where paddy fields are likely to be infested. Maintain the water in the plot and not let in new water.

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, water depth, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Net plot size: at least 15 sq m.

Replications: 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of golden apple snail, *Pomacea canaliculata* in rice. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All Applications should comply to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, seed treatment, broadcast) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

For the control period after first application assess the attack of the *Pomacea canaliculata* before and after sowing until the paddy plants become harden and not to be eaten by *Pomacea canaliculata*. Assess until 35 days after treatment (DAT).

For the effect of treatment on germination of treated seeds, 5 quadrates of 1 m^2 sizes each are randomly used in each plot for assessment as follows:

(a) Population count on number of live snails at pre-treatment and at 1, 3, 5 and 8 DAT. Visual observations on the percent attack on the germinated paddy seedlings are to be made at 10, 15, 20, 25, 30 and 35 DAT as follows:

0 – no attack is observed

1-100% – based on severity of attack

(b) Count on number of germinated paddy seedlings at 6 and 10 days after sowing.

3.2.2. Time and frequency

Preliminary assessment is to be made on number of live snails immediately before treatment. First assessment 1 DAT followed by at 3, 5 and 8 DAT. If long term effects are claimed, further assessments are to be carried out.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. discoloration, necrosis or deformation of leaves, stems or the inflorescences; delay in emergence of inflorescences or in ripening of grain, reduction in number of tillers, thinning in number of seedlings and inflorescences and any observed adverse effects on grain yield. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pests

Any effects, positive (effectiveness) or negative (development of resistance and resurgence), on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

For each plot record yield in kg and express as kg/ha adjusted to 14 percent moisture content for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Thrips on Eggplant

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of thrips, *Thrips palmi* on eggplant.

1.2. Trial conditions

Trials should be conducted on crops with known history of uniform high infestation of the target pest. Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at lest 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of thrips, *Thrips palmi* on eggplants. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All Applications should comply to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast) will normally be specified on the (proposed) label/ leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Assessments are to be made on thrips population on three leaves (top, middle and bottom) of the plant in a sample of ten randomly selected plants/plot tagged for the observations excluding border rows/plants.

3.2.2. Time and frequency

Pre-treatment population of thrips will be recorded one day before treatment.

Post-treatment population of thrips will be recorded after 1, 5, 7, 10 days of first spray and after 5 and 7 days of second spray. The data collected will be subjected to statistical analysis.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO guidelines on Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pests

Any effects, positive (effectiveness) or negative (development of resistance and resurgence), on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Crop yield should be recorded as kg/plot and should be converted in to kg/ha for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Leafminer on Chrysanthemum

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of leafminer, *Chromatomyia horticola* on chrysanthemum.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: at least 2.5 m^2 containing around 250 seedlings/plot.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of leafminer, *Chromatomyia horticola* on chrysanthemum. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All Applications should comply to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, soil application) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Application will be utilizing knapsack sprayer at 3 bar pressure up to run-off using an application interval of 10-15 days.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.1.2. Type

Record the number of fully expended leaves on the first four whorls of 20 plants/plot infested with leafminer, *Chromatomyia horticola*. Percent infestation of leaves is calculated based on total number of

leaves and number of infested leaves with leafminer larvae. Percent reduction in leaves infestation is computed based on the following:

$$\text{\% reduction In leaves infestation} = \frac{\text{\% infestation in control} - \text{\% infestation in treatment}}{\text{\% infestation in control}} \times 100\%$$

3.2.2. Time and frequency

Assessments for leaves infestation is to be done at weekly intervals beginning application of treatment until final application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO guidelines on Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pests

Any effects, positive (effectiveness) or negative (development of resistance and resurgence), on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Record flower yield/plot.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST POTOCOL

Weeds in Groundnut

The biological evaluation of a herbicide involves a programme of trials for assessment of efficacy in weed control and of selectivity to the crop (crop safety). Trials may be used for evaluating weed control or crop safety according to weed occurrence, provided the conditions specified in the test protocols are satisfied. This protocol gives detailed instructions for conduct of single trials and general recommendations for the whole evaluation programme which may include agronomic sustainability trials (practical use trials, succeeding crop trials, varietals trials, etc. (Appendix).

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop, cultivar and weeds

This test protocol is concerned with the efficacy evaluation of herbicides for the control of annual and perennial grass weeds like bermuda grass, *Cynodon dactylon,* goose grass*, Eleusine indica* and *Paspalum* spp. in groundnut during monsoon and winter crop seasons.

It is preferable to use normal cultivar, sowing rate, sowing depth and row spacing for the locality.

1.2. Weed situation

1.2.1. Evaluation of efficacy in weed control

The plots should be known to carry a varied but uniform weed population typical for groundnut. The weed population should correspond to the specific action spectrum of the herbicide to be tested (e.g. monocots and/or dicots, annuals and/or perennials).

1.2.2. Evaluation of crop safety

The plots should preferably be as free from weeds as possible. Remaining weeds may be removed by hand or mechanically. Other herbicides should not be used.

1.3. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

Record the preceding crop and any herbicide used on or after it. Avoid sites treated with herbicides known to have toxic effects on the succeeding crop.

1.4. Design and layout of the trial

1.4.1. Treatments

Test product(s), reference standard product(s) at individual doses and/or application times and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.4.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of weeds in groundnut. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy and/or duration of weed control and/or crop safety (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet and normally will be:

(a) before planting of the crop; and/or;

(b) after emergence of the crop.

In case of application after emergence of the crop the application time should be related to emergence of the crop and that of the weeds (for weed control testing) and will normally be at 2 to 6 leaves seedling stage in crop. The date of application should be recorded.

The state (emergence, growth stage) of both weeds and crop at application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in

kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

In selectivity testing, at least one higher dose (normally the double dose) should be included.

2.3.5. Data on chemicals used against pests and non-target weeds

If other chemicals have to be used (chemicals for the control of other than the target weeds like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENT

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

3.2.1.1. Observations on weeds

The weed population of a plot can be recorded in terms of numbers, cover or mass (normally dry weight). These may be assessed in absolute terms and/or estimated.

(a) Absolute assessment

Individual plants may be counted for each weed species or the mass of each species may be determined by weighing (normally dry weight). These assessments can be made on whole plots or on randomly selected marked quadrates (up to 1 sq m) in each plot. In certain cases, it may be preferable to count or measure particular plant organs (e.g. flowering or fruiting tillers in monocot weeds).

(b) Estimation

Each treated plot is compared with adjacent untreated plot or control strip, and the relative weed population is estimated. The assessment involves a general estimation of the total weed population or of individual weed species, combining in one figure an estimate of number, cover, height and vigour (i.e. virtually weed volume). It is in principle rapid and simple. The results may be expressed simply as a percentage (i.e. on a linear scale from 0 = no

weed to 100 = same weed infestation as untreated). An equivalent inverted scale may be used to express percent weed control. (0 = no weed control, 100 = full weed control) such as the following:

% Weed control

0	–	No weed control
10-30	–	Poor weed control
40-60	–	Moderate weed control
70-90	–	Satisfactory to very good weed control
100	–	Complete weed destruction

Information should also be provided on absolute level of weed infestation in the untreated plots or strips (absolute assessment of weed cover).

If it is found difficult to estimate percentage accurately a scale such as the following may be used:

1	=	no weeds
2	=	0-2.5% of untreated plot
3	=	2.5-5%
4	=	5-10%
5	=	10-15%
6	=	15-25%
7	=	25-35%
8	=	35-67.5%
9	=	67.5-100%

In order to describe exactly the mode of action of product, symptoms of damage to the weeds should be accurately described (stunting, chlorosis, deformation, etc.).

Effects on weeds can usefully be noted over 2 seasons. This is essential for deep rooted or difficult weeds (such as *Cyprus rotundus*) as they may be killed and might reappear the following year.

3.2.1.2. Observations on the crop

Phytotoxicity is evaluated primarily on crop safety plots which are also harvested. However, the type and extent of damage to the crop should be recorded on weed control plots which may provide useful additional information.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale or each treated plot is compared with an untreated plot and % phytotoxicity estimated.

The % of crop damage (phytotoxicity) may be observed as 0 = no crop injury, 100 = complete destruction as per following rating scale:

Rating (% of crop damage)	*Description of main categories*
0	No crop injury
10-30	Slight crop injury
40-60	Moderate crop injury
70-90	Heavy crop injury
100	Complete crop destruction.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

If the trial site can remain marked out until the following year, effects on succeeding crop can usefully be noted. If clear indications of such effects are obtained, it may be useful to set up agronomic sustainability trials (Appendix).

3.2.1.3. Observation on side-effects

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.2.2. Time and frequency

The times given apply to weed control and crop safety assessment, unless other wise indicated. Frequency of assessment should cover possibility of re-growth.

1st assessment (preliminary)	–	on the day of treatment
2nd assessment	–	3-5 days after treatment
3rd assessment	–	10-20 days after treatment
4th assessment	–	30-50 days after treatment
5th assessment	–	before harvest

3.3. Quantitative and/or qualitative recording of yield

For crop safety testing, trials should be taken to harvest, but this is optional for weed control testing.

The yield should be recorded in kg/plot and converted in to kg/ha for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

Agronomic sustainability Trials

SUCCEEDING CROP TRIALS

Such trials are useful if indications of persistence have been obtained in weed control or selectivity trials. They are used to determine which crops can safely be planted following the application of a herbicide to the preceding crop. They may be set up as follows:

(a) In "persistence" trials, the plots of a former trial are subjected to a variety of husbandry treatments (ploughing, minimum tillage, direct drilling) and are then sown with a variety of crops that might be used in a rotation. Phytotoxicity is assessed as in 3.2.1.2;

(b) In "crop failure" trials, a herbicide trial has been applied to a crop which fails at an early stage (this may be simulated). The land may then be subjected to a variety of husbandry treatments (as above) and is sown with a variety of crops which could in practice be used to replace the failed crop. Phytotoxicity is assessed as before.

VARIETAL SENSITIVITY TRIALS

In order to obtain a better knowledge of the selectivity of herbicide for a sown or planted annual or biennial crop, varietals sensitivity trials may be carried out. These trials are set up with a large number of cultivars, with limited replication, at several locations with distinct environmental conditions.

They are carried out as follows:

1. Plot size of the same order as for efficacy trials, or smaller if the crop is homogenous and the treatments are applied with care.
2. Cultivars in parallel rows, with a sufficient number of rows to avoid edge effects.
3. Homogenous land as free from weeds as possible.
4. Herbicide treatments applied perpendicularly to the cultivar rows.
5. At least one control strip per product, but it is preferable to have a control strip adjacent to each product/dose combination.
6. For the reference product, use a registered product which has proved satisfactory in practice. In general, formulation type and mode of action should be close to those of the test product. If possible, it is useful to include two reference products: one known to give varietals effects and the other not.
7. Recommended dose and double dose, and sometimes triple dose, in order to assess precisely the relative sensitivity of the cultivars.
8. Phytotoxicity assessed as in 3.2.1.2 at the times in 3.2.2. Visual scoring is used to decide whether a herbicide which can be used selectively on the species as a whole can also be used selectively on each cultivar.

These trials do not include as assessment of yield. If one or more cultivars do show phytotoxicity, further trials may be set up to assess the yield loss due to the herbicide on the sensitive cultivar(s) by comparison with tolerant cultivars.

EFFICACY TEST PROTOCOL

Pod borer on Green gram

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control pod borer, *Helicoverpa armigera* hub. on green gram, *Vigna radiata*. Ensure that plant population will be sufficient in each plot. It is preferable to use normal cultivar, sowing rate, sowing depth and row spacing for the locality.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of two growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test product(s)

The product (s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of pod borer, *Helicoverpa armigera* on green gram, *Vigna radiata*. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. Spray, broadcast) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use (conventional knapsack sprayer with single cone nozzle), properly calibrated to give intended rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may be affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally the first application is required to be made prior to flowering on small larval population when it reaches beyond economic threshold level which varies from 1-3/m^2. Further applications depend upon pest intensity.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content and soil humidity), seed bed quality and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Select 10 plants at random from each plot and tagged for larval population observations. The observations on larval population will be taken on selected plants leaving border rows/plants prior to first application and 7 days after each application.

At harvest pods damage can also be assessed from 10 randomly selected plants from each plot. The percent infested pods will be calculated from the total number of pods and that of the infested pods. The data obtained on various aspects will be subjected to statistical analysis.

3.2.2. Time and frequency

First assessment: immediately prior to first application.

Further assessments for larval population are to be done after 7 days of each application or prior to subsequent application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. discoloration, necrosis or deformation of cotyledons and leaves; delay in emergence and in reaching various growth stages in flowering and in ripening and any observed adverse effects on grain yield. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted.

Phytotoxicity is recorded as follows:

(a) If the effect can be counted or measured, it may be expressed in absolute figures;

(b) In other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pests

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pests) associated with the crop ecosystem. Any observed effects on human safely also be recorded.

3.5. Quantitative and qualitative recording of yield

Grain yield is to be recorded in kg/plot for possible yield loss and for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions. See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Anthracnose of Mango

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of fungicides for the control of anthracnose of mango caused by *Colletotrichum gloeosporioides* and *C. acutatum*. It is preferable to use of a susceptible variety for the trial. The orchard should be composed of mature trees of the same age where the disease was severe in the previous year. Off-year trees should not be selected. Some mango varieties have an off-season without bearing fruit in nature. The size of the trees should be convenient for sample collection and application of treatments.

1.2. Trial conditions

Cultural conditions (e.g. soil type, fertilization, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 years.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: at least 2 trees/plot.

Replicates: should be 3-4 per treatment (Provided the error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of anthracnose of mango. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of spray. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factor which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. Normally the first application is to be made as soon as the first disease symptoms are seen on the leaves in the trees. Further applications are made depending on the factors which influence disease development and its spread. The number of applications and the date of each application should be recorded. The frequency of applications may be reduced during drought season.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For spray, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target disease like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Assessments are to be made on 20 leaves and on 20 fruits selected randomly from the north, south, east, west and center of each tree. Estimate the percentage of leaf area infected on the following rating score:

% of leaf area infected	*Scoring*
<5%	1
5-10%	2
>10-20%	3
>20-30%	4
>30%	5

For assessment of infection on fruits use following scale:

0 = no infection
1 = only one or two small circular sunken spots per fruit
3 = two or three sunken spots of about 1 sq cm in size
6 = several bigger spots, more than 1 sq cm in size, discolored and rotting
9 = more than half of entire surface of the fruit discolored, black and rotting

3.2.2. Time and frequency

Preliminary assessment: immediately before first application.

Further assessments: Immediately before subsequent applications.

Final assessment: 10-15 days after the last application on leaves.

It is necessary to check disease symptoms on the leaves in ten to fifteen days after the last application.

On fruits the final assessment is made at harvest.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. discoloration, necrosis or deformation of leaves, shoots; delay in flowering, fruit ripening; acceleration in flower and fruit fall and any observed effects on quality and quantity of fruit yield. The type and extent of these should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence), on the incidence of other insect-pests should be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Record the yield of marketable fruits per plot for assessing the differences between different treatments.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Shoot and Fruit borer on Eggplant

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical Insecticides for the control of shoot and fruit borer, *Leucinodes orbonalis* Guenee on eggplant.

Use cultivar known to be susceptible (like long purple variety) to the test insect. Ensure that plant population will be sufficient in each plot.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of shoot and fruit borer, *Leucinodes orbonalis* on eggplant. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, soil incorporation) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded.

Normally the first application is required to be made 35-45 days after transplanting at late vegetative stage. If required, further applications are to be made at 10-15 days intervals. The growth stage of the crop should be recorded at the time of each application.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Shoot infestation: all the plants in the net plot area are to be examined for the shoot damage (the infestation will be identified by the presence of withered or dried shoot) by counting the total number of shoots and number of infested shoots per plot.

Fruit damage: Select 10 plants from each plot and tagged (excluding border rows/plants), the total number of fruits and number of infested fruits per plant will be counted (the infestation may be identified by the presence of small circular hole in the fruits filled with excreta). The percentage shoot and fruit damage will be calculated. Data on percent infested shoot and fruits will be transformed to aresin values and then subjected to statistical analysis. During each picking the healthy and infested fruits will be counted and weighed separately for determination of yield loss.

3.2.2. Time and frequency

First assessment: Immediately prior to first application.

Later assessments: At 7th day after each application or prior to subsequent application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

The yield of marketable (undamaged) and non-marketable (damaged) fruits will be recorded during each picking on whole plot basis for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Spodoptera on Tomato

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of cutworm, *Spodoptera litura* on tomato. Use susceptible variety locally grown.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, plant and row spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of *Spodoptera litura* on tomato. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. Normally the first application is required to be made when adequate level of insect, *S. litura* infestation (about 10 percent on plans) is observed in the unprotected plot. The number of applications and the date of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

The plant infestation will be assessed by recording the damage on leaves of 10 randomly selected plants in each plot, tagged for the purpose excluding border rows/plants, using a scale such as the following:

Scale	*Percent leaf area damage*
1	No damage
3	1 to 10
5	11 to 25
7	26 to 50
9	51 to 100

Population of *Spodoptera* larvae (all stages) will also be recorded on randomly selected plants in each plot.

3.2.2. Time and frequency

Assessments are to be made for larval population immediately before application and after 3, 5 and 7 days of each application. If long-term effects are claimed, further assessments should be made at weekly intervals. The plant infestation will be assessed after 35, 55 and 75 days of transplanting of the crop.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

The yield of marketable (healthy) and non-marketable (damaged) fruits is to be recorded in each picking for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Thrips on Orchid

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with efficacy evaluation of chemical insecticides for the control of thrips *Thrips palmi* Karny on orchid. Ensure that plant population will be sufficient in each plot. Orchid buds and new growths are especially susceptible to these sucking insects.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 5 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of thrips, *Thrips palmi* Karny on orchid. In general, formulation type and mode of action should be close to those the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. Normally the first application is required to be made when thrips, *T. palmi* population reaches four nymphs or adults per inflorescence (at least four blooms per inflorescence). Repeat applications may be necessary depending upon thrips intensity. The number of applications and date of each application along with the growth stage of the crop at the time of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all the plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Observations on thrips population are to be recorded on 20 flowers/plot selected at random.

3.2.2. Time and frequency

Assessments are to be made immediately before application of treatment and at 3, 5, 7 and 10 days after each application. If long-term effects are claimed, further assessments may be useful.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted**.**

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Not required.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Thrips on Citrus

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of thrips, *Scirtothrips dorsalis* Hood on citrus. Use a susceptible cultivar, for example, *Citrus aurantifolia* (lime), *C. reticulata* (tangerine) or *C. grandis* (pomelo).

1.2. Trial conditions

Trials should be carried out when young shoots are produced, preferably during the dry seasons.

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 years. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 2 trees/plot.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of thrips, *Scirtothrips dorsalis* on cirrus. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The first application is to be normally applied when young shoots are produced and thrips, *S. dorsalis* population is at least 2-3 individuals/shoot. Repeat applications may be necessary depending upon thrips intensity. Generally 2-3 applications may be required at an interval of 10-15 days. The number of applications and the date of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where insecticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Observations on thrips population are to be made on 10 new shoots/tree selected at random. Thrips population is to be recorded by direct count or by tapping shoots 2-3 times on the board.

3.2.2. Time and frequency

Assessments are to be made immediately or one day before treatment and at 3, 5, 7 and 10 days after each treatment. If long-term effects are claimed, further assessments may be useful.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects like discoloration, necrosis or deformation of leaves, shoots, delay in flowering, fruit ripening, acceleration in flower and fruit fall and any observed effects on quality and quantity of fruit yield. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Not required.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Dirty Panicles of Rice

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of fungicides for the control of dirty panicles (*Helminthosporium oryzae, Cercospora oryzae, Curvularia lunata, Acrocylindrium oryzae, Trichoconis padwickii, Fusarium semitectum*) of rice, either direct-seeded or transplanted. Use a susceptible cultivar.

1.2. Trial conditions

Trials should be set up in a rice area where paddy fields are likely to be infected. Use of nitrogen fertilizers, in-sufficient water and dense planting are favorable for the development of this disease.

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, water depth, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 15 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of dirty panicles of rice. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally the first application is required to be made at booting stage and second application during flowering stage. Further applications are to be made according to disease development.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target disease like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

For dirty panicle assessment, collect 50 panicles randomly from each plot. Count dirty panicle seeds and whole seeds for calculating the percentage of disease.

3.2.2. Time and frequency

Assessments are to be made 10-14 days before harvest.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects like discoloration, necrosis or deformation of leaves, stems or the inflorescences; delay in emergence of inflorescences or in ripening of grain, reduction in number of tillers, thinning in number of seedlings and inflorescences and any observed adverse effects on grain yield. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests/diseases should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Yield may be recorded in kg/plot and converted to kg/ha adjusted to 14 percent moisture content.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Spodoptera on Grape

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of *Spodoptera exigua* on grape. The trial may be conducted in the field on commonly grown *Vitis vinefera* crops. The grape varieties should represent the region where the trials are conducted.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, pruning) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 years. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a suitable statistical design.

1.3.2. Plot size and replication

Plot size: Net plot at least one single row for sampling (or 6 sq m).

If spray drift to neighboring plots can not be avoided, there should be guard rows on each side of the net plot.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1 Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of cutworm, *Spodoptera exigua* on grape. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. Normally the first application is required to be done one month after pruning of the crop or when the pest appears. The number of applications and the date of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Population of *Spodoptera exigua* larvae (all stages) is to be recorded on 20 grape shoots/plot.

3.2.2. Time and frequency

Assessments are to be made immediately before application and at 3, 5 and 7 days after each application. If long-term effects are claimed, further assessments may be useful.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted**.**

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Not required.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Mealy bug on desert Rose

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of mealy bug, *Adenium obesum* Balf. on desert rose.

1.2. Trial conditions

Trials should be carried out when young shoots are produced, preferably during the dry seasons. Cultural condition (e.g. soil type, fertilization, cultivar age) should be uniform for all plots of trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 years.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 pots/plot (pot diameter at least 12 inches).

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of mealy bug, *Adenium obesum* Balf. on desert rose or on other ornamental plants. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. Normally the first application is required to be made when the population of mealy bugs is (at least) 10/shoot. The number of applications and the date of each application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Mealy bugs could be artificially infested (by mass rearing in laboratory) on desert rose, 2-3 times until they augment on the plants. Observations are to be made on 10 shoots/plot (10 inches from the top of shoot). Number of mealy bugs (all stages: crawler, nymph or adult) are to be recorded.

3.2.2. Time and frequency

Assessments are to be made immediately before treatment and at 3, 5, 7 and 10 days after each treatment. If long-term effects are claimed, further assessments may be useful.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Not required.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Bollworm on Asparagus

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of bollworm, *Helicoverpa armigera* hub. on asparagus, *Asparagus officinalis* L. Ensure that plant population will be sufficient in each plot.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of bollworm, *Helicoverpa armigera* on asparagus. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast, etc.) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. Normally the first application is to be made when *H. armigera* population reaches beyond ETL i.e. 0.5 larvae/ plant. Repeat applications may be necessary depending upon *H. armigera* intensity. Generally 2-3 applications may be required at an interval of 10-15 days. Number and date of each application along with growth stage of the crop should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all the plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Select 10 plants randomly from each plot and tagged for larval population observations. Number of *H. armigera* larvae (all stages) is recorded on selected plants excluding border rows/plants.

At harvest, 10 plants are randomly selected from each plot and shoots from these plants will be assessed for *H. armigera* damage. The percentage of infested shoots will be calculated from total number of shoots and of infested shoots per plant (number of damaged shoot versus healthy shoots.)

Percent reduction of shoot damage will be calculated using Henderson and Tilton formula given below:

$$\text{Percent reduction of shoot damage} = \left(1 - \frac{\text{TaCb}}{\text{CaTb}}\right) \times 100$$

Where,

Ta = % shoot damage in the treatment plot after application (post treatment count)
Tb = % shoot damage in the treatment plot before application (1 day before 1st application)
Ca = % shoot damage in untreated check plot after application
Cb = % shoot damage in untreated check plot before application

3.2.2. Time and frequency

Assessments are to be made for larval population immediately prior to each application and at 7 days after each application. If long-term effects are claimed, further assessments may be useful.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Asparagus yield will be recorded in kg/plot for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Powdery mildew of Cucumber

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of fungicides for the control of powdery mildew, *Pseudoperonospora cubensis* of cucumber.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of powdery mildew, *Pseudoperonospora cubensis* of cucumber. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally the first application is to be made when disease symptoms are seen on the leaves. Subsequent applications are to be made throughout crop growth in relation to disease severity. Normally 3-4 applications are required at weekly intervals.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target disease like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Twenty plants are selected randomly for disease assessment from each plot excluding border rows/plants. The fifth to tenth leaves from the bottom of each selected plant are used to assess disease severity by comparing percent of disease symptoms on the leaves which are categorized in 6 levels as follows:

Scale		*Disease symptoms (severity) on the leaves*
1	=	no infection
2	=	up to 10% of leaf area
3	=	11-25% of leaf area
4	=	26-50% of leaf area
5	=	51-75% of leaf area
6	=	more than 75% of leaf area

3.2.2. Time and frequency

Disease assessment is to be made prior to each application. Final assessment is to be made 7 and 14 days after the last application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects. The type and extent of these effects should be recorded. In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other diseases should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Yield may be recorded in kg/plot for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST POTOCOL

Weeds in Mango

The biological evaluation of a herbicide involves a programme of trials for assessment of efficacy in weed control and of selectivity to the crop (crop safety). Trials may be used for evaluating weed control or crop safety according to weed occurrence, provided the conditions specified in the test protocols are satisfied. This protocol gives detailed instructions for conduct of single trials and general recommendations for the whole evaluation programme which may include agronomic sustainability trials.

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop, cultivar and weeds

This test protocol is concerned with the efficacy evaluation of herbicides for the control of weeds in mango. It is preferable to use normal cultivar and row spacing for the locality.

1.2. Weed situation

1.2.1. Evaluation of efficacy in weed control

The plots should be known to carry a varied but uniform weed population typical for mango. The weed population should correspond to the specific action spectrum of the herbicide to be tested (e.g. monocots and/or dicots, annuals and/or perennials).

1.2.2. Evaluation of crop safety

The plots should preferably be as free from weeds as possible. Remaining weeds may be removed by hand or mechanically. Other herbicides should not be used.

1.3. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 years. The timing, amount and method of irrigation, if applied, should be recorded.

1.4. Design and layout of the trial

1.4.1. Treatments

Test product(s), reference standard product(s) at individual doses and/or application times and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.4.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of weeds in mango. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy and/or duration of weed control and/or crop safety (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet and normally will be before or after weed emergence.

The state (emergence, growth stage) of both weeds and crop at application should be recorded. The date of application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

In selectivity testing, at least one higher dose (normally the double dose) should be included.

2.3.5. Data on chemicals used against pests and non-target weeds

If other chemicals have to be used (chemicals for the control of other than the target weeds like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENT

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

3.2.1.1. Observations on weeds

The weed population of a plot can be recorded in terms of numbers, cover or mass (normally dry weight). These may be assessed in absolute terms and/or estimated.

(a) Absolute assessment

Individual plants may be counted for each weed species or the mass of each species may be determined by weighing (normally dry weight). These assessments can be made on whole plots or on randomly selected marked quadrates (up to 1 sq m) in each plot. In certain cases, it may be preferable to count or measure particular plant organs (e.g. flowering or fruiting tillers in monocot weeds).

(b) Estimation

Each treated plot is compared with adjacent untreated plot or control strip, and the relative weed population is estimated. The assessment involves a general estimation of the total weed population or of individual weed species, combining in one figure an estimate of number, cover, height and vigour (i.e. virtually weed volume). It is in principle rapid and simple. The results may be expressed simply as a percentage (i.e. on a linear scale from 0 = no weed to 100 = same weed infestation as untreated). An equivalent inverted scale may be used to express percent weed control. (0 = no weed control, 100 = full weed control) such as the following:

% Weed control

0	–	No weed control
10-30	–	Poor weed control
40-60	–	Moderate weed control
70-90	–	Satisfactory to very good weed control
100	–	Complete weed destruction

Information should also be provided on absolute level of weed infestation in the untreated plots or strips (absolute assessment of weed cover).

If it is found difficult to estimate percentage accurately a scale such as the following may be used:

1 = no weeds
2 = 0-2.5% of untreated plot
3 = 2.5-5%
4 = 5-10%
5 = 10-15%
6 = 15-25%
7 = 25-35%
8 = 35-67.5%
9 = 67.5-100%

In order to describe exactly the mode of action of product, symptoms of damage to the weeds should be accurately described (stunting, chlorosis, deformation, etc.).

Effects on weeds can usefully be noted over 2 years. This is essential for deep rooted or difficult weeds (such as *Cyprus rotundus*) as they may be killed and might reappear the following year.

3.2.1.2. Observations on the crop

Phytotoxicity is evaluated primarily on crop safety plots which are also harvested. However, the type and extent of damage to the crop should be recorded on weed control plots which may provide useful additional information.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale or each treated plot is compared with an untreated plot and % phytotoxicity estimated.

The % of crop damage (phytotoxicity) may be observed as 0 = no crop injury, 100 = complete destruction as per following rating scale:

Rating (% of crop damage)	*Description of main categories*
0	No crop injury
10-30	Slight crop injury
40-60	Moderate crop injury
70-90	Heavy crop injury
100	Complete crop destruction

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.2.1.3. Observation on side-effects

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.2.2. Time and frequency

The times given apply to weed control and crop safety assessment, unless other wise indicated. Frequency of assessment should cover possibility of re-growth.

Preliminary assessment – just before the first application

1st assessment: 15 days after application
2nd assessment: 30 days after application
3rd assessment: 45 days after application
4th assessment: 60 days after application

3.3. Quantitative and/or qualitative recording of yield

Not required.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST POTOCOL

Weeds in Marigold

The biological evaluation of a herbicide involves a programme of trials for assessment of efficacy in weed control and of selectivity to the crop (crop safety). Trials may be used for evaluating weed control or crop safety according to weed occurrence, provided the conditions specified in the test protocols are satisfied. This protocol gives detailed instructions for conduct of single trials and general recommendations for the whole evaluation programme which may include agronomic sustainability trials (practical use trials, succeeding crop trials, varietals trials, etc. (Appendix).

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop, cultivar and weeds

This test protocol is concerned with the efficacy evaluation of herbicides for the control of weeds in marigold. It is preferable to use normal cultivar and row spacing for the locality.

1.2. Weed situation

1.2.1. Evaluation of efficacy in weed control

The plots should be known to carry a varied but uniform weed population typical for marigold. The weed population should correspond to the specific action spectrum of the herbicide to be tested (e.g. monocots and/or dicots, annuals and/or perennials).

1.2.2. Evaluation of crop safety

The plots should preferably be as free from weeds as possible. Remaining weeds may be removed by hand or mechanically. Other herbicides should not be used.

1.3. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

Record the preceding crop and any herbicide used on or after it. Avoid sites treated with herbicides know to have toxic effects on the succeeding crop.

1.4. Design and layout of the trial

1.4.1. Treatments

Test product(s), reference standard product(s) at individual doses and/or application times and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.4.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of weeds in marigold. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy and/or duration of weed control and/or crop safety (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet and normally will be before or after weed emergence.

The state (emergence, growth stage) of both weeds and crop at application should be recorded. The date of application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

In selectivity testing, at least one higher dose (normally the double dose) should be included.

2.3.5. Data on chemicals used against pests and non-target weeds

If other chemicals have to be used (chemicals for the control of other than the target weeds like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENT

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

3.2.1.1. Observations on weeds

The weed population of a plot can be recorded in terms of numbers, cover or mass (normally dry weight). These may be assessed in absolute terms and/or estimated.

(a) Absolute assessment

Individual plants may be counted for each weed species or the mass of each species may be determined by weighing (normally dry weight). These assessments can be made on whole plots or on randomly selected marked quadrates (up to 1 sq m) in each plot. In certain cases, it may be preferable to count or measure particular plant organs (e.g. flowering or fruiting tillers in monocot weeds).

(b) Estimation

Each treated plot is compared with adjacent untreated plot or control strip, and the relative weed population is estimated. The assessment involves a general estimation of the total weed population or of individual weed species, combining in one figure an estimate of number, cover, height and vigour (i.e. virtually weed volume). It is in principle rapid and simple. The results may be expressed simply as a percentage (i.e. on a linear scale from 0 = no weed to 100 = same weed infestation as untreated). An equivalent inverted scale may be used to express percent weed control. (0 = no weed control, 100 = full weed control) such as the following:

% Weed control

0	–	No weed control
10-30	–	Poor weed control
40-60	–	Moderate weed control
70-90	–	Satisfactory to very good weed control
100	–	Complete weed destruction

Information should also be provided on absolute level of weed infestation in the untreated plots or strips (absolute assessment of weed cover).

If it is found difficult to estimate percentage accurately a scale such as the following may be used:

1 = no weeds
2 = 0-2.5% of untreated plot
3 = 2.5-5%
4 = 5-10%
5 = 10-15%
6 = 15-25%
7 = 25-35%
8 = 35-67.5%
9 = 67.5-100%

In order to describe exactly the mode of action of product, symptoms of damage to the weeds should be accurately described (stunting, chlorosis, deformation, etc.).

Effects on weeds can usefully be noted over 2 years. This is essential for deep rooted or difficult weeds (such as *Cyprus rotundus*) as they may be killed and might reappear the following year.

3.2.1.2. Observations on the crop

Phytotoxicity is evaluated primarily on crop safety plots which are also harvested. However, the type and extent of damage to the crop should be recorded on weed control plots which may provide useful additional information.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale or each treated plot is compared with an untreated plot and % phytotoxicity estimated.

The % of crop damage (phytotoxicity) may be observed as 0 = no crop injury, 100 = complete destruction as per following rating scale:

Rating (% of crop damage)	*Description of main categories*
0	No crop injury
10-30	Slight crop injury
40-60	Moderate crop injury
70-90	Heavy crop injury
100	Complete crop destruction

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

If the trial site can remain marked out until the following year, effects on succeeding crop can usefully be noted. If clear indications of such effects are obtained, it may be useful to set up agronomic sustainability trials (Appendix).

3.2.1.3. Observation on side-effects

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.2.2. Time and frequency

The times given apply to weed control and crop safety assessment, unless other wise indicated. Frequency of assessment should cover possibility of re-growth.

Preliminary assessment – just before the first application
1st assessment: 15 days after application
2nd assessment: 30 days after application
3rd assessment: 45 days after application

3.3. Quantitative and/or qualitative recording of yield

Quality of marigold flowers may be graded in treated and untreated plots for comparison along with yield.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

Agronomic sustainability Trials

SUCCEEDING CROP TRIALS

Such trials are useful if indications of persistence have been obtained in weed control or selectivity trials. They are used to determine which crops can safely be planted following the application of a herbicide to the preceding crop. They may be set up as follows:

(a) In "persistence" trials, the plots of a former trial are subjected to a variety of husbandry treatments (ploughing, minimum tillage, direct drilling) and are then sown with a variety of crops that might be used in a rotation. Phytotoxicity is assessed as in 3.2.1.2;

(b) In "crop failure" trials, a herbicide trial has been applied to a crop which fails at an early stage (this may be simulated). The land may then be subjected to a variety of husbandry treatments (as above) and is sown with a variety of crops which could in practice be used to replace the failed crop. Phytotoxicity is assessed as before.

VARIETAL SENSITIVITY TRIALS

In order to obtain a better knowledge of the selectivity of herbicide for a sown or planted annual or biennial crop, varietals sensitivity trials may be carried out. These trials are set up with a large number of cultivars, with limited replication, at several locations with distinct environmental conditions.

They are carried out as follows:

1. Plot size of the same order as for efficacy trials, or smaller if the crop is homogenous and the treatments are applied with care.
2. Cultivars in parallel rows, with a sufficient number of rows to avoid edge effects.
3. Homogenous land as free from weeds as possible.
4. Herbicide treatments applied perpendicularly to the cultivar rows.
5. At least one control strip per product, but it is preferable to have a control strip adjacent to each product/dose combination.
6. For the reference product, use a registered product which has proved satisfactory in practice. In general, formulation type and mode of action should be close to those of the test product. If possible, it is useful to include two reference products: one known to give varietals effects and the other not.
7. Recommended dose and double dose, and sometimes triple dose, in order to assess precisely the relative sensitivity of the cultivars.
8. Phytotoxicity assessed as in 3.2.1.2 at the times in 3.2.2. Visual scoring is used to decide whether a herbicide which can be used selectively on the species as a whole can also be used selectively on each cultivar.

These trials do not include as assessment of yield. If one or more cultivars do show phytotoxicity, further trials may be set up to assess the yield loss due to the herbicide on the sensitive cultivar(s) by comparison with tolerant cultivars.

EFFICACY TEST POTOCOL

Weeds in Chinese kale (Broccoli)

The biological evaluation of a herbicide involves a programme of trials for assessment of efficacy in weed control and of selectivity to the crop (crop safety). Trials may be used for evaluating weed control or crop safety according to weed occurrence, provided the conditions specified in the test protocols are satisfied. This protocol gives detailed instructions for conduct of single trials and general recommendations for the whole evaluation programme which may include agronomic sustainability trials (practical use trials, succeeding crop trials, varietals trials, etc. (Appendix).

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop, cultivar and weeds

This test protocol is concerned with the efficacy evaluation of herbicides for the control of weeds in Chinese kale (Broccoli). It is preferable to use normal cultivar and row spacing for the locality.

1.2. Weed situation

1.2.1. Evaluation of efficacy in weed control

The plots should be known to carry a varied but uniform weed population typical for Chinese kale. The weed population should correspond to the specific action spectrum of the herbicide to be tested (e.g. monocots and/or dicots, annuals and/or perennials).

1.2.2. Evaluation of crop safety

The plots should preferably be as free from weeds as possible. Remaining weeds may be removed by hand or mechanically. Other herbicides should not be used.

1.3. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

Record the preceding crop and any herbicide used on or after it. Avoid sites treated with herbicides know to have toxic effects on the succeeding crop.

1.4. Design and layout of the trial

1.4.1. Treatments

Test product(s), reference standard product(s) at individual doses and/or application times and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.4.2. Plot size and replication

Plot size: Net plot at least 10 sq m.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product (s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of weeds in Chinese kale (Broccoli). In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy and/or duration of weed control and/or crop safety (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet and normally will be before or after weed emergence.

The state (emergence, growth stage) of both weeds and crop at application should be recorded. The date of application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

In selectivity testing, at least one higher dose (normally the double dose) should be included.

2.3.5. Data on chemicals used against pests and non-target weeds

If other chemicals have to be used (chemicals for the control of other than the target weeds like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENT

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

3.2.1.1. Observations on weeds

The weed population of a plot can be recorded in terms of numbers, cover or mass (normally dry weight). These may be assessed in absolute terms and/or estimated.

(a) Absolute assessment

Individual plants may be counted for each weed species or the mass of each species may be determined by weighing (normally dry weight). These assessments can be made on whole plots or on randomly selected marked quadrates (up to 1 sq m) in each plot. In certain cases, it may be preferable to count or measure particular plant organs (e.g. flowering or fruiting tillers in monocot weeds).

(b) Estimation

Each treated plot is compared with adjacent untreated plot or control strip, and the relative weed population is estimated. The assessment involves a general estimation of the total weed population or of individual weed species, combining in one figure an estimate of number, cover, height and vigour (i.e. virtually weed volume). It is in principle rapid and simple. The results may be expressed simply as a percentage (i.e. on a linear scale from 0 = no weed to 100 = same weed infestation as untreated). An equivalent inverted scale may be used to express percent weed control (0 = no weed control, 100 = full weed control) such as the following:

% Weed control

0	–	No weed control
10-30	–	Poor weed control
40-60	–	Moderate weed control
70-90	–	Satisfactory to very good weed control
100	–	Complete weed destruction

Information should also be provided on absolute level of weed infestation in the untreated plots or strips (absolute assessment of weed cover).

If it is found difficult to estimate percentage accurately a scale such as the following may be used:

1	=	no weeds
2	=	0-2.5% of untreated plot
3	=	2.5-5%
4	=	5-10%
5	=	10-15%
6	=	15-25%
7	=	25-35%
8	=	35-67.5%
9	=	67.5-100%

In order to describe exactly the mode of action of product, symptoms of damage to the weeds should be accurately described (stunting, chlorosis, deformation, etc.).

Effects on weeds can usefully be noted over 2 years. This is essential for deep rooted or difficult weeds (such as *Cyprus rotundus*) as they may be killed and might reappear the following year.

3.2.1.2. Observations on the crop

Phytotoxicity is evaluated primarily on crop safety plots which are also harvested. However, the type and extent of damage to the crop should be recorded on weed control plots which may provide useful additional information.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale or each treated plot is compared with an untreated plot and % phytotoxicity estimated.

The % of crop damage (phytotoxicity) may be observed as 0 = no crop injury, 100 = complete destruction as per following rating scale:

Rating (% of crop damage)	*Description of main categories*
0	No crop injury
10-30	Slight crop injury
40-60	Moderate crop injury
70-90	Heavy crop injury
100	Complete crop destruction

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

If the trial site can remain marked out until the following year, effects on succeeding crop can usefully be noted. If clear indications of such effects are obtained, it may be useful to set up agronomic sustainability trials (Appendix).

3.2.1.3. Observation on side-effects

Any observed environmental effects should also be recorded, especially effects on wildlife and/or beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.2.2. Time and frequency

The times given apply to weed control and crop safety assessment, unless other wise indicated. Frequency of assessment should cover possibility of re-growth.

Preliminary assessment – Just before the first application
1st assessment: 15 days after application
2nd assessment: 30 days after application
3rd assessment: 45 days after application

3.3. Quantitative and/or qualitative recording of yield

Yield data may be recorded on plot basis and converted to kg/ha for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

Agronomic sustainability Trials

SUCCEEDING CROP TRIALS

Such trials are useful if indications of persistence have been obtained in weed control or selectivity trials. They are used to determine which crops can safely be planted following the application of a herbicide to the preceding crop. They may be set up as follows:

(a) In "persistence" trials, the plots of a former trial are subjected to a variety of husbandry treatments (ploughing, minimum tillage, direct drilling) and are then sown with a variety of crops that might be used in a rotation. Phytotoxicity is assessed as in 3.2.1.2;

(b) In "crop failure" trials, a herbicide trial has been applied to a crop which fails at an early stage (this may be simulated). The land may then be subjected to a variety of husbandry treatments (as above) and is sown with a variety of crops which could in practice be used to replace the failed crop. Phytotoxicity is assessed as before.

VARIETAL SENSITIVITY TRIALS

In order to obtain a better knowledge of the selectivity of herbicide for a sown or planted annual or biennial crop, varietals sensitivity trials may be carried out. These trials are set up with a large number of cultivars, with limited replication, at several locations with distinct environmental conditions.

They are carried out as follows:

1. Plot size of the same order as for efficacy trials, or smaller if the crop is homogenous and the treatments are applied with care.
2. Cultivars in parallel rows, with a sufficient number of rows to avoid edge effects.
3. Homogenous land as free from weeds as possible.
4. Herbicide treatments applied perpendicularly to the cultivar rows.
5. At least one control strip per product, but it is preferable to have a control strip adjacent to each product/dose combination.
6. For the reference product, use a registered product which has proved satisfactory in practice. In general, formulation type and mode of action should be close to those of the test product. If possible, it is useful to include two reference products: one known to give varietals effects and the other not.
7. Recommended dose and double dose, and sometimes triple dose, in order to assess precisely the relative sensitivity of the cultivars.
8. Phytotoxicity assessed as in 3.2.1.2 at the times in 3.2.2. Visual scoring is used to decide whether a herbicide which can be used selectively on the species as a whole can also be used selectively on each cultivar.

These trials do not include as assessment of yield. If one or more cultivars do show phytotoxicity, further trials may be set up to assess the yield loss due to the herbicide on the sensitive cultivar(s) by comparison with tolerant cultivars.

EFFICACY TEST POTOCOL

Weeds in Cassava

The biological evaluation of a herbicide involves a programme of trials for assessment of efficacy in weed control and of selectivity to the crop (crop safety). Trials may be used for evaluating weed control or crop safety according to weed occurrence, provided the conditions specified in the test protocols are satisfied. This protocol gives detailed instructions for conduct of single trials and general recommendations for the whole evaluation programme which may include agronomic sustainability trials (practical use trials, succeeding crop trials, varietals trials, etc. (Appendix).

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop, cultivar and weeds

This test protocol is concerned with the efficacy evaluation of herbicides for the control of weeds like *Cyperus rotundus, Cyanodon dactylon* and *Panicum javanicum* in cassava.

1.2. Weed situation

1.2.1. Evaluation of efficacy in weed control

The plots should be known to carry a varied but uniform weed population typical for cassava. The weed population should correspond to the specific action spectrum of the herbicide to be tested (e.g. monocots and/or dicots, annuals and/or perennials).

1.2.2. Evaluation of crop safety

The plots should preferably be as free from weeds as possible. Remaining weeds may be removed by hand or mechanically. Other herbicides should not be used.

1.3. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 years. The timing, amount and method of irrigation, if applied, should be recorded.

Record the preceding crop and any herbicide used on or after it. Avoid sites treated with herbicides know to have toxic effects on the succeeding crop.

1.4. Design and layout of the trial

1.4.1. Treatments

Test product(s), reference standard product(s) at individual doses and/or application times and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.4.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the error or residual degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of weeds in cassava. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray) will normally be specified on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy and/or duration of weed control and/or crop safety (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet and normally will be before or after weed emergence.

The state (emergence, growth stage) of both weeds and crop at application should be recorded. The date of application should be recorded.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

In selectivity testing, at least one higher dose (normally the double dose) should be included.

2.3.5. Data on chemicals used against pests and non-target weeds

If other chemicals have to be used (chemicals for the control of other than the target weeds like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENT

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where pesticides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

3.2.1.1. Observations on weeds

The weed population of a plot can be recorded in terms of numbers, cover or mass (normally dry weight). These may be assessed in absolute terms and/or estimated.

(a) Absolute assessment

Individual plants may be counted for each weed species or the mass of each species may be determined by weighing (normally dry weight). These assessments can be made on whole plots or on randomly selected marked quadrates (up to 1 sq m) in each plot. In certain cases, it may be preferable to count or measure particular plant organs (e.g. flowering or fruiting tillers in monocot weeds).

(b) Estimation

Each treated plot is compared with adjacent untreated plot or control strip, and the relative weed population is estimated. The assessment involves a general estimation of the total weed population or of individual weed species, combining in one figure an estimate of number, cover, height and vigour (i.e. virtually weed volume). It is in principle rapid and simple. The results may be expressed simply as a percentage (i.e. on a linear scale from 0 = no weed to 100 = same weed infestation as untreated). An equivalent inverted scale may be used to express percent weed control (0 = no weed control, 100 = full weed control) such as the following:

% Weed control

0	–	No weed control
10-30	–	Poor weed control
40-60	–	Moderate weed control
70-90	–	Satisfactory to very good weed control
100	–	Complete weed destruction

Information should also be provided on absolute level of weed infestation in the untreated plots or strips (absolute assessment of weed cover). If it is found difficult to estimate percentage accurately a scale such as the following may be used:

1 = no weeds
2 = 0-2.5% of untreated plot
3 = 2.5-5%
4 = 5-10%
5 = 10-15%
6 = 15-25%
7 = 25-35%
8 = 35-67.5%
9 = 67.5-100%

In order to describe exactly the mode of action of product, symptoms of damage to the weeds should be accurately described (stunting, chlorosis, deformation, etc.).

Effects on weeds can usefully be noted over 2 years. This is essential for deep rooted or difficult weeds (such as *Cyprus rotundus*) as they may be killed and might reappear the following year.

3.2.1.2. Observations on the crop

Phytotoxicity is evaluated primarily on crop safety plots which are also harvested. However, the type and extent of damage to the crop should be recorded on weed control plots which may provide useful additional information.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale or each treated plot is compared with an untreated plot and % phytotoxicity estimated.

The % of crop damage (phytotoxicity) may be observed as 0 = no crop injury, 100 = complete destruction as per following rating scale:

Rating (% of crop damage)	*Description of main categories*
0	No crop injury
10-30	Slight crop injury
40-60	Moderate crop injury
70-90	Heavy crop injury
100	Complete crop destruction

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

If the trial site can remain marked out until the following year, effects on succeeding crop can usefully be noted. If clear indications of such effects are obtained, it may be useful to set up agronomic sustainability trials (Appendix).

3.2.1.3. Observation on side-effects

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.2.2. Time and frequency

The times given apply to weed control and crop safety assessment, unless other wise indicated. Frequency of assessment should cover possibility of re-growth.

Preliminary assessment – on the day of application
1st assessment: 15 days after application
2nd assessment: 30 days after application
3rd assessment: 45 days after application
4th assessment: 60 days after application

3.3. Quantitative and/or qualitative recording of yield

Yield data may be recorded on plot basis and converted in kg/ha for statistical comparison.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

Agronomic sustainability Trials

SUCCEEDING CROP TRIALS

Such trials are useful if indications of persistence have been obtained in weed control or selectivity trials. They are used to determine which crops can safely be planted following the application of a herbicide to the preceding crop. They may be set up as follows:

(a) In "persistence" trials, the plots of a former trial are subjected to a variety of husbandry treatments (ploughing, minimum tillage, direct drilling) and are then sown with a variety of crops that might be used in a rotation. Phytotoxicity is assessed as in 3.2.1.2;

(b) In "crop failure" trials, a herbicide trial has been applied to a crop which fails at an early stage (this may be simulated). The land may then be subjected to a variety of husbandry treatments (as above) and is sown with a variety of crops which could in practice be used to replace the failed crop. Phytotoxicity is assessed as before.

VARIETAL SENSITIVITY TRIALS

In order to obtain a better knowledge of the selectivity of herbicide for a sown or planted annual or biennial crop, varietals sensitivity trials may be carried out. These trials are set up with a large number of cultivars, with limited replication, at several locations with distinct environmental conditions.

They are carried out as follows:

1. Plot size of the same order as for efficacy trials, or smaller if the crop is homogenous and the treatments are applied with care.
2. Cultivars in parallel rows, with a sufficient number of rows to avoid edge effects.
3. Homogenous land as free from weeds as possible.
4. Herbicide treatments applied perpendicularly to the cultivar rows.
5. At least one control strip per product, but it is preferable to have a control strip adjacent to each product/dose combination.
6. For the reference product, use a registered product which has proved satisfactory in practice. In general, formulation type and mode of action should be close to those of the test product. If possible, it is useful to include two reference products: one known to give varietals effects and the other not.
7. Recommended dose and double dose, and sometimes triple dose, in order to assess precisely the relative sensitivity of the cultivars.
8. Phytotoxicity assessed as in 3.2.1.2 at the times in 3.2.2. Visual scoring is used to decide whether a herbicide which can be used selectively on the species as a whole can also be used selectively on each cultivar.

These trials do not include as assessment of yield. If one or more cultivars do show phytotoxicity, further trials may be set up to assess the yield loss due to the herbicide on the sensitive cultivar(s) by comparison with tolerant cultivars.

EFFICACY TEST PROTOCOL

Club root of Cabbage

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of synthetic fungicides for the control of club root disease, *Plasmodiophora brassicae* of cabbage crop.

1.2. Trial conditions

Use susceptible cultivars commercially used for brassicae production in fields which are naturally infested with the club root disease, *P. brassicae*. Higher temperatures (20-24 degree C), acidic soil and higher water content in soil promotes disease incidence.

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 9 sq m (5 m × 1.8 m) or 5 m long rows in raised beds.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of club root, *Plasmodiophora brassicae* of cabbage. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. soil application) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally one application is to be incorporated one day before planting date in the bands with the plants placed in line down the middle of the bands.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target disease like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENT

3.1. Meteorological and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

The following characteristics of the soil should be recorded: soil type, soil conditions (pH, organic matter content, and soil humidity), seed bed quality (tilth) and fertilizer regime where fungicides have been applied in soil.

3.2. Type, time and frequency of assessment

3.2.1. Type

Disease reduction (level of incidence and severity), head weight and yield of plants are used as a measure of effectiveness of the treatments.

Dig 25 plants/plot from net plot area excluding border rows and border plants and score them for club root symptoms in a scale of 0-3 as below;

Where 0 = no infection; 1 = main root healthy, galls present on one or more lateral roots; 2 = up to one-third of the main root galled; 3 = more than one-third of the main root galled. A disease severity index (DI) is to be calculated as below:

$$D.I = \frac{[n0 \times 0] + [n1 \times 1] + n2 \times 2] + [n3 \times 3]}{n0 + n1 + n2 + n3} \times \frac{100}{3}$$

Where n0 is the number of plants with a club root severity rating 0, n1 is the number of plants with a severity rating 1, etc. after the method of Doland *et al*. (2006).

3.2.2. Time and frequency

At full bloom or after 6-8 weeks of seeding.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. discoloration, necrosis or deformation of seedlings or of established plants and any observed adverse effects on yield and quality of produce. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other pests and diseases should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Yield estimate to be calculated by randomly selecting 25 heads of cabbage (broccoli) from each plot (excluding plants from the end of each row in the plot), cutting them to 15 cm in length and weighing them for statistical analysis. Marketability of the product may also be noted.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

EFFICACY TEST PROTOCOL

Gram pod borer in Chickpea

1. EXPERIMENTAL CONDITIONS

1.1. Selection of crop and cultivar, test organisms

This test protocol is concerned with the efficacy evaluation of chemical insecticides for the control of gram pod borer, *Helicoverpa armigera* hub. in chickpea. Ensure that plant population will be sufficient in each plot.

1.2. Trial conditions

Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials (6-8) should be carried out in different locations with distinct environmental conditions over a period of at least 2 growing seasons. The timing, amount and method of irrigation, if applied, should be recorded.

1.3. Design and layout of the trial

1.3.1. Treatments

Test product(s), reference standard product(s) and untreated control are to be arranged in a randomized block design or any other statistically suitable design.

1.3.2. Plot size and replication

Plot size: Net plot at least 20 sq m.

Replications: should be 3-4 per treatment (Provided the residual or error degrees of freedom are at least 12).

2. APPLICATION OF TREATMENTS

2.1. Test products(s)

The product(s) under investigation should be the named formulated product(s).

2.2. Reference product(s)

Reference standard product preferably a registered one known to be satisfactory for the control of gram pod borer, *Helicoverpa armigera* in chickpea, *Cicer arietinum*. In general, formulation type and mode of action should be close to those of the test product.

2.3. Mode of application

All applications should conform to good experimental practices.

2.3.1. Method of application

The method of application (e.g. spray, broadcast, etc.) should be the same or similar to the one recommended on the (proposed) label/leaflet.

2.3.2. Type of equipment used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 percent.

Precaution should be taken to avoid drift between plots by holding a screen around the plot being treated.

2.3.3. Time and frequency of application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. Normally the first application is to be made prior to flowering on small larval population when it reaches beyond economic threshold level i.e. 2 eggs or one larva per plant. Further applications depend upon pest intensity. 2-3 applications may be required at an interval of 10-15 days. The growth stage of the crop should be recorded at the time of each application.

2.3.4. Doses and volumes used

The product should be tested at the minimum effective dose recommended on the product label/leaflet and may also usefully be tested at other lower doses. The dosage applied will normally be expressed in kg or lit of formulated product/ha and it may also be useful to record the dose in g of active ingredient per ha. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given.

2.3.5. Data on chemicals used against other pests

If other chemicals have to be used (chemicals for the control of other than the target insect/pest(s) like plant growth regulators, stimulants, etc.). They should be applied uniformly to all plots, separately from test product(s) and reference product(s). Possible interference with these should be kept to a minimum. Precise data on the applications should be given.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1. Meteorological data and edaphic data

3.1.1. Meteorological data

Weather conditions should be measured at the trial site or may be obtained from a nearby meteorological station on the day of treatment. Ambient temperature, relative humidity, precipitation, wind speed and direction should be recorded, where relevant, just before, during and just after product application.

Temperature, relative humidity, precipitation and extreme weather conditions may also need to be recorded on a regular basis throughout the trial period.

3.1.2. Edaphic data

Not required.

3.2. Type, time and frequency of assessment

3.2.1. Type

Select 10 plants at random from each plot and tagged for larval population observations leaving border rows/plants. The observations on larval population (% pod damage) will be taken on selected plants prior to first application and 7 days after each application.

Percent reduction of pod damage will be calculated using Henderson and Tilton formula given below:

$$\text{Percent reduction of pod damage} = (1 - \frac{\text{TaCb}}{\text{CaTb}}) \times 100$$

Where,

Ta = % Pod damage in the treatment plot after application (post treatment count)
Tb = % pod damage in the treatment plot before application (1 day before 1st application)
Ca = % pod damage in untreated check plot after application
Cb = % pod damage in untreated check plot before application

At harvest, pods from these ten randomly selected plants will be assessed for pod borer damage. The percentage of infested pods will be calculated from total number of pods and that of infested pods per plant (number of damaged pods versus healthy pods).

3.2.2. Time and frequency

For larval population (% pod damage) first assessment is to be made immediately prior to first application. Further assessments are to be made after 7 days of each application or prior to subsequent application.

3.3. Direct effects on the crop

The crop should be examined for presence or absence of phytotoxic effects on the whole plant or any part of it i.e. thinning in number of plants; discoloration, necrosis or deformation of cotyledons and leaves; delay in emergence and in reaching various growth stages in flowering and in ripening and any observed adverse effects on grain yield. The type and extent of these effects should be recorded. In addition, any positive effects of test product on crop growth and yield (phytotonic) should also be noted.

Phytotoxicity is recorded as follows:

(a) if the effect can be counted or measured, it may be expressed in absolute figures;

(b) in other cases, the frequency and intensity of damage may be estimated. This may be done in either of two ways; each plot is scored for phytotoxicity by reference to a scale which should be recorded; or each treated plot is compared with a reference standard and an untreated plot and percent phytotoxicity estimated.

The scale on 1 to 10 for percent damage could be 0-10% = 1; 11-20% = 2; 21-30% = 3; 31-40% = 4; 41-50% = 5; 51-60% = 6; 61-70% = 7; 71-80% = 8; 81-90% = 9; 91-100% = 10.

In all cases, symptoms of damage to the crop should be accurately described (stunting, chlorosis, deformation, etc.). For further details, refer to the FAO Guidelines for Phytotoxicity Assessment which also contains sections on individual crops.

3.4. Effects on non-target organisms

3.4.1. Effects on other pest(s)

Any effects, positive (effectiveness) or negative (development of resistance and resurgence) on the incidence of other insect-pests should also be noted.

3.4.2. Effects on other non-target organisms

Any observed environmental effects should also be recorded, especially effects on wildlife and/or on beneficial non-target organisms (pollinators or natural enemies of the pest) associated with the crop ecosystem. Any observed effects on human safety should also be recorded.

3.5. Quantitative and/or qualitative recording of yield

Grain yield will be recorded in kg/plot for possible yield loss for statistical analysis.

4. RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions). See in particular FAO Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products; June 2006.

ATTACHMENT 4

GUIDELINES FOR HARMONIZATION OF PESTICIDE LABELLING

ABBREVIATIONS

ASEAN	Association of Southeast Asian Nations
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GIFAP	International Group of National Associations of Manufacturers of Agrochemical Products
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
ISO	International Organization for Standardization
ODS	Ozone Deleting Potential
PHI	Pre-harvest Interval
PSI	Pre-slaughtering Interval
TCP	Technical Cooperation Programme
WHO	World Health Organization

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SECTION 1: INTRODUCTION

1.1. About these guidelines

These guidelines were developed under a project of the FAO Technical Cooperation Programme (TCP) to assist countries in Southeast Asia in achieving pesticide regulatory harmonization in the region. One of the components of the project was to develop guidelines on harmonized pesticide labelling requirements to be used by pesticide regulatory authorities in the region to ensure that pesticide products in their own country will be labelled in accordance with the principle of these guidelines. These guidelines are also intended for use by the pesticide registrants in preparing labels which have to be submitted to regulatory authorities for approval. A harmonized pesticide labelling system will enhance the protection of human health and the environment by providing a regionally comprehensive labelling system for pesticide as well as facilitating regional trade in pesticides. The registrant will benefit from these guidelines, as the labelling requirements for all ASEAN countries would be similar except for the languages, and this will facilitate and expedite the registration of pesticides in the region.

These guidelines are based on international pesticide labelling and classification systems. The three main classification and labelling guidelines referred to during the preparation of these guidelines were: (i) FAO Guidelines on Good Labelling Practice for Pesticides 1995 and FAO Guidelines on Good Labelling Practice for Pesticides (Draft Revised Version 2009); (ii) WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2004 & 2009; and (iii) Globally Harmonized System of Classification and Labelling of Chemicals (GHS). During the development of these guidelines, labelling systems in selected ASEAN countries and their regulations were taken into account. Consideration was also given to the great diversity of languages and the levels of sophistication in pesticide regulations in the countries of the region.

1.2. The importance of label

The International Code of Conduct on the Distribution and Use of Pesticides (Code of Conduct) defines a label as **"the written, printed or graphic matter on, or attached to, the pesticide or the immediate container there of and also to the outside container or wrapper of the retail package of the pesticide"**.

Pesticide labels are very important, as they provide information to the user. They ensure that the pesticide products are used correctly for effective control of intended pests as well as to provide information regarding hazards and how to handle them safely to avoid any adverse effects to the applicator, non-target organisms and the environment as a whole. In addition, the labels also provide essential information regarding warnings and safety precautions to be observed when handling such products namely by the transporter, distributor, retailer and user to avoid any adverse effects. In many countries, the pesticide label is considered a legally binding documents, where it is illegal to use pesticide inconsistent with its label.

In order to ensure the label is read, understood and instructions on it are followed, it is important that the label is kept as simple and direct as possible, but without omitting any important messages, information and symbols for the effective and safe use of the product. The label should not be too complex, too technical or very difficult to understand as these would discourage users from reading the label. The use of symbols and pictograms to indicate hazard, advice and instruction are very useful especially for farmers from developing countries who have limited reading ability. There is, therefore, a great need for clear directions which can be easily understood by all potential users.

Lastly, labels should have physical durability. They should be resistant to normal wear and tear encountered in transport, storage and use. These requirements apply equally to the print on the label and the material on which the information is printed. Several years of storage may elapse between manufacture and final

use of the product. Without a complete and legible label during storage and at the time of final use, a pesticide is likely to present a serious potential hazard.

1.3. International pesticides classification and labelling system

Currently there are at least three main internationally recognized guidelines for the classification and labelling of chemical/pesticide available for reference, and they are:

1.3.1. FAO Guidelines on Good Labelling Practice for Pesticides (1995)

FAO first published its Guidelines on Good Labelling Practice for Pesticides in 1985 and revised them in 1995 to incorporate the field tested pictograms. These guidelines are intended for those involved in the preparation of pesticide labels as well as regulators responsible for their approval. These guidelines have gained wide acceptance in many pesticide regulatory authorities in developing countries, including Southeast Asia countries.

The document contains four main chapters with annexes. The first chapter identifies the main objectives and considerations in preparing a label. The second chapter identifies the information which must appear on a label. The third chapter deals with writing a label with maximum clarity and consideration of the level of knowledge of users. The fourth chapter discusses the establishment of toxicity and hazard classifications for a product. The annexes contain examples of labels, hazard statements, agricultural practice statements and other summaries of specific and generic label contents which can help to clarify the general text.

FAO currently is the process of updating the Guidelines on Good Labelling Practice for Pesticides (1995) to incorporate GHS elements.

1.3.2. WHO Recommended Classification of Pesticides by Hazard (2009)

The FAO Guidelines on Good Labelling Practice for Pesticides (1995) makes a special reference to The WHO Recommended Classification of Pesticides by Hazard, in which the classification of pesticides hazard for labelling purposes is to follow the principle set under these classification guidelines.

The WHO Recommended Classification of Pesticides by Hazard was first published in 1978 and has gained wide acceptance and are currently used in many countries to classify pesticide hazard as part of the requirements in pesticide registration. The guidelines were revised and reissued every few years to accommodate new elements. The latest edition is the 2009 version. It was revised with the objective to accommodate the harmonized GHS classification system.

1.3.3. Globally Harmonized System of Classification and Labelling of Chemical (GHS)

The GHS was first published in 2003. The GHS applies to all chemicals and mixtures of chemicals, but excludes pharmaceuticals, food additives, cosmetics and pesticide residues in food. Pesticides are thus included in the GHS and their classification and labelling should in principle follow its provisions. The GHS establishes classification criteria for physical, health and environmental hazards, along with associated hazard communication elements, notably symbols, signal words, and hazard statements for use on labels.

The hazard classification of the GHS refers principally to the hazards arising from the intrinsic properties of the pesticide. The GHS is not intended to harmonize risk assessment procedures and risk management decisions. However, the GHS does accept that countries may choose a risk-based approach to classification, in particular for consumer products.

The harmonized elements of the GHS can be seen as a collection of "building blocks" from which to form a regulatory approach. Countries are not obligated to cover all GHS classes and categories in order to be considered consistent with the GHS, just as current regulatory systems do not cover all GHS hazards. For instance, for pesticide labelling the physical hazard "explosives" in the GHS is not relevant as no pesticides are explosive. However, for those effects that are covered, it is expected that countries will consistently apply GHS criteria for classification and require GHS hazard communication elements.

1.4. The need for harmonization

The Code of Conduct provides the foundation for the harmonization of the pesticide regulatory process in the region. Greater cooperation among countries in the region through information exchange and pesticide harmonization is strongly encouraged by the Code of Conduct. The Code of Conduct calls on the governments to promote advantages of harmonization and cooperate with each other towards harmonization of pesticides regulations system as mentioned in Article 6.1.5 of the Code:

> **" The Governments should,** promote the advantages of, and cooperate with other governments in, the establishment of harmonized (regionally or by groups of countries) pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards, and where possible incorporate these standards into national or regional legislation".

At ASEAN level, the first serious efforts of the pesticide regulatory authorities towards harmonization of pesticide regulatory system began at the workshop on pesticides regulatory harmonization for ASEAN countries in 2002 in Thailand. The aim of the workshop was to assess the desire and needs for harmonization of the pesticide regulatory process among the participating countries. Regulators from seven participating ASEAN countries expressed strong interest in working towards achieving pesticide regulatory harmonization. At the second workshop in 2003 in Kuala Lumpur, the government representatives at that workshop expressed the need for assistance in the form of a FAO-TCP Project to realize the harmonization efforts due to lack of resources and expertise in the region. Without this intervention, countries in the region that have expressed the desire to harmonize their pesticide regulatory process would find it very difficult to achieve this objective. This assistance would provide the necessary technical inputs and impetus to countries in the region to work together more closely in the area of pesticide management in support of sustainable agricultural development.

One of the priority areas identified for harmonization in ASEAN countries through the FAO-TCP Project is pesticide labelling requirements. The importance of harmonized classification and labelling of pesticides is fundamental for sound pesticide management practice in the region. A harmonized classification and labelling system would not only facilitate the exchange of information between regulators, but would also lower the cost of registration of pesticide as all countries will follow the same classification and labelling system.

SECTION 2: LABEL CONTENTS

The purpose of the label is to provide the user with all the essential information about the product and how to use it safely and effectively. The exact content of a label is primarily subject to national regulations, however, it should be harmonized with these guidelines. With these regulations in mind, the minimum information on the label should be able to provide the user with the following information:

- how to identify it is a registered product;
- what is in the container;
- the hazard it represents;
- associated safety information;
- directions for use; and
- supplier identification.

Consistence with the requirements of the FAO Guidelines on Good Labelling Practice for Pesticides (1995), it is therefore crucial for the countries in Southeast Asia to make the following label elements as a harmonized requirement in pesticide labelling in this region:

2.1. Information to identify the product

a) Product trade name

b) Product category (e.g. herbicide, insecticide, fungicide, etc.)

c) Type of formulation (name and code according to the International Formulation Coding System, please refer Annex 1 for the list)

d) Active ingredient name (ISO common name should be used, or in the absence use IUPAC or name as approved by the authority)

e) Active ingredient content (this should normally be expressed as "contains *X* g a.i. per kg" (for solids, viscous liquids, aerosols or volatile liquids) or "contains *X* g a.i. per liter" (for other liquids). The content may also be expressed as percentage weight/weight (%W/W). For microbial pesticides the content normally be expressed as I.U. per mg)

f) Name of any dangerous co-formulants (e.g. solvents, etc.)

g) Net contents (this should be expressed in metric units (e.g. liter, gram, kilogram, which can be abbreviated to l, g and kg) unless the country does not use, or only partly uses, metric units. In such situations, local units should take precedence, but metric units should also be given)

h) Batch number

i) Registration or approval number assigned by the Pesticides Registration Authority

j) Name, address and telephone number of the registrant

2.2. Hazard and safety information

k) Hazard symbol(s)

All health, environmental and physical hazard symbols appropriate for the hazard category should be printed on the colour band of the label and the hazard symbols must be placed close to the signal word and hazard statements.

With regard to health hazard symbols, if after classification, more than one hazard symbol is called for, precedence for their allocation may apply. For instance, if the skull and crossbones apply, the exclamation mark should not appear on the label. Similar precedence applies to health hazard and corrosive symbols, where an exclamation mark should not

appear on the label if health hazard and corrosive symbols are already allocated. For further specific advice on precedence for hazard symbols, reference to GHS documents should be made.

l) Signal word

Depending on the hazard category, the signal word "Danger" or "Warning" should appear on the colour band of the label close to hazard symbols. The principle of precedence also applies for signal words. If the signal word "Danger" applies, the signal word "Warning" should not appear on the label.

m) Hazard statement(s)

Depending on the hazard category, appropriate hazard statements should appear on the colour band of the label close to the hazard symbols and signal word.

All assigned hazard statements should appear on the label. The regulatory authority may choose to specify the order in which they appear.

n) Colour band

Depending on the hazard category, all label must display the hazard colour band assigned to the pesticide and the colour band must be at least 10 percent of the label height that runs from the left to the right of the lowest part of the label. Only hazard symbols, signal word, hazard statements and safety pictograms may be printed on the colour band.

o) Safety statements

If appropriate, the following general category of safety statements should be stated at the most appropriate place of the label to warn the user of the potential hazard of the pesticide:

- General precautionary statements or warnings
- Product specific precautionary statements or warning
- Relevant protective clothing
- Precaution when handling the concentrate
- Precaution before, during and after application
- Environmental and non-target organisms precautions
- A warning against the reuse of containers and instructions for the safe disposal or decontamination of the product and used containers.

Please refer to Annex 2 for the standardized safety and precautionary statements recommended by FAO.

p) Safety/Advice pictograms

The use of safety/advice pictograms (other than mandatory hazard symbols) in reinforcing the safety and precautionary statements should be encouraged and if space is not a constraint, the pictograms may be placed on the colour band.

If safety/advice pictograms are to be used, the standardized pictograms as recommended by FAO/CropLife (GIFAP) should be used (Please refer to Annex 3).

q) First aid and medical advice

Labels should carry first aid and medical advice, where relevant. Additional information regarding symptoms, special tests and antidotes may be added, where appropriate, for particular products.

2.3. Use instructions

r) Directions for use

The directions for use on the label must clearly indicate how, when and where the product can be legally used with maximum efficiency and safety. Practical advice must be included on:

- How to mix and apply the product, and rate of use;
- When to use the product (including timing and frequency of application) or when not to use the product (e.g. during the flowering period of the crop);
- Where to use the product: crops, targets pests, areas;
- Any limitations, such as susceptible crops or varieties, weather conditions, application equipments, etc.;
- Withholding periods and pre-harvest intervals;
- Compatibility with other products, where appropriate;
- Resistance prevention and management information.

Please refer to Annex 4 for the standardized pre-harvest interval (PHI) and pre-slaughtering interval (PSI) statements recommended by FAO.

2.4. Other relevant information

s) Product or user category

If the pesticide is classified by product or user categories (e.g. professional users, domestic users, licensed users, restricted use products), its product or user category should therefore appear on the label.

t) Good agricultural practice statements (Some example of standardized GAP statements are given in Annex 5).

u) Date of manufacture/formulation (Actual date of manufacture).

v) Expiry date or similar statement such as the shelf-life (month/year).

SECTION 3: DESIGNING A LABEL

This section considers the practical aspects of good, clear label design and layout, how to check individual labels and the use of pictograms. Examples of different labels layout are given in order to show a clear application of the principles of good labelling. It is recommended that these example labels are referred for guidance not only by the authority but also by the industry who submit the proposed label for evaluation by the authority. It is a desirable principle to be harmonized, but not essential.

3.1. Layout of information on the label

Layout should be considered before a proof is prepared. Labels may have one, two, three or more panels. Examples of how to structure the different labels are given as follows. An actual example of a one panel label layout is shown in *Annex 6*.

One panel layout

(Information on product identification, safety information and use instructions)
1. Product trade name
2. Product use category
3. Formulation type
4. Active ingredient name
5. Active ingredient content
6. Registration number as assigned by the authority
7. Name, address and telephone number of registrant
8. Net contents
9. Batch number
10. Manufacturing/formulation date
11. Expiry date (optional)
12. Directions for use (in table form)
13. Withholding period (pre-harvest interval or pre-slaughtering interval)
14. Re-entry period
15. Safety statements (precautionary statements and warning phrases)
16. Good Agricultural Practice (GAP) statements
17. First aid instructions
18. Symptoms of poisoning
19. Medical treatments/advice to doctors

Two panel layout

In this case, the main panel would contain the information needed to identify the product, and provide the key information on summary of uses, safety precautions and hazard symbol. The second (ancillary) panel would contain the rest of the essential information, such as directions for use, warning phrases, etc. An actual example of a two panel label layout is shown in *Annex 7*.

Main panel (Information on product identification)	Second panel (Safety information and use instructions)
1. Product trade name 2. Product use category 3. Formulation type 4. Active ingredient(s) name 5. Active ingredient(s) content 6. Registration number as assigned by authority 7. Name and address of registrant 8. Batch number 9. Net contents 10. Manufacturing/Formulation date 11. Expiry date (optional)	12. Directions for use (in table form) 13. Withholding period (pre-harvest interval and pre-slaughtering interval) 14. Re-entry period 15. Safety statements (precautionary and warning) 16. Good Agricultural Practice (GAP) statements 17. First aid instructions 18. Symptoms of poisoning 19. Medical treatment/advice to doctors

Three panel layout

If label size allows, the three panel layout shown below is suggested. The main panel would need to identify the product with other essential information, while the two other panels can be separately devoted to safety and instructions for use. An actual example of a three panel label layout is shown in *Annex 8*.

Ancillary panel (Safety information)	Main panel (Information on product identification)	Ancillary panel (Use instructions)
12. Safety statements (precautionary and warning) 13. Good Agricultural Practice (GAP) statements 14. First aid instructions 15. Symptoms of poisoning 16. Medical treatment/advice to doctors	1. Product trade name 2. Product use category 3. Formulation type 4. Active ingredient(s) name 5. Active ingredient(s) content 6. Registration number as assigned by authority 7. Name and address of registrant 8. Batch number 9. Net contents 10. Manufacturing/formulation date 11. Expiry date (optional)	17. Directions for use (in table form) 18. Withholding period (pre-harvest interval and pre-slaughtering interval) 19. Re-entry period

3.2. Labels for small packs/supplementary leaflets

The increasing use of small packs to suit smallholder users can present problems with labelling due to the limited space available for text. However, if local or national regulations permit, information can be printed on a separate extension or attached leaflet. When using a supplementary leaflet, always ensure:

- On the *label* include the instruction "*Read the leaflet before using the product*".
- The use of a separate or attached leaflet is permitted by the relevant local/national regulation. Leaflet must be firmly attached to product container so that it stays with the product through sale and use.
- Key information on the label is repeated in the packaging leaflet.

An example for separation of information on label and packaging leaflets is given below.

<table>
<tr><th>Label</th><th colspan="2">Packing leaflet</th></tr>
<tr><td rowspan="2">1. Product trade name
2. Product use category
3. Formulation type
4. Active ingredient name
5. Active ingredient content
6. Registration number
7. Name, address and telephone number of registrant
8. Net contents
9. Batch number
10. Manufacturing/formulation date
11. Expiry date (optional)
12. Directions for use (in table form)
13. Withholding period (pre-harvest interval or pre-slaughtering interval)
14. Re-entry period
15. Safety statements (precautionary statements and warning phrases)
16. Good Agricultural Practice (GAP) statements
17. First aid instructions
18. Symptoms of poisoning
19. Medical treatments/advice to doctors</td><td>(Use instructions)</td><td>(Safety information)</td></tr>
<tr><td>1. Product trade name
2. Directions for use
3. Re-entry period
4. Pre-harvest interval
5. Legal responsibility of manufacturer</td><td>1. Safety statements (precautionary statements and warning phrases)
2. Good Agricultural Practice (GAP) statements
3. First aid instructions
4. Symptoms of poisoning
5. Medical treatments/ advice to doctors</td></tr>
<tr><td>"Before using product, read leaflet"</td><td colspan="2">"Before using product, read the label"</td></tr>
</table>

3.3. Dual/multi-language labels

Where the label is required to be printed in more than one language, each language should ideally have its own complete label. Translations must convey the same meanings in each language. Only in extremely rare circumstances will there be sufficient space on a single label for two or more complete sets of information in separate languages. This shortage of space can be overcome by having the primary language on the container label and other languages on an attached leaflet. If possible, key safety information in all required languages should be on the label firmly attached to the container.

3.4. Style and wording of text

3.4.1. Print size and style

It is recommended that all safety text should be at least 8-point, and that all other text should be at least 6-point. Highlighting with bold letters is more effective than using capitals. The followings should be avoided:

- Italics, except for Latin names
- Vertical or diagonal text
- Overprinting illustrations

3.4.2. Effective use of space

Since space is usually at a premium on most labels, one way of gaining space, and thus enabling a larger print size to be used, is to reduce text by avoiding unnecessary information, keeping sentences short and precise, and generally making the text as economical as possible, whilst retaining all essential information. The following guidance may be used:

- To reduce white space (that part of the label which is not printed on).
- Reduce long sentences and long words to shorter ones, provided the meaning is not lost.
- Remove any non-essential information, such as overly technical descriptions of the activity of a product, or simplify these to a few words.
- Tabulate information on rates of use, volumes, etc.

3.5. Use of colour

Red is a generally accepted warning colour and should be used only to highlight warning phrases, or for hazard symbols and safety and precaution statements. For best contrast and easy reading, the text on labels should be mainly black on a plain white background. The following colour combinations may also be considered:

- Black on yellow
- Green on white
- White on blue

On leaflets and brochures, colour will generally enhance attractiveness. Showing things in their true colour will increase understanding. Important parts of drawings can be emphasized by contrasting colours. But beware – too many, or too intense, colours can distract from the intended message.

SECTION 4: HAZARD/RISK CLASSIFICATION

Besides providing necessary information to the user on how to use a product effectively for the intended purposes, another important function of the label is to warn the user of the **hazard** of the pesticide and, where possible, of the **risk** of its specific use. The Code of Conduct defines both hazard and risk.

- Hazard means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).
- Risk is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.

So the risk of using a pesticide in a specific situation is a function of the hazard of the pesticide and the degree of exposure in that situation. Even a highly hazardous pesticide will present a low risk when exposure is very low or absent.

Three types of hazards or risks are generally shown on the pesticide label:

- Physical hazards (e.g. flammability, corrosiveness)
- Health hazards (e.g. acute toxicity, skin irritation)
- Environmental hazards (e.g. for aquatic organisms, depletion of ozone layer)

In principle, the pesticide product or pesticide formulation, as it is being offered for distribution, sale or use, should be classified, and this would take into account the properties of the solvents, adjuvants or other co-formulants in addition to the active ingredient. However, in some cases, classification will only be based on the active ingredient.

To be able to communicate a hazard or risk effectively, the pesticide needs to be classified according to its hazards and/or risks. The hazard classifications proposed here are based on the GHS and in these guidelines, only those classification are presented as far as they are relevant for pesticide labelling as follows:

- Hazard symbol
- Signal word
- Hazard statement

However, the classification criteria and procedures are not discussed here. These can be found in the relevant chapter of the GHS or in other cited references.

4.1. Physical hazards

The physical hazard classification recommended for pesticide labels follows the GHS in terms of classification criteria and label elements (hazard symbol, signal word and hazard statement). Nevertheless, not all physical hazards described in the GHS are relevant to pesticides, because in most cases substances would not be authorized by the authority as a pesticide if they would pose such hazards (e.g. explosive substances or self-reactive substances).

Only eight out of sixteen physical hazards classification recommended under the GHS are relevant for pesticide labelling and they are:

- Flammable gases
- Flammable aerosols
- Gas under pressure
- Flammable liquids

- Substances or mixtures which, in contact with water, emit flammable gases
- Oxidizing liquids
- Oxidizing solids
- Corrosive to metal

Please refer to *Annex 9* for the classification of physical hazard that are likely relevant for pesticide label and are crucial to be harmonized in Southeast Asia. Reference should be made to the relevant chapter of GHS if label elements are needed for other physical hazards.

4.2. Health hazards/risks

The Code of Conduct, in its Article 6 on regulatory and technical requirements, stipulates that governments should "conduct risk evaluations and make risk management decisions based on all available data or information, as part of the registration process. The preference for risk assessment over hazard assessment is also reflected in the FAO/WHO pesticide registration guidelines, because risk assessment takes into account the level of exposure to the pesticide.

The GHS, on the other hand, is based on an assessment of the intrinsic hazardous properties of the chemicals involved, without assessing levels of exposure. This is justifiable in the case of acute (immediate) health hazards, which may occur after short exposure to (often) a relatively large amount of a pesticide (e.g. splashes during mixing or loading, accidental spills of the concentrated product, leaking spray equipment). In such cases, the intrinsic hazard of a pesticide will to a large extent reflect risk.

However, for chronic health hazards, which may only occur after repeated and/or long-term exposure to a pesticide, the intrinsic hazard of the pesticide may overestimate actual risk. The GHS therefore accepts that risk-based labelling can be applied by the competent authority to the chronic health hazards of chemicals in the consumer product setting.

For the purpose of these guidelines, pesticides are considered as consumer products from the moment they are distributed, sold or used. Therefore, for chronic health hazards, labelling may be based on risk assessment. However, it is also recognized that carrying out risk assessments which are appropriate for local conditions may not always be feasible in Southeast Asia, and it may not be possible either to extrapolate risk assessments carried out elsewhere in a scientifically sound manner. In such cases, hazard-based labelling may be the only option also for chronic health hazards.

The label elements recommended by the GHS and FAO/WHO for the various health hazard categories that are crucial to be harmonized in Southeast Asia are provided in *Annex 10*. For acute toxicity, in addition to hazard symbols, signal word and hazard statements, each hazard category will also be assigned a specific colour band.

4.3. Environmental hazards/risks

As in the case for health aspects, for the environmental aspects of pesticides a full risk assessment is preferred over a hazard assessment as the basis for classification on the product label. Environmental risk is determined to a large extent by the level of exposure to the pesticide in addition to its intrinsic toxicity. The GHS, however, stipulates that classification of environmental aspects should always be done on the basis of a hazard classification. The option to use risk-based classification for environmental aspects does not exist in the GHS.

Furthermore, the GHS at present only classifies aquatic hazards and hazards to the ozone layer. No other environmental components or non-target organisms are covered. Please refer to *Annex 11* for the environmental hazard classifications that are crucial to be harmonized in Southeast Asia.

Traditionally, in pesticide registration, environmental risks are assessed for a much wider range of environmental aspects, such as persistence in soil and water, leaching to groundwater, bioaccumulation potential, risk to birds, mammals, honey bees, soil organisms, etc. Since those environmental aspects are not yet classified under GHS, an appropriate safety and precautionary statements as recommended (under Section 2.2(o)) should therefore be used to indicate other environmental hazard/risks on the label.

Annex 1

INTERNATIONAL FORMULATION CODING SYSTEM

The following is the list of formulation types and their international codes as introduced by CropLife (GIFAP) and now adopted by FAO. These two letter codes should be used on labels.

CODE	FORMULATION TYPE
AE	Aerosol generator
AL	Other liquids to be applied undiluted
AP	Other powder to be applied undiluted
BR	Briquette
CB	Bait concentrate
CP	Contact powder
CS	Capsule suspension
DC	Dispersible concentrate
DP	Dustable powder
DS	Powder for dry seed treatment
DT	Tablet for direct application
EC	Emulsifiable concentrate
EG	Emulsifiable granule
EO	Emulsion, water in oil
EP	Emusifiable powder
ES	Emulsion, for seed treatment
EW	Emulsion, oil in water
FS	Flowable concentrate for seed treatment
FU	Smoke generator
GA	Gas
GE	Gas generating product
GL	Emulsifiable gel
GR	Granule
GS	Grease
GW	Water soluble gel
HN	Hot fogging concentrate
KK	Combi-pack solid/liquid
KL	Combi-pack liquid/liquid
KN	Cold fogging concentrate
LN	Long-lasting insecticidal net

CODE	FORMULATION TYPE
LS	Solution for seed treatment
MC	Mosquito coil
ME	Micro-emulsion
OD	Oil dispersion
OF	Oil miscible flowable concentrate (oil miscible suspension)
OL	Oil miscible liquid
OP	Oil dispersible powder
PA	Paste
PR	Plant rodlet
PS	Seed coated with a pesticide
RB	Ready-to-use-bait
SC	Suspension concentrate
SD	Suspension concentrate for direct application
SE	Suspo-emulsion
SG	Water soluble granules
SL	Soluble concentrate
SO	Spreading oil
SP	Water soluble powder
SU	Ultra-low volume (ULV) suspension
TB	Tablet
TC	Technical material
TK	Technical concentrate
UL	Ultra-low volume (ULV) liquid
VP	Vapour releasing product
WG	Water dispersible granules
WP	Wettable powder
WS	Water dispersible powder
WT	Water dispersible tablet
XX	Others

Annex 2

EXAMPLES OF FAO RECOMMENDED SAFETY AND PRECAUTIONARY STATEMENTS

GENERAL SAFETY STATEMENTS

1. "KEEP LOCKED UP OUT OF REACH OF CHILDREN"
2. "READ THE LABEL BEFORE USE"
3. "DO NOT smoke, eat or drink when using this product"
4. "WHEN WORKING WITH OR PREPARING PRODUCT:"
   - "AVOID: dust, smoke, vapour, spray mist, gas, contact with mouth, skin or eyes"
   - "WEAR: synthetic rubber gloves, apron, overalls, rubber boots, goggles, face shield, head cover or hood, dust mask or respirator"
5. "IF CONTAMINATION OCCURS"
   - "Immediately take off heavily splashed or contaminated clothing"
   - "Wash affected parts thoroughly with plenty of water"
6. "AFTER USE:"
   - "Wash hands and exposed skin before eating, drinking or smoking
   - "Wash overalls, boots, hat and protective clothing thoroughly, especially inside the gloves"

CARE, USE AND DISPOSAL OF CONTAINERS

1. "Keep tightly closed in original labelled container".
2. "DO NOT re-use this container for any other purpose".
3. "Keep labelled container in a safe place away from food, children and animals".
4. "Remove used container and dispose of safely".
5. "Empty containers must be triple rinsed, puncture/broken and dispose of safely".
6. "Empty containers must be washed out".
7. "Mark baits 'POISON' and place out of reach of children and animals".

CARE OF EQUIPMENT, AREA TO BE TREATED AND OCCUPANTS OF TREATED AREAS

1. "Keep application equipment in good condition, free from leaks and external contamination".
2. "DO NOT use where food could be contaminated".
3. "Remove or cover food before treatment".
4. "Before treatment remove livestock, birds, fish, domestic pets".
5. "DO NOT apply directly to livestock, feed or water tanks".
6. "Before treatment, cover or remove any equipment used with food or drink".
7. "DO NOT apply to clothing, bedding or fabrics".
8. "Warn occupants against placing food onto treated surfaces".
9. "Keep animals/birds/domestic pets/children away from premises or materials being fumigated or ventilated after fumigation".

Annex 3

FAO/CROPLIFE (GIFAP) PICTOGRAMS ON A PESTICIDE LABEL

Type	Pictogram and message		
Storage pictograms	 Keep locked away and out of reach of children		
Advice pictograms	 Wear gloves	 Wear face shield	 Wear boots
	 Wear protection over nose and mouth	 Wear respirator	
	 Wear overalls	 Wear apron	 Wash after use
Warning pictograms	 Dangerous/harmful to animals		

Annex 4

EXAMPLES OF FAO RECOMMENDED WITHHOLDING PERIOD STATEMENTS

1. "DO NOT apply later than . . . days/weeks before harvest".

2. "DO NOT treat/apply to stock later than . . . days before slaughter".

3. "Dangerous/harmful to livestock. Keep livestock out of treated areas for at least . . . hours/days after last treatment".

4. "Keep unprotected persons out of treated areas for at least . . . days after last treatment".

5. "Keep animals/children out of treated areas for . . . days/hours after last treatment".

6. "DO NOT use treated product for human consumption for . . . hours/days after last treatment".

7. "DO NOT process into food for . . . days after last treatment".

8. "For use on following crops only, with stated minimum interval between last application and harvesting".

9. "Ventilate treated areas/buildings for . . . hours before re-occupation".

Annex 5

EXAMPLES OF FAO RECOMMENDED GAP STATEMENTS

ANIMALS AND THE ENVIRONMENT

1. "Dangerous/harmful to domestic animals and wildlife".

2. "Keep stock out of treated areas until all the weeds are dead".

3. "Do not contaminate lakes, rivers, ponds or streams with waste chemical or used container".

FOOD AND ANIMAL FEEDSTUFFS

1. "DO NOT apply to food or feed crops".

2. "DO NOT apply to surfaces coming into contact with food".

3. "Keep away from food, drink and animal feeding stuffs".

TREATED SEED

1. "This seed has been chemically treated – do not handle unnecessarily".

2. "DO NOT re-use sacks for food or animal feed".

3. "DO NOT use treated seed for food or animal feed".

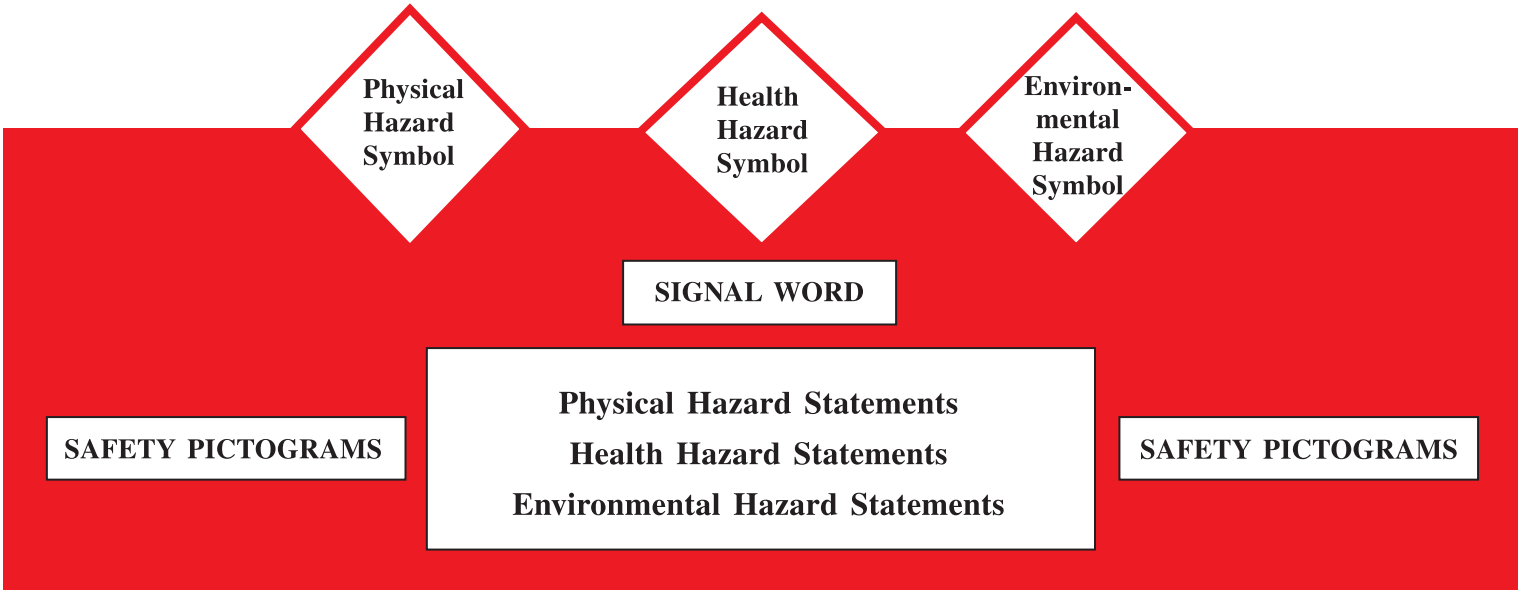
Annex 6

EXAMPLE OF LAYOUT OF ELEMENTS IN ONE PANEL LABEL

1. Product trade name
2. Product category
3. Type of formulation
4. Active ingredient(s) name
5. Active ingredient(s) contents
6. Registration number
7. Name, address and telephone number of registrant
8. Batch number
9. Net contents
10. Manufacturing/formulation date
11. Expiry date (optional)
12. General safety statements

13. Directions for use in table form
14. Withholding period (pre-harvest interval or pre-slaughtering interval)
15. Re-entry periods

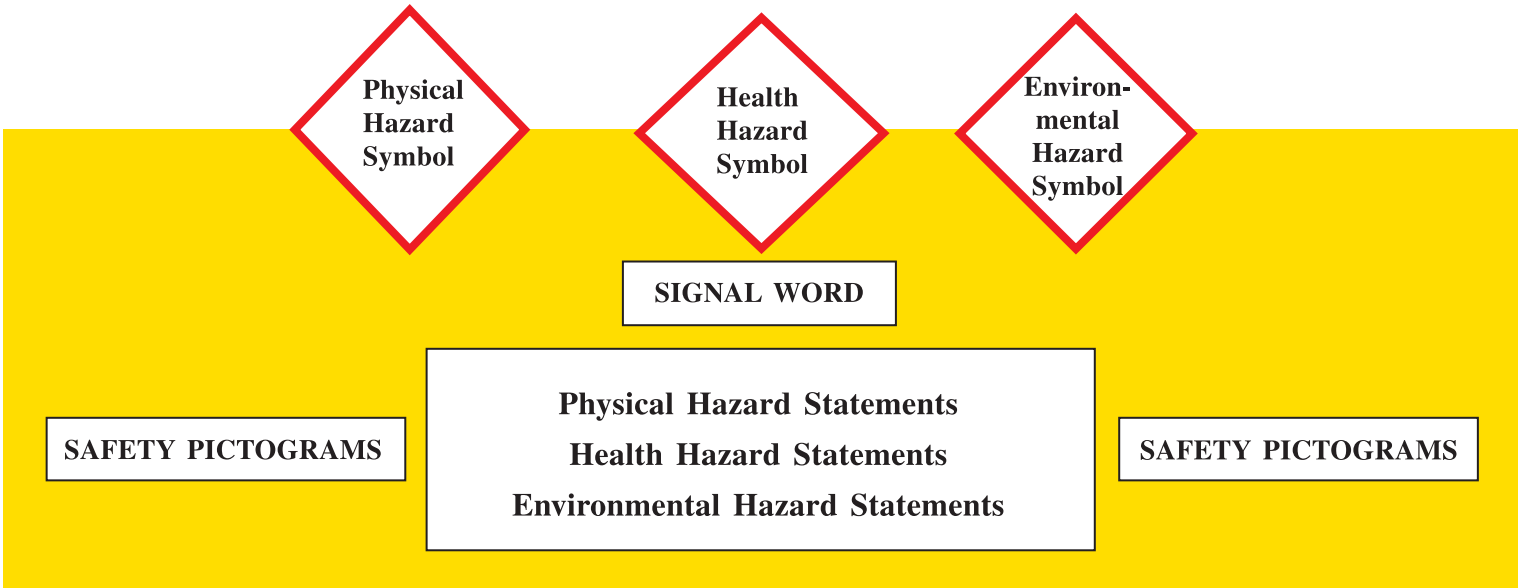
16. Safety statements (Precautionary statements and warning phrases)
17. Good Agricultural Practice (GAP) statements
18. First aid instructions
19. Symptom of poisoning
20. Medical treatment/advice to doctors



Annex 7

EXAMPLE OF LAYOUT OF ELEMENTS IN TWO PANEL LABEL

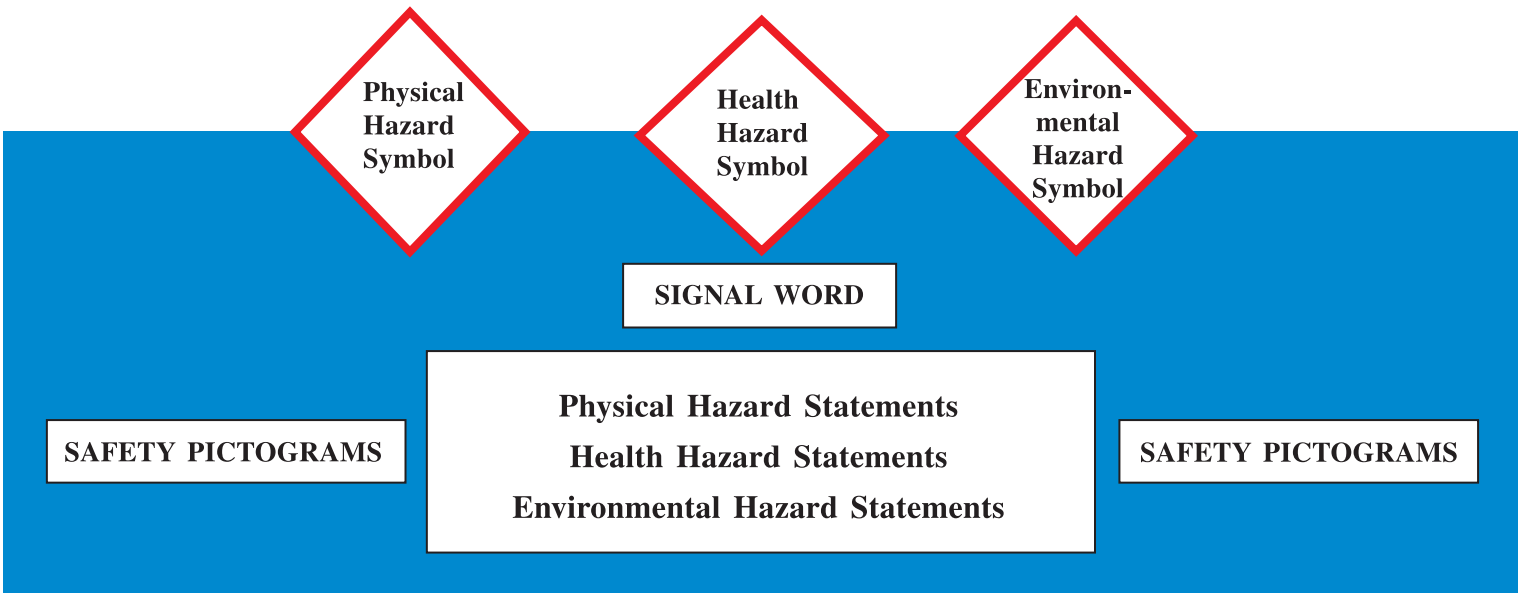
Main panel (Information on product identification)	Ancillary panel (Safety information and use instructions)
1. Product trade name 2. Product category 3. Type of formulation 4. Active ingredient(s) name 5. Active ingredient(s) contents 6. Registration number 7. Name, address and telephone number of registrant 8. Batch number 9. Net contents 10. Manufacturing/Formulation date 11. Expiry date (Optional) 12. General Safety Statements	13. Directions for use in table form 14. Withholding period (pre-harvest interval or pre-slaughtering interval) 15. Re-entry periods 16. Safety statements (Precautionary statements and warning phrases) 17. Good Agricultural Practice (GAP) statements 18. First aid instructions 19. Symptoms of poisoning 20. Medical treatment/advice to doctors



Annex 8

EXAMPLE OF LAYOUT OF ELEMENTS IN THREE PANEL LABEL

Ancillary panel (Safety information)	Main panel (Information on product identification)	Ancillary panel (Use instructions)
16. Safety statements (Precautionary statements and warning phrases)	1. Product trade name	13. Directions for use in table form
17. Good Agricultural Practice (GAP) statements	2. Product category	14. Withholding period (pre-harvest interval or pre-slaughtering interval)
18. First aid instructions	3. Type of formulation	15. Re-entry periods
19. Symptoms of poisoning	4. Active ingredient(s) name	
20. Medical treatment/ advice to doctors	5. Active ingredients content	
	6. Registration number	
	7. Name, address and telephone number of registrant	
	8. Batch number	
	9. Net contents	
	10. Manufacturing/ Formulation date	
	11. Expiry date (Optional)	
	12. General Safety Statements	



Annex 9

CLASSIFICATION OF PHYSICAL HAZARDS

This annex contains label elements of physical hazards relevant to pesticides which are recommended for pesticide labelling in Southeast Asia. These label elements (symbols, signal words and hazard statements) follow GHS. The detailed classification criteria for the different hazard categories however are not included here, as they can be found in the Annex 2 (Classification and Labelling Summary Tables) of GHS.

1. Flammable gases

A flammable gas is defined by the GHS as, *"a gas having a flammable range with air at 20 ºC and a standard pressure of 101.3 kPa"*. The label elements for the different hazard categories of flammable gases are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Extremely flammable gas**
Category 2	(No symbol)	**Warning**	**Flammable gas**

2. Flammable aerosols

Aerosols, considered to mean aerosol dispensers, are described by the GHS as, *"any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state"*. The label elements for the different hazard categories of flammable aerosols are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Extremely flammable aerosol**
Category 2		**Warning**	**Flammable aerosol**

3. Gases under pressure

Gases under pressure are defined by the GHS as, *"gases which are contained in a receptacle at a pressure not less than 280 kPa at 20 ºC or as a refrigerated liquid"*. The label elements for the different hazard categories of gases under pressure are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Compressed gas		**Warning**	**Contains gas under pressure; may explode if heated**
Liquefied gas		**Warning**	**Contains gas under pressure; may explode if heated**
Refrigerated liquefied gas		**Warning**	**Contains refrigerated gas under pressure; may explode if heated**
Dissolved gas		**Warning**	**Contains gas under pressure; may explode if heated**

4. Flammable liquids

A flammable liquid is defined by GHS as,“ *liquid having a flashpoint of not more than 93 ºC”*. The label elements for the different hazard categories of flammable liquids are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Extremely flammable liquid and vapour**
Category 2		**Danger**	**Highly flammable liquid and vapour**
Category 3		**Warning**	**Flammable liquid and vapour**
Category 4	(No symbol)	**Warning**	**Combustible liquid**

5. Substances and mixtures which, in contact with water, emit flammable gases

Substances or mixtures which, in contact with water, emit flammable gases are defined by the GHS as: *"solid or liquid substances or mixtures which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities"*. The label elements for the different hazard categories of substances or mixtures which, in contact with water, emit flammable gases are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**In contact with water releases flammable gases which may ignite spontaneously**
Category 2		**Danger**	**In contact with water releases flammable gases**
Category 3		**Warning**	**In contact with water releases flammable gases**

6. Oxidising liquids

An oxidizing liquid is defined by the GHS as, *"a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material"*. The label elements for the different hazard categories of oxidizing liquids are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**May cause fire or explosion; strong oxidizer**
Category 2		**Danger**	**May intensify fire; oxidizer**
Category 3		**Warning**	**May intensify fire; oxidizer**

7. Oxidising solids

An oxidizing solid is defined by the GHS as, *"a solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material"*. The label elements for the different hazard categories of oxidizing solids are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**May cause fire or explosion; strong oxidizer**
Category 2		**Danger**	**May intensify fire; oxidizer**
Category 3		**Warning**	**May intensify fire; oxidizer**

8. Corrosive to metals

A substance or mixture that is corrosive to metals is defined by the GHS as, *"a substance or mixture which by chemical action will materially damage, or even destroy, metals"*. The label elements for the different hazard categories of flammable gases are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Warning**	**May be corrosive to metals**

CLASSIFICATION OF HEALTH HAZARDS

This annex contains label elements of health hazards pesticides recommended for pesticide labelling in Southeast Asia. These label elements (symbols, signal words and hazard statements) follow GHS. Except for acute toxicity, detailed classification criteria for the different hazard categories however are not included, as they can be found in the Annex 2 (Classification and Labelling Summary Tables) of GHS.

1. Acute toxicity

As defined by the GHS, *"acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours"*.

In addition to the GHS (symbol, signal word and hazard statement and classification criteria), each hazard category will also be assigned a different colour band as recommended by FAO/WHO. The label elements for the different hazard categories for acute toxicity are as follows.

Hazard category	**Classification criteria (LD_{50} mg/kg/bw)**	**Label elements**		
		Symbol and signal word	**Hazard statement**	**Colour band***
Category 1	***Oral*** *<5* ***Dermal*** <50	 **Danger**	**Fatal if swallowed** ***or*** **Fatal in contact with skin** ***or*** **Fatal if inhaled**	PMS red 199 C
Category 2	***Oral*** *5-50* ***Dermal*** *50-200*	 **Danger**	**Fatal if swallowed** ***or*** **Fatal in contact with skin** ***or*** **Fatal if inhaled**	PMS red 199 C
Category 3	***Oral*** *50-300* ***Dermal*** *200-1 000*	 **Danger**	**Toxic if swallowed** ***or*** **Toxic in contact with skin** ***or*** **Toxic if inhaled**	PMS Yellow C

Hazard category	Classification criteria (LD_{50} mg/kg/bw)	Label elements		
		Symbol and signal word	Hazard statement	Colour band*
Category 4	***Oral*** *300-2 000* ***Dermal*** *1 000-2 000*	 **Warning**	**Harmful if swallowed** ***or*** **Harmful in contact with skin** ***or*** **Harmful if inhaled**	PMS Blue 293 C
Category 5	***Oral*** *2 000-5 000* ***Dermal*** *2 000-5 000*	(No symbol)	**Maybe harmful if swallowed** ***or*** **Maybe harmful in contact with skin** ***or*** **Maybe harmful if inhaled**	PMS Green 347 C

* PMS is a colour matching system, mainly used by printers, devised and patented by Pentone Inc, USA

2. Skin corrosion or irritation

As defined by the GHS, *"**Skin Corrosion** means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours; and Skin Irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours"*. The label elements for the different hazard categories of skin corrosion/irritation are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Causes severe skin burns and eye damage**
Category 2		**Warning**	**Causes skin irritation**
Category 3	(No symbol)	**Warning**	**Causes mild skin irritation**

3. Serious eye damage or eye irritation

As defined by the GHS, "*Serious eye damage* means the production of tissue damage in the eye, or serious physical decay of vision, following the application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application; and *Eye irritation* means the production of changes in the eye following the application of a test substance to the anterior surface of the eye, which are fully reversible within 21 days of application". The label elements for the different hazard categories of serious eye damage/eye irritation are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Causes serious eye damage**
Category 2A		**Warning**	**Causes serious eye damage**
Category 2B	(No symbol)	**Warning**	**Causes eyes irritation**

4. Respiratory sensitizer

As defined by the GHS, *"A **respiratory sensitizer** means a substance that induces hypersensitivity of the airways following inhalation of the substance"*. The label elements for the different hazard categories of respiratory sensitization are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**May cause allergy or asthmatic symptoms or breathing difficulties if inhaled**

5. Skin sensitizer

As defined by the GHS, *"A **Skin sensitizer** means a substance that will induce an allergic response following skin contact"*. The label elements for the different hazard categories of skin sensitisation are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Warning**	**May cause an allergic skin reaction**

6. Germ cell mutagenicity

As defined by the GHS, *"chemicals which cause germ cell mutagenicity are those chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. A mutation means a permanent change in the amount or structure of the genetic material in a cell"*. The label elements for the different hazard categories of germ cell mutagenicity are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1A		**Danger**	**May cause genetic defects** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 1B		**Danger**	**May cause genetic defects** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 2		**Warning**	**Suspected of causing genetic defects** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***

7. Carcinogenicity

As defined by the GHS, *"a carcinogen means a chemical substance or a mixture of chemical substances which induces cancer or increases its incidence"*. The label elements for the different hazard categories for carcinogenicity are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1A		**Danger**	**May cause cancer** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 1B		**Danger**	**May cause cancer** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 2		**Warning**	**Suspected of causing cancer** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***

8. Reproductive toxicity

As defined by the GHS, *"reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring"*. The label elements for the different hazard categories for reproductive toxicity are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1A		**Danger**	**May damage fertility or the unborn child** ***(state specific effect if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 1B		**Danger**	**May damage fertility or the unborn child** ***(state specific effect if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 2		**Warning**	**Suspected of damaging fertility or the unborn child** ***(state specific effect if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Additional category for effects on or via lactation	(No symbol)	(No signal word)	**May cause harm to breast-fed children**

9. Specific target organ toxicity – single exposure

As defined by the GHS, *"specific target organ toxicity means non lethal target organ toxicity arising from a single exposure. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed by other health hazard classes in the GHS, are included"*. The label elements for the different hazard categories for specific target organ toxicity – single exposure are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Causes damage to organs** ***(or state all organs affected, if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 2		**Warning**	**May cause damage to organs** ***(or state all organs affected, if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 3		**Warning**	**May cause respiratory irritation;** ***or*** **May cause drowsiness and dizziness**

10. Specific target organ toxicity – repeated exposure

As defined by the GHS, *"specific target organ toxicity means non lethal target organ toxicity arising from repeated exposure. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed by other health hazard classes in the GHS, are included"*. The label elements for the different hazard categories for specific target organ toxicity – repeated exposure are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**Causes damage to organs through prolonged or repeated exposure** ***(or state all organs affected, if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***
Category 2		**Warning**	**May cause damage to organs through prolonged or repeated exposure** ***(or state all organs affected, if known)*** ***(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)***

11. Aspiration hazard

As defined by the GHS, *"aspiration means the entry of a liquid or solid chemical product into the trachea and lower respiratory system directly through the oral or nasal cavity, or indirectly from vomiting. Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration"*. The label elements for the different hazard categories for aspiration hazard are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Danger**	**May be fatal if swallowed and enters airways**
Category 2		**Warning**	**May be harmful if swallowed and enters airways**

CLASSIFICATION OF ENVIRONMENTAL HAZARDS

This annex contains label elements of environmental hazards pesticides recommended for pesticide labelling in Southeast Asia. These label elements (symbol, signal word and hazard statement) follow GHS. The detailed classification criteria for the different hazard categories however are not included, as they can be found in the Annex 2 (Classification and Labelling Summary Tables) of GHS.

1. Acute hazards to the aquatic environment

As defined by the GHS, *"**Acute Aquatic Toxicity** means the intrinsic property of a substance to be injurious to an organism in a short-term aquatic exposure to that substance; and **Acute Hazard** means the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical"*. The label elements for the different hazard categories for acute aquatic hazard are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Warning**	**Very toxic to aquatic life**
Category 2	(No symbol)	(No signal word)	**Toxic to aquatic life**
Category 3	(No symbol)	(No signal word)	**Harmful to aquatic life**

2. Long-term hazards to the aquatic environment

As defined by the GHS, *"**Chronic Aquatic Toxicity** means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism; and **Long-Term Hazard** means the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment"*. The label elements for the different hazard categories for chronic aquatic hazard are as follows:

Hazard category	Label elements		
	Symbol	Signal word	Hazard statement
Category 1		**Warning**	**Very toxic to aquatic life with long lasting effects**
Category 2		(No signal word)	**Toxic to aquatic life with long lasting effects**
Category 3	(No symbol)	(No signal word)	**Harmful to aquatic life with long lasting effects**
Category 4	(No symbol)	(No signal word)	**May cause long lasting harmful effects to aquatic life**

3. Hazards to the ozone layer

A substance is hazardous to ozone layer if it has Ozone Deleting Potential (ODS), and GHS defines ODS as *"the ratio of integrated perturbations to the total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11"*. The label elements for the hazard category for ozone layer hazard are as follows:

Hazard category	**Label elements**		
	Symbol	**Signal word**	**Hazard statement**
Category 1		**Warning**	**Harms public health and the environment by destroying ozone in the upper atmosphere**

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ATTACHMENT 5

GUIDELINES FOR PESTICIDE RESIDUE MONITORING SYSTEM

ABBREVIATIONS

ASEAN	Association of Southeast Asian Nations
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	Gas Chromatograph
GC-MS	Gas Chromatograph-Mass Spectrophotometer
GLP	Good Laboratory Practices
HPLC	High Performance Liquid Chromatography
ILC	Inter-Laboratory Calibration
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC-MS	Liquid Chromatograph-Mass Spectrophotometer
LOD	Limit of Detection
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
OECD	Organization of Economic Cooperation and Development
PRMS	Pesticide Residue Monitoring System
RSD	Relative Standard Deviation
SEA	Southeast Asia
SOP	Standard Operation Procedure
WHO	World Health Organization

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SECTION 1: INTRODUCTION

1.1. Scope

This document provides guidance for establishing a pesticide residue monitoring system among Southeast Asian countries in line with international agreements and guidelines.

1.2. Objectives and purpose

The objective of these guidelines is to facilitate harmonization of residue monitoring in agriculture products among Southeast Asian countries in order to protect human health and the environment, as well as to enhance inter- and intra-regional trade.

These guidelines will help the Southeast Asian countries in establishing a harmonized pesticide residue monitoring system (PRMS) in line with international agreements, standards and guidelines for implementation.

1.3. Background and justification

In an effort to raise food production, many countries in Southeast Asia have significantly increased the use of pesticides. The increase can have adverse effects on risk to human health and the environment, due to their non-judicious use or poor quality and possible also due to residues of highly toxic pesticides. In view of growing concerns for food safety, there is a need to monitor and analyse pesticide residues in agricultural commodities in different agro-ecological regions of Southeast Asian countries. These guidelines were developed as a part of the FAO-TCP Project to assist the countries in Southeast Asia towards achieving pesticide regulatory harmonization.

These guidelines have been developed after taking into account the provisions of international agreements and food standards (such as Codex) and the International Code of Conduct on the distribution and use of pesticides established by FAO and other relevant guidelines established in the area of pesticide residue monitoring.

As such, there is no available international guideline for a pesticide residue monitoring system. The requirements of a pesticide residue monitoring system are classified into two broad categories, namely general and specific requirements. The Codex, OECD, EU, and FAO guidelines that are related to the various aspects of a pesticide residue monitoring programme such as sampling, sample preparation, analytical pesticide standards, analytical methods, validation of testing protocols, analytical calibration, reporting of results and interpretation of results have been taken into consideration for drafting the specific requirements.

The draft guidelines for some specific requirements such as selection of commodity/pesticide combination, assignment of food commodities to laboratories, selection of geographical location and source of sample collection have been finalized taking into account the monitoring programmes conducted by various organizations such as US-FDA, European Union and the national monitoring programme in India.

1.4. Definitions and terms

Pesticide: Pesticide means any substance or mixture of substances, or micro-organisms including viruses, intended for repelling, destroying or controlling any pest, including vectors of human or animal disease, nuisance pests, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as insect or

plant growth regulators, defoliant, desiccants, agents for setting, thinning or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term also includes pesticide synergists and safeners, where they are integral to the satisfactory performance of the pesticide.

Pesticide residues: Residue means any specified substances in or on food, agricultural commodities or animal nourish resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental) as well as known uses of the chemical.

Good Agricultural Practice (GAP): The use of pesticides includes the officially recommended or nationally authorized uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Withholding period/waiting period/pre-harvest interval: Minimum permissible time between the last application of a pesticide to a crop (including pasture) and harvesting, for human consumption or grazing with livestock. The minimum permissible time between the final application of a pesticide to an animal and collection of eggs or milks, or slaughter, for human consumption.

Maximum Residue Limit (MRL): Maximum Residue Limit (MRL) means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff.

MRL exceedance: Since the MRLs are closely linked to the Good Agricultural Practices (GAP), MRLs may be exceeded in cases where the GAP was not respected, such as the use of unauthorised pesticides, the use of pesticides not authorised for a specific crop; the use of an authorised pesticide on a crop for which an authorisation was granted, but not in compliance with the authorised GAP (e.g. higher application rate or shorter pre-harvest intervals), spray drift from neighbouring treated fields; contamination of crops at storage or packaging level and unfavourable weather conditions associated with a reduced residue degradation rate.

MRL compliance/non-compliance: If the residue level measured in a sample, taking into account the measurement uncertainty exceeds the legal MRL, the sample is considered as non-compliant and the competent national authorities shall apply the sanctions applicable to the infringements. The sanctions must be effective, proportionate and dissuasive. A sample is compliant with the MRL if the measured value does not exceed the MRL.

Reporting level (RL): The Reporting Level is lowest level at which residues will be reported. It may represent the practical LOQ, or it may be above that level.

Sample: One or more units selected from a population of units, or a portion of material selected from a larger quantity of material. A representative sample is intended to be representative of the lot, the bulk sample, the animal, etc., in respect of its pesticide residue content and not necessarily in respect of other attributes.

Lot: A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc. A suspect lot is one which, for any reason, is suspected to contain an excessive residue. A non-suspect lot is one for which there is no reason to suspect that it may contain an excessive residue.

Sampling officer: A person trained in sampling procedures and, where required, authorised by the appropriate authorities to take samples.

Sampling: The procedure used to draw and constitute a sample.

Sampling strategy: The sampling strategy is the approach used to select the units of the target population subject to control. Implementation of an efficient, targeted sampling strategy would result in a higher percentage of positive findings and non-compliant results.

Surveillance sampling: samples are collected without any particular suspicion towards a particular producer, consignment, etc. Surveillance samples could be targeted for specific food products and countries, but the selection of samples is randomized.

Enforcement sampling: Samples are taken if there is suspicion about the safety of a product and/or as a follow up of violations previously found. The selection of samples is not randomized and therefore cannot be considered representative of the food available in the market. Follow up or enforcement sampling is directed to a specific grower/producer and to a specific consignment.

Sample size: The number of units, or quantity of material, constituting the sample.

Bulk sample: For products other than meat and poultry, the combined and well mixed aggregate of the primary samples taken from a lot. For meat and poultry, the primary sample is considered to be equivalent to the bulk sample.

Primary sample: One or more units taken from one position in a lot.

Laboratory sample: The sample sent to, or received by, the laboratory. A representative quantity of material removed from the bulk sample.

Analytical sample: The material prepared for analysis from the laboratory sample, by separation of the portion of the product to be analysed and then by mixing, grinding, fine chopping, etc., for the removal of analytical portions with minimal sampling error.

Multi-residue method: Analytical method, which measures a number of pesticide residues simultaneously.

Recovery: Recovery is the amount measured as a percentage of the amount of analyte(s) (active substance and relevant metabolites) originally added to a sample of the appropriate matrix, which contains either no detectable level of the analyte or a known detectable level. Recovery experiments provide information on both precision and trueness (bias), and thereby the accuracy of the method.

Selectivity (specificity): Selectivity refers to the extent to which the method can be used to determine particular analytes in mixtures or matrices without interferences from other components of similar behaviour. Some regulatory authorities use the term specificity to refer to selectivity.

Calibration: Calibration refers to the ability of a detection system to produce an acceptable, well defined, correlation between the instrumental response and the concentration of the analyte in the sample. The analyte concentration to be measured should be within the defined dynamic range of the instrument.

Repeatability: Repeatability refers to the closeness of agreement between mutually independent test results obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time. The repeatability (within-run effect) includes contributions from any part of the procedure that varies within a run, including contributions from normal gravimetric and volumetric errors, heterogeneity of the test material, and other procedural errors during the analysis.

Reproducibility: Reproducibility refers to the closeness of agreement between independent results obtained with the same method on identical test material obtained but under different conditions. Within-

laboratory or intra-laboratory reproducibility or single-laboratory reproducibility (run effect) contributes to day-to-day variations in the analytical system due to changes of analyst, batches of reagents, recalibration of instruments and laboratory environment (e.g. temperature changes). Between-laboratory or inter-laboratory or multiple-laboratory reproducibility (laboratory effect) contributes to additional variations such as variations in calibration standards, differences between local interpretations of a protocol, differences in equipment or reagent source, or environmental factors, such as differences in average climatic conditions.

Limit of detection (LOD): The limit of detection of an analytical procedure is the lowest amount of an analyte in a sample that can be detected but not necessarily quantitated as an exact value. At the limit of detection, a positive identification can be achieved with reasonable and/or previously determined confidence in a defined matrix using a specific analytical method. The LOD is typically not required. However, if needed for a refined assessment (or some other purpose), an explanation of how the LOD was derived should be provided.

Limit of quantitation (LOQ): Limit of quantitation (LOQ), defined from a regulatory perspective as the lowest concentration tested at which an unambiguous identification of the analyte can be proven and at which an acceptable mean recovery with an acceptable relative standard deviation (RSD) is obtained, also referred to as the limit of determination (LOD) or Lowest Limit of Method Validation. The LOQ should be low enough to achieve the intended purpose of the method. From an analytical perspective, 6-10 times the standard deviation of the noise provides an estimate of the LOQ, which is then verified by the fortification experiments.

Measurement uncertainty: Measurement uncertainty is a quantitative indicator of the confidence in the analytical data and describes the range around a reported or experimental result within which the true value can be expected to lie within a defined probability (confidence level). Uncertainty ranges must take into consideration all sources of error.

Quality assurance (QA): An integrated system of activities involving quality planning, quality control, quality assessment, quality reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality control (QC): The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical. For analytical chemistry, it is a set of procedures applied to an analytical methodology to demonstrate that the analysis is in control.

Laboratory accreditation: Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/measurements, based on third party assessment following an international standard.

SECTION 2: GENERAL REQUIREMENTS

2.1. Designation of authority

The national government will designate an appropriate authority, which shall be responsible for overall coordination, management and implementation of the residue monitoring system in the country. In countries, where more than one governmental agency is involved in residue monitoring (such as agriculture, food and environmental sector agencies), an apex body or umbrella organization representing the relevant sectoral agencies will be constituted. Its role is to give advice to the national government in framing policies on pesticide residue risk management, to guide relevant sectoral agencies for proper implementation of residue monitoring plans and to coordinate all the activities relevant to residue monitoring performed by the relevant sectoral agencies.

2.2. Organization/management structure of PRMS

The designated national authority and/or apex body, which will be assisted by programme director(s) in implementation of residue monitoring plan(s) of the country. The national authority and/or apex body (representing sectoral agencies) will designate national referral laboratory(ies) for residue determination in the event of requirement for validation of testing protocols. The national authority and/or apex body (representing sectoral agencies) will also accredit the testing laboratories in the region for undertaking regular analysis of samples referred for residue determination. The regional officers/area inspectors will assist the programme director in implementation of residue monitoring programme within the region/area of jurisdiction.

2.3. Role and responsibilities

The PRMS requires a clear definition of the responsibilities of each participating individual or group. Preparation of an organization chart and its inclusion in the study protocol would be appropriate. Participants of PRMS may include the study director and principal investigators in the sample collection and analytical phase, as well as sponsor representative, technical consultants, residue analytical laboratories and quality assurance specialists. The study director is responsible for implementation of all the technical aspects of the study and is the primary contact point for all pesticide information involved.

A workshop/group meeting of all the stake holders involved in the monitoring study must be conducted prior to the implementation of the study so that everyone involved is made aware that once the data collection and reporting process has been agreed, each laboratory will be expected to follow it without modification and reinforce the lines of communication. It is the responsibility of everyone involved in the study to observe the necessity for rapid communication and solution of operational problems arising during the study from field and laboratories.

2.4. Infrastructure/equipment facilities

2.4.1. Laboratory

The laboratory and its facilities will be designed in such a way that there is a minimum chance of contamination and provide maximum personal safety. Separate rooms may be assigned for sample receipt and storage, sample preparation, extraction and clean-up and instrumentation used in the analysis step.

Receiving samples, their storage and processing for residue analysis should be handled only in areas assigned for the respective work. All basic principles of good laboratory practices (GLP) such as smoking, eating, drinking or application of cosmetics should not be permitted in the working area.

2.4.2. Equipment and supplies

The laboratory will have all appropriate analytical equipment like gas chromatograph with ECD/NPD/FPD/Mass detectors; liquid chromatography with UV/VIS/PDA/Post column derivatization/Mass detectors; spectrophotometers, analytical balances, sample preparation equipments like homogenizer, centrifuges, oven, sonicator, refrigerator, etc. The equipments will be serviced and calibrated regularly and a record of all servicing/repairs must be maintained for every such item of equipment. The laboratory will require reliable supply of electricity and water. Equipment used must be suitable for the specific purpose.

2.5. Human resources and training requirements

Residue analysis consists of a chain of procedures which are readily understood by a trained chemist. Staff will be fully trained to be experienced and competent for the proper handling of apparatus and analytical equipment for trace level analysis in the range µg/kg and will have the required professional qualifications. In addition, each analyst using the standard operating procedure (SOP)/method for the first time should be able to demonstrate that they can use the method within the expected performance parameters established during method validation prior to analysis of samples. They will have an understanding of the principles of pesticide residue analysis and the requirements of quality assurance (QA) and quality control (QC) systems. They will understand the purpose of each stage in the method, the importance of following the SOP/methods exactly as described. They will also be trained in the evaluation and interpretation of the data that they produce. A record of training and experience will be kept for all laboratory staff.

2.6. Operational plan

The national government will implement an operational plan(s) for monitoring pesticide residues in agricultural and food products. The operational plan should clearly specify the national policies; regulatory provisions; scope and broad objectives of the implementation of plan; expected outputs; work plan of activities and duration; management of plan (identification of sectoral agency/institutional support); resource requirements (human, equipment, financial resources); training; funding agency; target areas/regions of the country; target pesticides/commodities; stages of residues monitoring (production, marketing, consumer, port levels); methods of sampling and residue determination; reporting of activities; and auditing and review of activities of plan.

2.7. Designation of national reference laboratory

There will be at least one national reference laboratory for every participating country. These laboratories shall be responsible for:

- coordinating the technical progress of the participating laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned
- collect and analyse monitoring data from the participating laboratories
- organizing the plan for monitoring residues
- periodically conducting inter-laboratory comparison (ILC)
- ensuring that participating laboratories follow the limits and standards laid down
- assist participating laboratories in obtaining accreditation
- organizing training programmes for the participating laboratories

2.8. Documentation

Monitoring systems generate a large volume of data that should be manipulated, stored, and retrieved in a systematic manner. Monitoring data will be stored for later comparison and analysis. Personnel will be suitably trained for handling the monitoring data.

2.9. Quality assurance

Quality Assurance (QA) is a most important aspect of any technical study. It is particularly crucial in PRMS because a large number of participants from different laboratories that are widely separated geographically is involved.

2.10. Accreditation of laboratory

The laboratories should be accredited according to ISO/IEC 17025 as per the scope of the laboratory. Audit of the pesticide residue laboratory should be conducted to examine the establishment, implementation and effectiveness of the quality management system as per ISO/IEC 17025.

SECTION 3: SPECIFIC REQUIREMENTS

3.1. Selection of commodity-pesticide combination

Under the PRMS, commodities can be chosen from all the food items available to consumers. The final selection of commodities might consider such factors as (a) the portion of the consumer diet represented by the commodity, (b) whether the commodity makes up an appreciable part of the diet of consumers, and (c) if the commodity is likely to be available throughout the geographical coverage area and the study period. Because the conclusions that can be reached from the study depend critically on the choice of commodities, involvement of relevant regulatory agencies should be considered. Agreement on the choice of commodities by such authorities will ensure that the study and its outcome will be acceptable for regulatory purposes.

The PRMS offers a means to evaluate actual dietary exposures to residues of the pesticides which have been banned in the past and might be entering into the country through the imported food, and will also be monitored in the study. PRMS is intended to investigate not just one but several different pesticides of the same or different chemical classes. In addition, such a study might include pesticides not used in the country but for which import tolerances exist. PRMS offers a means to evaluate actual dietary exposures to residues of such pesticides. The combinations to be monitored will take care of the common interest of member countries.

Factors that shall be considered in planning commodity-pesticide combination to be monitored include:

- food consumption pattern
- volume of individual commodities of domestic food produced for trade and of imported food
- commodity/pesticide information from recently generated residue data from monitoring study
- with sufficient understanding about environmental mobility of contaminants, indicator foods can be used
- pesticide use pattern on major crops
- legislation on the use of pesticides (authorized/unauthorized) to be monitored
- persistence and toxicity of the pesticide(s) of concern
- monitoring of banned pesticides
- data from a survey or surveillance study or any other problematic situation (rejection of exports/import)
- health problems related to contaminated food

3.2. Priority categorisation of commodities

Based on the evidence of incidence of pesticide residue problems and dietary importance, the commodities are classified into:

i. Low priority level
- no evidence of exceeded MRL or non-approved pesticide problems on this commodity
- low incidence of residues expected on the commodity
- commodity is not a major component of the diet for any population consumption group

The low priority commodities may be examined only every five or more years.

ii. Medium priority level
- some evidence of non-compliance
- residues expected on the commodity
- the commodity is consumed regularly by consumer populations
- or rapid popularity has promoted influx of commodity from a range of new sources

The medium priority commodities may be examined only every 2 to 3 years.

iii. High priority level

- recent evidence of non-compliance
- evidence that intakes could exceed the acute reference dose of residues on this commodity and/or commodity is of significant dietary importance by some consumer groups e.g. milk and infants

The high priority commodities needs to be examined annually

The major groups of pesticides that are an integral part of the pesticide residue monitoring programme are insecticides (organochlorine; organophosphorous; synthetic pyrethroids; carbamates; neonicotinoids etc.); herbicides; fungicides, growth regulators and other new generation pesticide molecules.

3.3. Assignment of food commodities to laboratories

Under the PRMS, the participating laboratories will be required to analyse a large number of different kind of food commodities. Therefore, the analytical workload will have to be divided among the participating laboratories.

Analytical results are generally more reliable and consistent if the same laboratory analyses the same matrix over a period of time so that chemists get familiar with the analytical routine and would have more experience with how the method works on the specific product to be analyzed. Therefore, assigning more number of samples of same matrix to a single analytical laboratory is preferable than to assign equal distribution of same commodity to all the participating laboratories.

The relative difficulty of analysis of each matrix and the capacities and capabilities of the laboratories will be considered before assigning the number of samples and matrix. Difficult matrices will be divided among the laboratories or assigned to the laboratory that is considered most capable of dealing with the difficulties.

The matrices will be divided on the basis of the food commodity that one laboratory might analyze only fruit, another only leafy vegetables and brassica, and a third only marine products so that each laboratory would face only one set of problems in analyzing only one type of matrix. The technical programme of PRMS for analysis should be designed in such a way that no one laboratory should be overburdened.

3.4. Sampling plan

The protocol will include in detail the strategy for collection of the chosen commodities, i.e., the sampling plan. All aspects of the sampling plan will be consistent with the study objectives, including the number of individual commodities to be collected, the geographical area from which they will be drawn, the type of sample collection points from which commodities will be collected, and the frequency and period over which collection will be done. Therefore, the sampling plan has to be statistically designed and well thought out in respect of the study objectives and how the study results will satisfy the PRMS. Once the target number of samples are defined, the frequency of collection and the number of samples to be collected on each collection date are determined, based on an overall total sampling period of 1 year. The sampling plan is designed in such a way that it accommodates the workload at the analytical laboratories smoothly.

Samples will be collected and transported during the week to overcome problems with shipping samples over the weekend. In the monitoring study, samples collection points are based on the statistical design which including the geographic location, size and location of the collection point. In addition, secondary stores are designated in case when a commodity is not available at the identified collection point.

3.4.1. Selection of geographical location

Factors that shall be considered in planning the geographical locations for sample collection include analysis of areas where high levels of pesticide residues have been reported, areas with extreme pesticide usage, origin of imported food and intensive growing areas of the commodities.

3.4.2. Source of sample collection

Sample collection points for the domestic samples shall be as close as possible to the point of production in the distribution system such as farm gate; market yard-wholesale; retail outlets or stored grain samples in warehouses.

Import samples shall be collected at the point of entry into the country. The export samples may be classified into two categories, namely, samples produced exclusively for export and samples collected from markets and exported.

3.4.3. Sample collection personnel

The monitoring plan will have the provision of a sufficient number of trained manpower to cover the wide range of geographical area for timely collection of samples. Detailed written instructions in the form of a standard operating procedure (SOP) and sample collection information like where to collect, how much to collect, how to package and label the samples, where and how to ship the samples will be available. The personnel must fill all the details in the sample collection form. The personnel will be informed, trained and educated regarding sample collection.

3.4.4. Sampling

Laboratory samples should be taken in accordance with Directive 2002/63/EC. Where it is impractical to take primary samples randomly within a lot, the method of sampling must be recorded.

3.4.5. Laboratory sample transportation

Samples must be transported under appropriate conditions to the laboratory in clean containers and robust packaging. Polythene bags, ventilated if appropriate, are acceptable for most samples but low-permeability bags (e.g. nylon film) must be used for samples to be analysed for residues of fumigants. Samples of commodities pre-packed for retail sale should not be removed from their packaging before transport. Very fragile or perishable products (e.g. ripe raspberries) may have to be frozen to avoid spoilage and then transported in “dry ice” or similar, to avoid thawing in transit. Samples that are frozen at the time of collection must be transported without thawing. Samples that may be damaged by chilling (e.g. bananas) must be protected from both high and low temperatures.

Rapid transportation to the laboratory, preferably within one day, is essential for samples of most fresh products. The condition of samples delivered to the laboratory should approximate to that acceptable to a discerning purchaser, otherwise samples should normally be considered unfit for analysis.

Samples must be identified clearly and permanently, in a way that prevents inadvertent loss or confusion of labelling. The use of marker pens containing organic solvents should be avoided for labelling bags containing samples to be analysed for fumigant residues, especially if an electron capture detector is to be used.

3.4.6. Sample preparation and processing prior to analysis

On receipt, each sample must be allocated a unique reference code by the laboratory. Sample preparation, sample processing and sub-sampling to obtain analytical portions should take place before visible

deterioration occurs. This is particularly important when the analytical result is to be used to assess consumer intake. Canned, dried or similarly processed samples should be analysed within the stated shelf life. Sample preparation must be in accordance with the definition of the commodity and the part(s) to be analysed (Codex CAC/GL 41-1993).

Sample processing and storage procedures should be demonstrated to have no significant effect on the residues present in the analytical sample. Where there is evidence that comminution (cutting and homogenisation) at ambient temperature has a significant influence on the degradation of certain pesticide residues, it is recommended that samples are homogenised at low temperature (e.g. frozen and/or in the presence of "dry ice"). Where comminution is known to affect residues (e.g. dithiocarbamates or fumigants) and practical alternative procedures are not available, the test portion should consist of whole units of the commodity, or segments removed from large units. For all other analyses, the whole laboratory sample (in most cases 1-2 kg) needs to be comminuted. All analyses should be undertaken within the shortest time practicable, to minimise sample storage. Analyses for residues of very labile or volatile pesticides should be started, and the procedures involved in potential loss of analyte completed, on the day of sample receipt. In any case, sample comminution should ensure that the sample is homogeneous enough so that sub-sampling variability is acceptable. If this is not achievable, the use of larger test portions should be considered.

If a single analytical portion is unlikely to be representative of the analytical sample, replicate portions must be analysed, to provide a better estimate of the true value.

3.5. Analytical pesticide standards

All laboratories require pesticide reference standards of known and acceptably high purity. Analytical standards will be available for all parent compounds for which the laboratory is monitoring samples, as well as those metabolites that are included in MRLs.

3.5.1. Identity, purity and storage of standards

"Pure" standards of analytes will be of known purity and each must be uniquely identified and the date of receipt recorded. They will be stored at low temperature, preferably in a freezer, with light and moisture excluded, i.e. under conditions that minimise the rate of degradation. Under such conditions, the supplier's expiry date, which is often based on less stringent storage conditions, may be replaced, as appropriate for each standard, by a date allowing for storage up to 10 years. The pure standard may be retained if its purity is shown to remain acceptable. The purity will be checked by the allocated time after which a "pure" standard may be retained if its purity is shown to remain acceptable and a new expiry date is allocated. Ideally, the identity of freshly acquired "pure" standards will be checked if the analytes are new to the laboratory.

3.5.2. Preparation and storage of stock standards

When preparing stock standards (solutions, dispersions or gaseous dilutions) of "pure" standards of analytes and internal standards, the identity and mass (or volume, for highly volatile compounds) of the "pure" standard and the identity and amount of the solvent (or other diluents) must be recorded. The solvent(s) will be appropriate to the analyte (solubility, no reaction) and method of analysis. Moisture will be excluded during equilibration of the "pure" standard to room temperature before use and concentrations will be corrected for the purity of the "pure" standard.

Not less than 10 mg of the "pure" standard will be weighed up to 5 decimal place in the electronic balance. The ambient temperature should be that at which the glassware is calibrated, otherwise preparation of the standard should be based on mass measurement. Stock standards will be labelled properly, allocated an expiry date and stored at low temperature in the dark in containers that prevent any loss of solvent

and entry of water. Weight of the flask should be recorded. If there is any change in weight during storage, the same should be made up with the same solvent. Currently available data show that stock standards of the large majority of pesticides in toluene and acetone are stable for at least 5 years in the freezer when stored in tightly closed glass containers.

3.5.3. Preparation, use and storage of working standards

When preparing working standards, a record must be kept of the identity and amount of all solutions and solvents employed. The standards must be labelled properly, allocated an expiry date and stored at low temperature in the dark in containers that prevent any loss of solvent and entry of moisture. After the equilibration to room temperature, solutions must be re-mixed and a check made to ensure that no analyte remains undissolved, especially where solubility at low temperatures is limited.

3.5.4. Testing and replacement of standards

Whenever any standard is used beyond its expiry date, its stability will be verified. Existing stock and working solutions may be tested against newly prepared solutions by comparing the detector responses obtained from appropriate dilutions of individual standards or mixtures of standards. The purity of an old "pure" standard may be checked by preparing a new stock standard and comparing the detector responses obtained from freshly prepared dilutions of old and new stock standards.

The means from at least three replicate measurements for each of two solutions (old and new) will not normally differ by more than ±10 percent. The mean from the new solution is taken to be 100 percent. If the mean response of the old standard differs by more than ±10 percent from the new, storage time or conditions must be adjusted as necessary on the basis of the results and will be checked against a second solution independently prepared from the first one. The use of an internal standard may reduce the number of replicate injections required to achieve a ±10 percent difference.

3.6. Analytical methods

The results of monitoring analysis are strongly influenced by the analytical methods used to analyse the samples. Also the scope of the analytical methods (the list of pesticides included in the analytical methods) has an impact on the number of positive findings in samples analysed. If the analytical method applied is not capable of detecting a certain pesticide active substance applied to the crop – or its toxicologically relevant metabolites or break-down products – the sample may be considered by mistake to be free of pesticide residues. Additionally, if the analytical method is not sensitive enough, the pesticide will not be detected in cases where the residue occurs at a low concentration. Therefore, the results reported by reporting countries have to be considered in the context of the analytical methods used.

The analytical methods used today to detect and quantify pesticide residues in food commodities fall into two general types of method: multi-residue and single-residue methods. Multi-residue methods are able to analyse a high number of different pesticide residues in the same sample. However, certain pesticides and metabolites cannot be included in multi-residue methods because of their physical-chemical properties (e.g. acidic or polar chemicals). In these cases, single-residue methods have to be applied. Single-residue methods allow the identification and quantification of only one or a few pesticide residues in one sample. Since these two types of method require a comparable processing time per sample, multi-residue methods are usually preferred over single-residue methods, as they are generally more efficient in terms of cost/benefit ratio. Single-residue methods are therefore preferable for samples where previous experience shows that it is likely that residues of the pesticides in question will be found.

3.6.1. Extraction conditions and efficiency

Test portions should be disintegrated thoroughly during extraction to maximise extraction efficiency, except where this is known to be unnecessary or inappropriate (e.g. for determination of fumigants or

surface residues). Temperature, pH, etc., must be controlled if these parameters affect extraction efficiency, analyte stability or solvent volume. To improve the extraction efficiency of low moisture containing commodities (cereals, dried fruits), it is recommended to add water to the samples before extraction is carried out. However, the time between addition of water and extraction should be controlled in order to avoid any significant losses of pesticides.

3.6.2. Extract concentration and dilution to volume

Great care must be exercised when extracts are evaporated to dryness, as trace quantities of many analytes can be lost in this way. A small volume of high boiling point solvent may be used as a "keeper" and the evaporation temperature should be as low as practicable. Frothing and vigorous boiling of extracts, or dispersion of droplets, must be avoided. A stream of dry nitrogen or vacuum centrifugal evaporation is generally preferable to the use of an air stream for small-scale evaporation, as air is more likely to lead to oxidation or to introduce water and other contaminants. Where extracts are diluted to a fixed volume, accurately calibrated vessels of not less than 1 ml capacity should be used and further evaporation avoided. Analyte tability in extracts should be investigated during method validation. Storage of extracts in a refrigerator or freezer will minimise degradation but potential losses at the higher temperatures of an autosampler rack should not be ignored.

3.6.3. Contamination

Samples must be separated from each other, and from other sources of potential contamination, during transit to, and storage at, the laboratory. This is particularly important with surface or dusty residues, or with volatile analytes. Samples known, or thought, to bear such residues should be doubly sealed in polythene or nylon bags and transported and processed separately.

Pest control in, or near, the laboratory must be restricted to pesticides that will not be sought as residues. Volumetric equipment, such as flasks, pipettes and syringes must be cleaned scrupulously, especially for re-use. As far as practicable, separate glassware, etc., should be allocated to standards and sample extracts, in order to avoid cross-contamination. Avoid using excessively scratched or etched glassware. Solvents used for fumigant residues analysis should be checked to ensure that they do not contain the analyte.

Where an internal standard is used, unintended contamination of extracts or analyte solutions with the internal standard, or vice versa, must be avoided.

Where the analyte occurs naturally in, or is produced from, samples (e.g. inorganic bromide in all commodities; sulphur in soil; or carbon disulfide produced from the Brassicaceae), low-level residues from pesticide use cannot be distinguished from natural levels. Natural occurrence of these analytes must be considered in the interpretation of results. Dithiocarbamates, ethylene thiourea or diphenylamine can occur in certain types of rubber articles and this source of contamination must be avoided.

3.6.4. Interference

Equipment, containers, solvents (including water), reagents, filter aids, etc., should be checked as sources of possible interference. Rubber and plastic items (e.g. seals, protective gloves, wash bottles), polishes and lubricants are frequent sources. Vial seals should be PTFE-lined. Extracts should be kept out of contact with seals, especially after piercing, by keeping vials upright. Vial seals may have to be replaced quickly after piercing, if re-analysis of the extracts is necessary. Analysis of reagent blanks should identify sources of interference in the equipment or materials used.

Interference from natural constituents of samples is frequent. The interference may be peculiar to the determination system used, variable in occurrence and intensity, and may be subtle in nature. If the interference takes the form of a response overlapping that of the analyte, a different clean-up or determination system may be required.

3.6.5. Confirmatory techniques

The development of a separate confirmatory method is not generally needed when the original method is based on mass spectrometry or another highly specific method. For example, GC/MS is considered to be highly specific for the analyte provided at least three fragment ions with an m/z ratio of greater than 100 are used for identification/quantification. The ions selected should be reported and the reasons for their selection given. In case of HPLC/MS-MS, the method is regarded as highly specific when two ion transitions have been validated. Under these prerequisites, an additional confirmatory method is not necessary. The following techniques are considered acceptable confirmatory techniques: GC/MS or LC/MS, provided that a sufficient number of ions are monitored and the reasons for their selection given; HPLC/DAD, if the UV spectrum is characteristic in samples spiked at the limit of quantitation. In this case, an UV-spectrum obtained under the conditions of the determination should be submitted. Other acceptable confirmatory techniques include an alternative chromatographic principle deviating from the original method (HPLC/GC); an alternative detection technique; derivatization (if it was not the first choice method) and significantly different chromatographic stationary or mobile phases of different selectivity. In addition, variation of partitioning and clean-up steps can also be useful for confirmation.

3.6.6. Derivatization

For analysis of some compounds, such as those with high polarity or with poor chromatographic properties, derivatization may be called for. Derivatives may be prepared prior to chromatographic analysis or as part of the chromatographic procedure (pre- or post-column). The use of derivatization methods should be fully reported and justified. The derivative should be stable and its formation reproducible.

When quantification is based on the determination of a derivative, the calibration is preferably conducted using standard solutions of that derivative, unless the derivatization step is an integral part of the detection system. If the derivative is not available as a reference standard, it should be generated within the analytical set by using the same derivatization procedure as that applied for the samples. Under these circumstances, a full justification should be given. The mean yield and precision of the derivatization step should be demonstrated where possible.

3.7. Analytical calibration

Correct calibration is dependent upon correct identification of the analyte. Residues below the Lowest Calibrated Level (LCL), if corresponding with the Reporting Limit (RL), should be considered uncalibrated, and therefore reported as <RL, whether or not a response is evident. If it is desirable to report measurable residues below the original RL and corresponding LCL, determinations must be repeated with a lower LCL. If the signal to noise ratio produced by the target LCL is inadequate (less than 6:1), a higher level must be adopted as the LCL. An additional calibration point, for example at two times the target LCL, provides a back-up LCL if there is a risk that the target LCL will not be measurable. Validation of analytical methods should include determination of recovery at the proposed RL.

Single-level calibration may provide more accurate results than multi-level calibration if the detector response is variable with time. When single-level calibration is employed, the sample response should be within ±20 percent of the calibration standard response if the MRL is exceeded. If the MRL is not exceeded, the sample response should be within ±50 percent of the calibration response, unless further extrapolation is supported by evidence of acceptable linearity of response. Where analyte is added for recovery determination at a level corresponding to the LCL, recovery values <100 percent may be calculated using a single point calibration at the LCL. This particular calculation is intended only to indicate analytical performance achieved at the LCL and does not imply that residues <LCL should be determined in this way.

3.8. Stability investigations

3.8.1. Stability of the analytes in stored extracts of the final volume

Ideally, the validation samples are analysed within 24 hours after initial extraction. Under some circumstances they may be stored longer under ambient conditions, e.g. in the autosampler or in a refrigerator, e.g. if the analyses cannot be completed within one working day. In this case, information on the storage stability of the analytes in extracts and in the final volume should be provided. If the analytes were stable under comparable conditions in similar solvent systems, any degradation during short-term storage is unlikely. The relevant information on the stability in the final or any intermediate step can be derived from the fortification experiments performed during method validation. If the recoveries in the fortified samples are within the acceptable range of 70-120 percent, stability is sufficiently proven.

3.8.2. Stability of working (fortification/calibration) solutions

If stability under controlled storage conditions has been demonstrated, the fortification and calibration solutions can be used over an extended time period. Otherwise, the solutions have to be prepared freshly on a daily basis. The duration of the stability test should reflect typical usage. In general, they are used over a periods of several days or weeks. In general, solutions are used over a periods of several days or weeks. The test conditions, e.g. appropriate solvent systems, ambient temperature or refrigerator, light/dark, should be selected to reflect usual storage conditions applied within the conduct of analyses. For testing, the stability of the stored solutions (typically in peak area or peak height) should be compared with freshly prepared fortification and/or calibration solutions. The concentrations should be chosen so that potential degradation can be observed. If no concentration dependency is observed, it is not necessary to investigate all concentrations applied. In order to obtain reliable data, at least three injections of stored and freshly prepared solutions should be compared.

3.9. Validation of testing protocols

In the Pesticide Residue Monitoring System (PRMS), the participating countries shall ensure that official samples are analyzed using methods that ensure the quality and comparability of the analytical results generated by laboratories. This will be achieved by using quality assurance systems and specifically by applying of methods validated according to common procedures and performance criteria and by ensuring traceability to common standards or standards commonly agreed upon.

To be suitable for the intended purpose, the method should meet standards for certain validation parameters. Typical validation characteristics for residue analytical methods that should be considered are recovery, selectivity (specificity), calibration, precision (repeatability, reproducibility), limit of detection (LOD), and limit of quantitation (LOQ).

3.9.1. Independent laboratory validation studies

Independent laboratory validation (ILV) studies are required for proving the suitability of established multi-residue methods. The method(s) should be suitable for the determination of all compounds included in the residue definition for compliance with the MRL. The suitability of the method(s) should be proven by appropriate experiments. At least one matrix should be independently validated – typically the most difficult target crop/commodity for which an MRL is set. One important purpose of the method could be to detect any misuse. Also any subsequent additions or modifications to the original method should be also reported.

3.9.2. Validation levels for independent laboratory validation studies

The **independent laboratory validation studies** should include fortifications at the LOQ and the MRL. If the residue levels are low, the LOQ should be 0.01-0.05 mg/kg. The selection of an appropriate LOQ depends on the analyte/matrix combination. However, the laboratories are encouraged to develop methods which allow the determination of residues at low LOQs by using state-of-the art technology. In any case where a high LOQ is selected (e.g. for difficult matrices) a full justification should be given.

3.9.3. Number of fortification experiments

Recovery data should be generated for the following fortification levels: LOQ (5 samples); 10 × LOQ or MRL, whichever is greater (5 samples); and controls (2 samples). If matrices are difficult to analyse and the expected residue levels are of minor toxicological importance (e.g. for minor uses), a reduced sample set may be acceptable. However, six samples (three at each fortification level) and one control sample are the minimum.

3.9.4. Calibration

Analytical calibration should extend over a range appropriate to the lowest and highest nominal concentration of the analyte in relevant analytical solutions. Duplicate determinations at three or more concentrations or single determinations at five or more concentrations should be performed. Raw data of calibration have to be provided with studies.

3.9.5. Minimum performance characteristics for methods

For demonstrating the suitability of the method for its purpose, information on performance characteristics should be provided.

Range of acceptable recoveries

In general, the mean recovery at each fortification level and for each commodity should be in the range given in Table 1. In certain justified cases, recoveries outside of this range will be accepted for matrices which are difficult to analyse, e.g. tobacco, hops, coffee, tea and spices, providing that precision data are acceptable, or in cases of very low concentration levels. If matrix effects are noted, recoveries may be corrected by using matrix-matched standards.

Selectivity (matrix interference)

Uncorrected recoveries and blank (control) values should be reported. Blank values in the area of analytical interest (untreated samples and procedural blanks) have to be determined from the matrices used in fortification experiments and should not be higher than 30 percent of the LOQ. If this is exceeded, detailed justification should be provided. Matrix effects such as peak suppression and enhancement can also occur with some techniques such as HPLC/MS-MS and GC. Therefore, standard solutions should be added to the final volume of an untreated sample ("quality control samples") to check for these effects.

Precision – repeatability (expressed as relative standard deviation)

The precision of the method in a validation study should be reported as the relative standard deviation (RSD) of repeatability at each fortification level. As specified above, five determinations should be made at each fortification level. In certain justified cases (e.g. in cases of difficult matrices or very low concentration levels) a higher variability may be accepted. The correlation between the concentration level and the repeatability is given in the Table 1.Values for repeatability was calculated from 0.67 × Horwitz equation:

$RSD = 2^{(1-0.5\log C)}$ where C is concentration (1 mg/kg = 10^{-6}).

Table 1: Laboratory repeatability criteria for analysis of pesticide residues

Concentration level	Repeatability (relative standard deviation)	Range of mean% recovery
≤1 µg/kg	35	50-120
>1 µg/kg ≤0.01 mg/kg	30	60-120
>0.01 mg/kg ≤0.1 mg/kg	20	70-120
>0.1 mg/kg ≤1.0 mg/kg	15	70-110
>1.0 mg/kg	10	70-110

If unacceptable variability of results is noted during validation, efforts should be made to identify and control those method parameters with a major influence on method performance (ruggedness testing). The ruggedness of an analytical method is the resistance to change in the results produced when minor changes are made from the conditions described in the procedure.

3.10. Reporting/submission of results

3.10.1. Expression of results

Results for individual analytes should be expressed as the chemical name defined by the MRL residue definition and in mg/kg. Where the MRL is a sum of metabolites, degradates or transformation products, the concentrations of these products should be expressed according to the residue definition and then added to the total residue concentration. Residues below the Reporting Limit should be reported as <RL mg/kg.

3.10.2. Calculation of results

In general, residues data do not have to be adjusted for recovery, when the mean recovery is in the range of 70-120 percent. If residues data are adjusted for recovery, then this must be stated.

Where confirmed data are derived from a single test portion (i.e. the residue does not exeed the MRL), the reported result should be that derived from the detection technique considered to be the most accurate. Where results are obtained by two or more equally accurate techniques, the mean value may be reported. Where two or more test portions have been analysed, the arithmetic mean of the most accurate results obtained from each portion should be reported. Where good comminution and/or mixing of samples has been undertaken, the RSD of results between test portions should not exceed 30 percent for residues significantly above the LOQ. Close to the LOQ, the variation may be higher and additional caution is required in deciding whether or not a limit has been exceeded.

3.10.3. Qualifying results with uncertainty data

It is a requirement under ISO/IEC 17025 that laboratories determine and make available the uncertainty associated with analytical results. To this end, laboratories should have available sufficient data derived from method validation/verification, inter-laboratory studies (e.g. proficiency tests) and in-house quality control tests, which are applied to estimate the uncertainties.

Uncertainty data should be applied cautiously to avoid creating a false sense of certainty about the true value. Estimates of typical uncertainty are based on previous data and may not reflect the uncertainty associated with analysis of a current sample. The uncertainty may be estimated using an ISO (Anonymous 1995, 'Guide to the expression of uncertainty in measurement' ISBN 92-67-10188-9) or Eurachem (EURACHEM/CITAC Guide, Quantifying Uncertainty in Analytical Measurement, 2nd edition, (http://www.measurementuncertainty.org/mu/guide/index.html) approach.

3.11. Interpretation of results

Assessment of whether or not a sample contains a violative residue is generally only a problem in cases where the level is relatively close to the MRL. The decision should take account of the results obtained from replicate test portions, together with any assessment of typical uncertainty. The possibility of residue loss or cross-contamination having occurred before, during or after sampling must also be considered.

It is common practice that pesticide analysis results are not corrected for recovery, but may be corrected if the average recovery is significantly different from 100 percent (typically if outside of the range 70-120 percent, with good precision). In those cases, the uncertainty associated with recovery correction should also be taken into account.

If required, the result should be reported together with the expanded uncertainty (U), as follows:

Result = × ± U (units), with × representing the measured value.

SECTION 4: REFERENCES

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ATTACHMENT 6

RECOMMENDATIONS FOR INFORMATION EXCHANGE ON PESTICIDE REGULATORY MATTERS

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Preface

The revised *International Code of Conduct on the Distribution and Use of Pesticides,2002 (1)* provides guidance to reduce the adverse effects of pesticides on health and the environment and to support sustainable agricultural practices. Its Article 9 **'Information Exchange'** and Article 12 **'Monitoring and observance'** of Code of Conduct address the issue of information exchange. Subsequently, the FAO *Guidelines on Monitoring and Observance of the Code of Conduct* were issued in 2006 to provide guidance on reporting and monitoring the observance of the FAO Code of Conduct, and for this purpose two types of formats were prescribed, namely regular reporting in Annex A and adhoc reporting in Annex B. Further, the WHO/FAO *Guidelines on Developing a Reporting System for Health and Environmental Incidents Resulting from Exposure to Pesticide* were issued in 2009. Under the UNEP/ FAO **Rotterdam Convention** *on Prior Informed Consent Procedures for Certain Hazardous Chemicals & Pesticides in International Trade,* which was revised in 2005. the member countries are required to notify final regulatory action in respect of certain hazardous chemicals and pesticides covered in Annex III and as well as prior informed consent procedures as per format prescribed in Annex V. Notification of regulatory actions is also covered under the Basel and Stockholm Conventions. The FAO-TCP Project on Pesticide Regulatory Harmonization implemented in 2010-11 included strengthening the existing network for information exchange among pesticide regulatory authorities in Southeast Asian countries to facilitate pesticide regulatory harmonization.

Recently, the APPPC website (www.apppc.org) was developed in close collaboration with the IPPC Secretariat and IT experts of IPP. It was launched in July 2011 and tested by the participants who attended the training workshop on information exchange through the use of the IPP Portal. The APPPC website serves as a regional platform for the exchange of information relevant to plant protection including pesticide management.

These guidelines provide general requirements for information exchange, namely a responsible authority; contact points; data protection and information security; internal/external linkages for information sharing; log-in credentials; language; authenticity and updating of information. They also provides specific requirements for information exchange such as types of information for sharing at regional, national, provincial and community levels and as well as specific formats for information sharing.

So far, no specific guidelines have been developed to provide appropriate guidance for information sharing relevant to pesticide regulatory matters except for the reporting obligations under the FAO Code of Conduct and international conventions listed above. The following parameters were identified to be crucial for information sharing among the member countries in Southeast Asia, namely designation of a responsible authority and contact, establishing specific regulations that administer information sharing as well as necessary computer and internet facilities. The following types of information are considered crucial to facilitate pesticide regulatory harmonization in this region namely, (i) pesticide regulation and registration requirements (ii) list of registered pesticides (iii) list of banned/restricted use pesticides (iv) establishment of maximum residue limits (v) notification of regulatory actions covered under the international conventions relevant to pesticide matters (vi) implementation of pesticide risk reduction programmes such as IPM (vii) health and environmental monitoring and (viii) monitoring of residues in food and environment. It is desirable to have a national information management system as a long-term strategy for sharing information at national, provincial and community levels. The guidance provided under this document will further sustain the information sharing among member countries in this region.

GUIDELINES FOR INFORMATION EXCHANGE ON PESTICIDE REGULATORY MATTERS AMONG COUNTRIES IN SOUTHEAST ASIA

1. SCOPE

This document provides guidance for information exchange on pesticide regulatory matters among countries in Southeast Asia in order to achieve harmonization in pesticide management.

2. OBJECTIVES AND PURPOSE

The main objective of these guidelines is to assist countries in Southeast Asia in facilitating expeditious information exchange related to pesticide regulatory matters, so as to achieve harmonization in pesticide management. In addition, they should strengthen existing information management system on pesticide regulatory matters at national, provincial and local levels to minimize pesticide risks.

Such information sharing on pesticide regulatory matters is seen as a vital input for harmonized pesticide management among countries in Southeast Asia, so that the pesticides registered in one country can be moved and/or transported to another country for distribution, sale and use while safeguarding human health and the environment.

3. BACKGROUND AND JUSTIFICATION

FAO has implemented a regional TCP Project on pesticide regulatory harmonization with the main objective of assisting Southeast Asian countries towards achieving harmonization in the pesticide regulatory process in line with the provisions of the FAO International Code of Conduct on the Distribution and Use of Pesticides. One of the focus area identified under this project was to strengthen the existing network for information exchange among pesticide regulatory authorities in Southeast Asian countries.

These guidelines were developed under a technical consultancy on information exchange provided under this project. They are intended to help the national governments to formalize the information exchange process related to pesticide regulatory matters leading to the development of a sustainable information management system for the expeditious exchange of information using internet facility. This would also facilitate the harmonization of pesticide management in this region.

4. DEFINITION OF TERMS

AI means active ingredient.

Banned pesticide means a pesticide for which all uses have been prohibited by final regulatory action, in order to protect human health or the environment. The term includes a pesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Contact point means an officer designated by the responsible authority for exchange of information related to pesticide regulatory matters among the participating.

IPR means intellectual property right.

Misbranded pesticide means any pesticide product is manufactured, distributed and sold in the market without confirming to the labelling requirements of registration as to the kind, grade, quality or

composition and/or that the pesticide product of one manufacturer is distributed or sold in the name of another manufacturer illegally.

Maximum Residue Limit (MRL) means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff.

Obsolete pesticides means the stocked pesticides that can no longer be used for their original purpose or any other purpose and therefore require disposal. These pesticides can no longer be used because they have been banned, deteriorated or unsuitable for their original intended use and cannot be used for another purpose or easily modified to become usable.

Participating countries means the countries participating in harmonization of pesticide registration process in Southeast Asia region under the Regional FAO-TCP Project.

PHI means pre-harvest interval. It is the time interval between when the pesticide last sprayed and the harvest of produce in the field.

Severely restricted pesticide means a pesticide for which virtually all use has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a pesticide that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Spurious pesticide means a pesticide product, which lack authenticity or validity in essence or origin and/or not genuine or false or fraudulently distributed and sold in the market.

Substandard pesticide means a pesticide product manufactured, distributed and/or sold in the market, which does not confirm with the quality standards established by the responsible authority.

Responsible authority means the government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and more generally for implementing pesticide legislation.

WTO-TRIPS Agreement means WTO-Trade Related Intellectual Property Rights Agreement.

5. GENERAL REQUIREMENTS

The countries in the Southeast Asia region will ensure that the following general requirements for information sharing on pesticide regulatory matters are met.

5.1. Designation of a responsible authority

The responsible authority will promote the establishment and strengthening of networks for information exchange on pesticides through national institutions, international, regional and sub-regional organizations and public sector groups in accordance with provisions of the FAO Code of Conduct on Pesticides.

The responsible authority will facilitate, coordinate and collaborate information sharing on pesticide regulatory matters using the internet. The responsible authority will establish a dynamic information management system and network for sharing information on pesticide regulatory matters at the national, provincial and local levels and manage a national website and pesticide databases.

5.2. Contact point for information exchange

The responsible authority will establish and designate a contact point for information exchange related to pesticide regulatory matters. The establishment and designation of a contact point should be notified

to each of the member countries in this region. The contact point information will include: Name and designation of the officer, mailing address, telephone, fax and mobile number, e-mail address and website URL, if any. The designated contact point will be responsible for providing and sharing information on pesticide regulatory matters at national level, regionally and internationally using the internet.

5.3. Communication language

The countries in Southeast Asia will adopt English as the common language for sharing information regionally or internationally. However, they may use their national language for information sharing at national, provincial and community levels.

Where it is not possible to share all the information in English, due to the constraints of translation and/or limited resources, at least an abstract or a summary of the information should be provided in English together with the titles and sub-titles.

5.4. Currency of information

The responsible authority will ensure that the information provided/shared is current and up-to-date and will delete obsolete and/or outdated information so as to avoid any conflicting information.

5.5. Frequency of information exchange

The responsible authority will immediately notify of any changes to contact point. They will also provide and share any amendments to the pesticide act and regulations and when new regulations are published.

Other types of information relevant pesticide matters will be exchanged at quarterly or half-yearly intervals depending upon the volume of information, However, pesticide news and alerts should be exchanged as and when published, as well as information on meetings, conferences and workshops, etc. as and when they are scheduled.

5.6. Authenticity of information

The responsible authority will ensure that all the information shared should be authenticated and the source of information should be appropriately acknowledged. They will be responsible for seeking prior approval from the author or publisher before providing and sharing copyrighted information.

5.7. Data protection and requirements of IPR

The responsible authority will establish specific guidelines and procedures for handling proprietary information and/or data protection in accordance with provisions of the WTO-TRIPS Agreement.

5.8. Information security

The responsible authority will take into account the guidelines for security of information systems and networks established by the Organization for Economic Cooperation and Development (OECD), while communicating and exchanging information using the internet and should promote a culture of security.

5.9. Log-in credentials

The responsible authority will provide appropriate log-in credentials to designated staff to facilitate the uploading, editing and updating of information. However, the public may be allowed to view, download and export information relevant to pesticide matters except for proprietary information related to pesticide registration, which is dealt with in accordance with guidelines and procedures established for confidential business information sharing.

5.10. Establishment of specific regulations and administrative procedures

The responsible authority will establish specific regulations for providing to the public information about pesticide risks, the regulatory process and administrative procedures. This will provide transparency and facilitate the participation of the public in the registration process.

5.11. Type of information required to be shared

The responsible authority will take into account the type of information required to be shared at regional, national, provincial, district or community levels, as given in Annex 1.

6. SPECIFIC REQUIREMENTS

The responsible authority will adopt appropriate formats for sharing specific information on pesticide regulatory matters, as given in **Annex 2(a) to 2(n).**

6.1. Pesticide act and regulations

The responsible authority will exchange information related to the pesticide act and regulations as well as its amendments, if any, as and when they are published and/or at drafting stage to invite for comments.

While exchanging information on the pesticide act and regulations, the responsible authority will provide the notification number/decree/presidential order, date of issue/commencement, title of notification/decree/presidential order, source of publication and a brief summary or abstract of provisions of the act and regulations in English as the common language.

6.2. Guidelines, standards and test protocols for pesticides

The responsible authority will exchange information related to the guidelines and standards established in relation to pesticide regulatory matters such as registration, quality control, residue determination and test protocols for pesticides including bio-efficacy test protocols.

While exchanging such information, the responsible authority will provide the title of guidelines and standard established, date of adoption, scope and outline of requirements of standard, in English as the common language.

However, the responsible authority will provide complete information on testing protocols including bio-efficacy test protocols, which are developed to meet the conditions of registration, to facilitate their validation, in English as the common language. In case where the responsible authority has adopted the internationally accepted and validated test protocols, such exchange of information will be limited to literature citations in English.

6.3. Minimum data requirements

The responsible authority will exchange information on minimum data requirements to facilitate harmonized registration of pesticides within this region.

While exchanging such information, the responsible authority will ensure that the minimum data requirements are as for as possible harmonized with established international standards and guidelines, after taking into account the specific agro-climatic conditions of this region.

6.4. Registered pesticides

The responsible authority will exchange information regarding the list of pesticides registered for use within the country or establish an appropriate web-based database of registered pesticides for easy retrieval.

Such data bases should be maintained in the national language as well as in English as the common language and be kept up-to-date for the benefit of other countries in this region.

6.5. Banned and severely restricted use pesticides

The responsible authority will promptly exchange information related to banned and severely restricted use pesticides, as soon as they are notified and/or published.

While exchanging such information, the responsible authority will provide information such as chemical name of pesticide, toxicity category, particulars of the notification, decree or presidential order, and reasons for banning or severely restricting the use of pesticide. Such information should be notified and/or published in the national language as well as in English.

6.6. Maximum Residue Limits (MRLs)

The responsible authority will readily exchange information regarding the maximum residue limits established by the country in respect of agricultural, food and feed commodities, including the scientific basis for specifying the MRLs and the testing protocols for residue determination. Such information regarding MRLs established and/or adopted by the responsible authority should be communicated both in the national language as well as in English.

6.7. Implementation of the FAO Code of Conduct, international conventions and agreements relevant to pesticide matters

The responsible authority will exchange information relevant to Article 9 of the ***FAO International Code of Conduct on the Distribution and Use of Pesticides***. This will include information about the establishment or strengthening of networks for information exchange at national, regional and international levels; actions taken to ban or severely restrict a pesticide in order to protect human health or the environment; scientific, technical, economic, regulatory and legal information concerning pesticides including toxicological, environmental and safety data; the availability of resources and expertise associated with pesticide regulatory activities; specific regulations established for permitting information sharing about pesticide risks and the regulatory process; administrative procedures to provide transparency and facilitate the participation of the public in the registration process.

The responsible authority will exchange information related to the current status of implementation of international conventions and treaties related to pesticides such as the Basel Convention, Stockholm Convention, Rotterdam Convention, Strategic Approach to International Chemical Management (SAICM), Montreal Protocol, Chemical Weapons Convention (CWC), and others. This may include the status of ratification, establishment of specific regulations for implementation, implementing authority, and reporting of actions taken, especially the notifications of national final regulatory actions (FRA) and prior informed consent (PIC) procedures as required under the Rotterdam Convention.

6.8. Publications/reports

The responsible authority may exchange information on publications and reports produced in relation to pesticide management for the benefit of other participating countries in this region.

Such information may include the title of the publication or report, year of publication, name of the institute or organization and catalogue number, if any.

6.9. Projects/programmes

The responsible authority may exchange of information about on-going and/or completed projects and programmes related to pesticide risk reduction.

While exchanging such information, the responsible authority may provide information on the title of the project or programme, date of commencement, duration, implementing institute or organization, funding agency, as well as a brief summary of the project, in English.

6.10. Meetings, conferences, workshops and training programmes

The responsible authority may exchange information on meetings, conferences, workshops and training programmes related to pesticide management organized nationally, regionally or internationally sufficiently in advance to facilitate active participation by other countries in this region in order to achieve harmonization in pesticide management.

While exchanging such information, the responsible authority may providing the title of the meeting, conference, workshop or training programme; scheduled dates and venue; objectives, agenda; composition of participants; and – after the event – the proceedings, preferably in English.

6.11. Videos and publicity material

The responsible authority may share information about any videos and/or extension publicity material published to educate the public and community about pesticide safety and health hazards.

While exchanging such information, the participating countries may provide the title of the video or publicity material, duration, institute or organization, and highlights of video-contents and publicity material, in English.

6.12. Pesticide news, events and alerts

The responsible authority may exchange information on any news, events or alerts concerning pesticides published in daily newspapers or news bulletin. While exchanging such information, the participating countries may provide in English the headlines, news abstract, source and date of publication.

6.13. Any other relevant information

The responsible authority may exchange any other relevant information such as pesticide poisonings, diagnostics and treatment as well as measures taken to prevent such instances. Also they may like to exchange information on the disposal of obsolete pesticides; intimation about quality control of pesticides; residue monitoring; illegal import of pesticides and integrated pest management programmes.

7. REFERENCES

Guidelines for registration and control of pesticides, FAO, Rome. 1985.

Guidelines for Harmonization of Pesticide Registration Requirements among Participating Countries in Southeast Asia, 2010. FAO, RAP, Bangkok (draft under preparation).

FAO. *International Code of Conduct on the Distribution and Use of Pesticides* (Revised Version), 2003, Food & Agriculture Organization of United Nations, Rome.

OECD. *Guidelines for the security of information systems and networks-towards culture of security*, 2002, Organization for Economic Cooperation and Development (OECD), Paris, France.

UNEP. *Guidelines for the Exchange of Information on Chemicals in International Trade*, 1989, United Nations Environment Programme (UNEP), Office of United Nations, New York, USA.

WTO. *Trade Related Intellectual Property Rights (TRIPS) Agreement*, 1995. World Trade Organization, Geneva, Switzerland.

Annex 1

TYPE OF INFORMATION SHARING ON PESTICIDE MATTERS AT REGIONAL, NATIONAL, PROVINCIAL AND COMMUNITY LEVELS

1. At regional level

- Regional Website URL
- About regional pesticide regulatory information management network
- Contact details
- Implementation of international agreements/conventions/protocols
- Information resources on pesticide management
- Regional meetings/workshops/training programmes
- Publications/meeting reports
- Regional pesticides database
- External links to APPPC/FAO/WHO/UNEP/CODEX/WTO-SPS ETC.
- Log-in credentials for country portals

2. At national level

- National website URL, if any
- Responsible authority-organization chart
- Contact details
- National pesticide legislation/regulations
- National guidelines/standards/bio-efficacy test protocols
- Registration process of pesticides
- Minimum data requirements for pesticide registration
- List of registered pesticides/registered pesticide database
- Banned/severely restricted use pesticides
- Maximum Residue Limits (MRLs)
- IPM Projects
- Publications/reports
- Monitoring reports of quality testing of pesticides (national level)
- Health & environmental monitoring reports (national level)
- Residue monitoring in agriculture/food/feed products (national level)
- Designated referral laboratory for quality testing
- Designated referral laboratory for residue determination
- National conferences/workshops/meetings
- Accredited treatment providers (MB)
- Statistical reports of pesticide trade, manufacturing & consumption
- Pesticide review meeting reports
- Links to other relevant national government agencies' website URLs/international/regional organisations
- Log-in credentials to provincial portals

3. At provincial level

- Licensing procedures
- Licensed pesticide manufacturing units
- Licensed pesticide stockiest/distributor/retailers
- Licensed pest control operators
- Quality testing of pesticides (sampling/testing methodology)/enforcement
- Designated pesticide inspectors/analysts
- Designated quality testing laboratories (provincial level)
- Designated residue testing laboratories (regional level)
- Testing & certification of pesticide application equipments & personal protection equipments
- Health & Environmental Monitoring (provincial level)
- State level meetings/workshops/training programmes
- Crop/pests information
- State level pest distribution maps
- Field diagnostics of pests
- Pest surveillance reports
- Extension education/training
- Integrated pest management programmes (provincial level)
- Links to community level information kiosks

4. At community level

- Understanding labelling/packaging requirements
- Health hazards & safety precautions regarding use of pesticides
- Pesticide poisoning diagnostics/treatment/first aid measures
- Pesticide poisoning treatment centres
- Recommended use of pesticides/pre-harvest intervals
- Use of personal protection equipments
- Proper use/maintenance of application equipments
- Safe storage of pesticides
- Disposal of empty containers/obsolete pesticides
- IPM/GAPs (farmer field schools)
- Pesticide education campaigns/awareness programmes
- How to detect illegal pesticides?
- Community reporting of health/environmental impacts of use of pesticides

Annex 2A

GENERAL FORMAT FOR THE EXCHANGE OF INFORMATION RELEVANT TO ORGANIZATIONAL STRUCTURE, RESPONSIBLE AUTHORITY, CONTACT POINT, AREA OF RESPONSIBILITY AND TYPES OF INFORMATION SHARED*

1.	**Name of country:**	
2.	**Organization structure:**	
	i) Ministry	
	ii) Department	
	iii) Sub-department, if any	
3.	**Responsible authority:**	
	i) Name	
	ii) Designation	
	iii) Office held	
4.	**Contact details:**	
	i) Mailing address	
	ii) Telephone/Mobile/Fax	
	iii) E-mail ID	
	iv) Website URL, if any	
5.	**Area of Responsibility/Activity Relating to Pesticides (tick out in appropriate box)**	
	☐ Legislation/regulation ☐ Enforcement/inspection ☐ Quality testing ☐ Residue Monitoring in Food ☐ Extension/training	☐ Pesticide registration ☐ Facility licensing ☐ Health/Environmental Monitoring ☐ Integrated Pest Management ☐ Others (Specify)
6.	**Type of pesticides regulated by this Agency***	
	☐ Agriculture pesticides ☐ Veternery pesticides ☐ Public health pesticides ☐ House hold pesticides	
	*Indicate seprately if morethan one agency involved	
6.	**Type of Information shared (tick out in appropriate box):**	
	☐ *National pesticide legislation and regulations	
	☐ *National guidelines/standards/testing protocols	
	☐ *Minimum data requirements for pesticide registration (including biopesticides)	
	☐ *List of registered pesticides (including biopesticides)	
	☐ *List of banned/severely restricted use pesticides (including prohibited pesticides)	
	☐ *Maximum residue limits established by the country, if any	
	☐ *Status of implementation of international conventions (tick out the appropriate ones)	
	☐ FAO Code of Conduct on Pesticides (monitoring and observance)	
	☐ Basel Convention (ratification/adherence, contact point, notification of regulatory action)	
	☐ Stockholm Convention (ratification/adherence, focal point, notification of regulatory action	
	☐ Rotterdam Convention (ratification/adherence, DNA, notification of PIC procedures)	
	☐ Montreal Protocol (ratification/adherence, notification of quantitative reductions)	
	☐ Chemical Weapons Convention (CWC) (ratification/adherence, contact point, notification of regulatory action)	
	☐ Strategic Approach to International Chemical Management (SAICM) (ratification/adherence, notification of regulatory action)	

		*Health/environmental monitoring reports (including survey/methodology)		
		*Residue monitoring reports (including survey/methodology)		
		*Monitoring reports of illegal trade in pesticides (incidences, method of detection/enforcement)		
		*Monitoring quality of pesticides (quality testing/enforcement)		
			Publications/reports on pesticide management	
			Pesticide risk reduction projects/IPM Projects	
			Meetings/workshops/training programmes relevant to pesticide management	
			Videos/publicity material on pesticide safety	
			Pesticide news/alerts/summaries	
			Others (Specify)	
	*Information exchange crucial for regional harmonization			
6.	**Name/Designation/Signature of authority providing information with seal & date**			

Annex 2B

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION RELATED TO THE PESTICIDE ACT/RULES/REGULATIONS AND AMENDMENTS ISSUED THEREUNDER

Notification/ decree/ presidential order No.	**Date of publication**	**Title of notification/decree/ presidential order**	**Abstract/summary** (in English)

Annex 2C

SPECIFIC FORMAT FOR THE INFORMATION EXCHANGE RELATED TO NATIONAL GUIDELINES/STANDARDS/TESTING PROTOCOLS (TPS) ESTABLISHED BY THE COUNTRY

Reference No.	Date of publication	Title of guidelines/standards/TPs	Outline of requirements of guidelines/standards/TPs (in English)

Annex 2D

SPECIFIC FORMAT FOR THE INFORMATION EXCHANGE ON MINIMUM DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES (IF REQUIRED BY IMPORTING COUNTRY)*

	Name of importing country	
	Name of exporting country	
	Name of chemical pesticide/BCPA/MCPA	
	Whether technical grade/formulated product	
	Type of Registration	
	☐ Provisional registration ☐ Supplementary (me-too) registration	☐ Proprietary registration ☐ Re-registration
	Minimum Data requirements*	
	☐ Chemistry/botanical/microbial data ☐ Toxicity data ☐ Bio-efficacy data ☐ Residue data ☐ Environmental fate and effects data ☐ Labeling/package/storage data ☐ Additional data requirements, if any	
	* Information to be provided as per the formats established under the Guidelines for harmonization of pesticide registration established under the FAO-TCP project.	
	Name and Signature of Responsible Authority	

Annex 2E

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION ON THE LIST OF REGISTERED PESTICIDES (INCLUDING BIOPESTICIDES)

Chemical information				Product information				Registration information			Crop/pest information			
Clause No.	Chemical name	Chemical group	Use type	Product name	Formula-tion/AI	Toxicity group	Manu-facturer	Reg. No/ date	Date of expiry	Reg. category	Name of crop	Name of pest(s)	Dosage/ rate	PHI

Annex 2F

SPECIFIC FORMAT FOR THE INFORMATION EXCHANGE ON THE LIST OF BANNED AND/OR RESTRICTED USE PESTICIDES

Clause No.	Chemical name	WHO class	Product name	Formulation/ AI	Reg. No/ date	Banned and/or restricted use	Notification/ decree number/ date of publication

Annex 2G

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION ON MAXIMUM RESIDUE LIMITS (MRLS) ESTABLISHED BY THE COUNTRY

Clause No.	Chemical name	Crop/ commodity name	Produce/ product	MRLs established by the country	Testing method	Particulars of notification/ publication	Technical justifications, where required

Annex 2H

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION RELEVANT TO THE LIST OF PUBLICATIONS/REPORTS ON PESTICIDE MANAGEMENT

Author(s)	Year	Title of publication/report	Journal/volume/No.	Publisher's name

Annex 2I

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION RELEVANT TO PESTICIDE RISK REDUCTION/IPM PROJECTS AND OTHER RELEVANT PROJECTS BEING UNDERTAKEN BY THE COUNTRY

Project/ programme Ref. No.	Title of project	Start date	End date	Budget	Funded by	Executed by	Abstract or summary of project (in English)

Annex 2J

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION ON MEETINGS, WORKSHOPS AND TRAINING PROGRAMMES (TPS) ON PESTICIDE MANAGEMENT

Scheduled date(s)		**Name of meeting/ conference/workshops/ TPs, etc.**	**Venue**	**Sponsored by**	**Highlights of meeting/ conferences/workshops/ TPs, etc.** (in English)
From	**To**				

Annex 2K

SPECIFIC FORMAT FOR THE EXCHANGING INFORMATION ON VIDEOS/FIELD PUBLICITY MATERIAL BROUGHT OUT ON PESTICIDE SAFETY

Title of video/ publicity material	**Duration of videos (in min)**	**Institute/ organization, which developed**	**Language in which video graphed/ published**	**A brief description of contents of video/ other publicity material** (in English)

Annex 2L

SPECIFIC FORMAT FOR THE EXCHANGE OF INFORMATION ON PESTICIDE NEWS, ALERTS OR SUMMARIES PUBLISHED IN NEWSPAPERS OR MAGAZINES

Headline of pesticide news or alerts	Content of pesticide news or alerts	Title of newspaper or magazine and date of publication

ATTACHMENT 7

CHECK LIST

GUIDELINE PARAMETERS REQUIRED FOR HARMONIZATION OF PESTICIDE REGISTRATION REQUIREMENTS AMONG SOUTHEAST ASIAN COUNTRIES

CHECK LIST

Guideline parameters required for harmonization of pesticide registration requirements among Southeast Asian countries

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Vietnam
6.	**GENERAL REQUIREMENTS FOR PESTICIDE REGISTRATION**							
6.1.	***Registration process compliant with Code of Conduct & International Conventions***							
6.1.1.	FAO Code of Conduct on Pesticides							
6.1.2.	Rotterdam Convention							
6.1.3.	Stockholm Convention							
6.1.4.	Basel Convention							
6.1.5.	Montreal Protocol							
6.1.6.	Guidelines "Designing national pesticide legislation FAO, 2007							
6.1.7.	Guidelines on compliance and enforcement of a pesticide regulatory programme, FAO, Rome, 2006							
6.2.	***Designation of Responsible Authority & adequate facilities***							
6.2.1.	Designated responsible authority for registration and control of pesticides							
6.2.2.	Adequate infrastructure facilities							
6.2.3.	Each and every product of pesticide is registered before import, export, manufacture, storage, distribution, sale and use in the country							
6.3.	***Existing of a system of monitoring & observance of Code of Conduct***							
6.3.1.	Regular reporting (as per Annex A) and Adhoc reporting (as per Annex B) of *Guidelines on monitoring and observance of the Code of Conduct, FAO, Rome, 2006*							
6.4.	***Documentation of Registration Process***							
6.4.1.	Documentation of the entire registration process of pesticides imported and manufactured for distribution and sale and use in the country and exported outside the country after taking into account the Guidelines for registration and control of pesticides, FAO, Rome. 1985 and the Guidelines for the registration of pesticides, FAO, Rome, 2010 (International Code of Conduct on the Distribution and Use of Pesticides) (draft)							
6.4.2.	Harmonized registration process							
6.4.3.	Information exchange relevant to registration process among member countries in the region							
6.5.	***Establishment of Pesticide Board/Technical Committee***							
6.5.1.	Pesticide Board to render advice on pesticide matters							
6.5.2.	An appropriate technical committee to assist in conducting pesticide risk evaluations and making risk management decisions							
6.6.	***Establishment of Registration Requirements & Procedures***							
6.6.1.	Harmonized pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards							

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Vietnam
6.6.2.	Incorporation of internationally agreed technical guidelines and standards into national legislation							
6.6.3.	Establishing a re-registration procedure to ensure periodic review of registered pesticides							
6.7.	***Establishment of Monitoring & Reporting Procedures***							
6.7.1.	Monitoring and reporting procedures on health and environmental incidents resulting out of exposure to pesticides							
6.7.2.	Appropriate measures to minimize the incidents after taking into account the guidelines established by FAO							
SPECIFIC REQUIREMENTS OF PESTICIDE REGISTRATION								
7.	**Different registration procedures for each kind of registration**							
7.1.	***Provisional pesticide registration for 2 years***							
7.1.1.	Minimum data requirements							
7.1.2.	Quantity restrictions							
7.2.	***Proprietary pesticide registration for 5 years***							
7.2.1.	Use of standard information and data requirements (as per Annex 2A, 2B, 3A, 3B, 4A and 4B of *Guidelines for pesticide regulatory harmonization, 2011)*							
7.2.2.	Protection of proprietary data & confidential business information							
7.3.	***Supplementary (me-too) pesticide registration (after 5 years of original registration)***							
7.3.1.	Use of standard data requirements (Annex 2C, 3C and 4C)							
7.3.2.	Agreement entered with original registrant							
7.4.	***Re-registration of pesticides for another 5 years after the expiry of registration***							
7.4.1.	Additional information requirements, if any							
8.	**Existence of exemptions from registration requirements**							
8.1.	***Non-pesticide active ingredient substances used in formulating pesticides***							
8.2.	***Emergency use based on registration in a foreign country and with conditions specified by the Registration Authority***							
9.	**Registration of Application**							
9.1.	***Application Form***							
9.1.1.	Harmonized single application format (Annexure 1A) for pesticide registration (in five copies)							
9.1.2.	Bank draft (registration fees)							
9.1.3.	Applicant's summary statement/conclusions in respect of data fulfillment in support of registration							
9.1.4.	Information content include: – identity of Applicant, – type of registration requested, – identity of technical grade active ingredient/formulated product, – chemical toxicity category, – use type & use pattern, – registration data requirements,							

Clause	Guideline parameters	Cambodia	Lao PDR	Myanmar	Malaysia	Philippines	Thailand	Vietnam
	– additional information if any, – fee details, – list of attached documents, – verification/declaration/signature by applicant.							
9.2.	***Establishment of separate fees structure for***							
9.2.1.	Each type of registration (viz., provisional registration, proprietary registration, supplementary (me-too) registration & re-registration							
9.2.2.	Issue of import permit and or/export authorization							
9.2.3.	Licensing of: – manufacturing facility – storage – repacking – transport – distribution – sale of pesticides – pest control operators							
9.3.	***Receipt of Application/Issue of acknowledgement***							
9.3.1.	Receipt of applications and issue of acknowledgement by the registration counter/desk							
9.3.2.	On-line submitted applications will automatically generate acknowledgement							
9.4.	***Document verification/Check list of documents***							
9.4.1.	A check list (Annexure IB) of documents be established for each kind of registration to facilitate verification of receipt of various documents by the registration counter/desk							
9.4.2.	Information furnished in the application is correct and complete in all respects before accepting the application for registration							
9.4.3.	Online monitoring of registration process in order to avoid time delays							
10.	**Minimum data requirements**							
10.1.	***Existence of harmonized minimum data requirement lists for***							
10.1.1.	Provisional registration							
10.1.2.	Proprietary (original) pesticide registration							
10.1.3.	Supplementary (me-too) registration (commodity product registration) and/or							
10.1.4.	Re-registration							
10.2.	***Submission of minimum data in the following separate sealed folders***							
10.2.1.	Chemistry/Biochemical/Microbiological data (Folder A)							
10.2.2.	Toxicity data (Folder B)							
10.2.3.	Bio-efficacy data (Folder C)							
10.2.4.	Labelling/Packaging/Storage (Folder D)							
10.2.5.	Health Exposure/Environmental fate & effects' data (Folder E)							
10.2.6.	Residues data (Folder F)							
10.2.7.	Additional information, if any (Folder G)							

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10.3.	***Proprietary data handling and confidential business information***							
10.3.1.	Specific authorization of staff							
10.3.2.	Documentation of specific procedures							
11.	**Technical evaluation of Registration Dossiers**							
11.1.	***Verification that the data submitted fulfills all the requirements of registration***							
11.2.	***Verification of data waiver of requirements in certain instances***							
11.3.	***Verification of analytical methods/test protocols***							
11.4.	***Verification of manufacturing process, where necessary***							
11.5.	***Verification to meet FAO/WHO specifications***							
11.6.	***Consideration of validation studies of existing/new data***							
11.7.	***Comprehensive summaries and conclusions by the reviewer for Pesticide Board decision***							
11.8.	***Decision by the Pesticide Board/Committee to grant a provisional or regular registration, with or without restrictions and/or conditions, or refusal***							
11.9.	***Acceptance of data obtained under controlled laboratory conditions or under similar agro-climatic conditions based on internationally accepted test protocols and adequate scientific standard***							
11.10.	***Verification of compliance with Good Laboratory Practices (GLP):*** Verification of authenticity of the data with the concerned GLP certified laboratory							
12.	**Data Protection/Data Access/Information sharing**							
12.1.	***Internal guidelines to protect and safeguard the proprietary rights to the data and confidential business information***							
12.2.	***Public access to health and safety data***							
12.3.	***Information sharing on pesticide regulatory system with other member country in this region in order to achieve pesticide regulatory harmonization***							
13.	**Time period for review of data/Communication of data gaps**							
13.1.	***Prescribing specified time period for completion of registration process***							
14.	**New data submission to fill the data gaps**							
14.1.	***Provision of notice to applicant to provide new data to fill the data gaps identified during the technical review of data giving appropriate time period for the submission of new data***							
14.2.	***Provision of notice to applicant to provide additional information requirements, in the event of Re-registration***							
15.	**Pesticide Risk Assessment (as per FAO guidelines)**							
15.1.	***Detailed toxicological data***							
15.2.	***Data on long time dietary exposure***							
15.3.	***Data on health exposure to very low level of pesticides***							
15.4.	***Environmental fate/effects' data***							
15.5.	***Development of pest resistance***							
15.6.	***Assessment of phytotoxicity***							

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16.	**Bio-efficacy Assessment as per FAO Guidelines**							
16.1.	***Adoption of new modality guidelines for preparation of efficacy test protocols in the harmonized process***							
16.2.	***Adoption of 29 new efficacy test protocols developed and modifications of existing 40 efficacy test protocols developed by FAO on new modality guidelines***							
17.	**Classification of pesticides based on hazard & toxicity**							
17.1.	***According to the WHO hazard classification/modified toxicity classification***							
18.	**Review of labelling/packaging/storage requirements**							
18.1.	***Reviewing of pesticide labelling according to harmonized guidelines***							
18.2.	***Bilingual labelling format (English/National)***							
18.3.	***Testing tamper-proof packaging***							
18.4.	***Testing storage stability (shelf life) of product***							
19.	**Approval & issue of registration certificate**							
19.1.	***Guidelines for approval of registration***							
19.2.	***Issue of Registration Certificate with a unique registration number, date of issue and validity, date & signature by registration authority***							
20.	**Validity period of certificate for different kind of registration**							
20.1.	***Provisional registration: 2 years***							
20.2.	***Proprietary (original) registration: 5 years***							
20.3.	***Supplementary (me-too) registration: 5 years after original registration***							
20.4.	***Re-registration***							
21.	**Denial of issue of Registration Certificate**							
21.1.	***Issue a notice of denial of registration to the applicant of registration within reasonable period of time giving reasons for denial by the Registration Authority***							
22.	**Appeal by the Applicant/Appeal Procedures**							
22.1.	***Providing for appeal by the applicant against the decision giving grounds for appeal within 30 days of issue of denial notice by the Registration Authority***							
22.2.	***Establishing a formal approval procedure under pesticide regulations***							
23.	**Notification of prior informed consent (PIC) procedures**							
23.1.	***Notification of final regulatory action for certain hazardous chemicals and pesticides included under Rotterdam Convention***							
23.2.	***Notification of prior informed consent procedures for certain hazardous chemicals & pesticides included under Rotterdam Convention***							
24.	**Un-conditional/Conditional registration**							
24.1.	***Providing of appropriate criteria for unconditional registration, which include:***							
	(a) that the application was complete and was accompanied by all materials required by the requirements of registration, including but not limited to, evidence that the applicant had complied with the data compensation requirements;							

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	(b) all relevant data in its possession were reviewed and accepted;							
	(c) no further additional data were necessary to make the determinations required under pesticide regulation with respect to the subject product;							
	(d) the composition of the product is such as to warrant the proposed bio-efficacy claims for it, if bio-efficacy data were required;							
	(e) the product will perform its intended function without adverse effects on the environment, and that when used in accordance with widespread and commonly recognized practice including instructions and information on the label, the product will not cause adverse effects on the environment;							
	(f) provided that the proposed labelling bears directions for use on food, animal feed, or food or feed crops, or the intended use of the pesticide results and/or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances or exemptions from the requirement of a tolerance, and food additive regulations, have been accounted for; and							
	(g) Unconditional registrations can be granted for a variety of applications such as identical/substantially similar (me-too) (described below), new uses, or new active ingredients as long as all criteria above are met with.							
24.2.	(h) Providing appropriate criteria for Conditional registration, which include:							
	(i) Registration Authority may conditionally approve an application for registration or amend a registration of a pesticide product. This may occur if Registration Authority determines that, while a registration decision can be made, further data, studies, or action by the registrant is required by the Registration Authority for further review. This conditional registration may be granted depending on whether it is a new active ingredient, a new use, or an identical/substantially similar (formerly "me-too") product or it is for a new use.							
	(j) Registration Authority may not approve the conditional registration of a pesticide product for a new use if the pesticide is the subject of a special review, based on its use that results in human dietary exposure and that the proposed new use is for a major food or feed crop, or involves use on a minor food or feed crop for which there is an effective alternative registered pesticide that does not meet the risk criteria associated with human dietary exposure is available.							
25.	**Amendments to previous registration**							
25.1.	***Any amendments issued to previous registration certificates should be limited to extension of label claims, formulation change, repacking and local formulation and subject to provision of additional data requirements***							
25.2.	***Any amendment issued to previous registration certificate should be properly endorsed by the Registration Authority and have linkage to the previous registration certificate***							

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26.	**Re-registration**							
26.1.	***The Registration Authority may issue a re-registration certificate for previously registered products prior to expiry of previous registration granted to the original applicant. Before any such re-registration granted, the Registration Authority will review previous data submitted by the applicant as well as any new data generated consequent to previous registration***							
26.2.	***The re-registration certificate issued will bear linkage to the previous registration and is valid for further period of five years. (However, no banned and/or severely restricted pesticide should be allowed for re-registration)***							
27.	**Supplementary (me-too) registration**							
27.1.	***The Registration Authority may consider supplementary (me-too) registration only after the expiry of period of registration granted to the original applicant (i.e. after five years)***							
27.2.	***Supplementary registration will be subject to production of a written agreement that was entered upon with the original registrant and the supplementary (me-too) applicant***							
27.3.	***Supplementary (me-too) registration will be granted after following the guidelines established under the FAO/WHO chemical equivalence process for supplementary registration***							
28.	**Import/Export Authorization**							
28.1.	***The Registration Authority will ensure that all pesticides imported into their territory from foreign manufacturers are covered under import permit system and registered before further manufacturing (where applicable), distribution, sale and use and meet all the requirements applicable to domestic producers***							
28.2	***However, a sample quantity of new pesticide may be permitted for import as a registration sample only for experimental purpose under provisional registration***							
28.3.	***The Registration Authority will ensure that all pesticides exported outside the country conform to the registration requirements of importing country. The pesticides must be registered in the country in which they are manufactured even it is meant exclusively for export and are covered under export license***							
29.	**Licensing of manufacturing facility/repacking facility**							
29.1.	***The licensing authority will undertake a site visit to the manufacturing facility/repacking facility to ensure that the facility is in compliance with the pesticide regulations and other relevant regulations and that appropriate safeguards are in place to protect workers safety including effluent treatment and monitoring of air pollutants, where applicable***							
30.	**Licensing of stockiest/distributors/retailers & storage premises**							
30.1	***The licensing authority will undertake inspection of premises for the purpose of licensing of stockiest/distributor for stock/distribution/sale and storage for sale of pesticide in compliance with the provisions of pesticide regulations***							
31.	**Licensing of pest control operators**							
31.1.	***The licensing authority will undertake licensing of pest control operators to ensure that all commercial pest control operations are carried out according to the provision of pesticide regulation***							

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32.	**Quality control of pesticides**							
32.1.	***Employing of qualified personnel as pesticide inspectors for drawing pesticide samples from import entry points, manufacture premises, storage houses, distribution/sale points for quality control of pesticides***							
32.2.	***Employing qualified personnel as pesticide analyst for testing pesticide samples***							
32.3.	***Establishing of pesticide testing laboratory(s) for routine testing the quality of pesticides and,***							
32.4.	***Designation of an apex laboratory for reference analysis of pesticides in the event of legal disputes***							
33.	**Cancellation/suspension of registration/licensing**							
33.1.	***Existence of procedures to cancel/suspend the registration/licensing in the event of violation of pesticide regulations***							
34.	**Pesticide review/Re-evaluation of Pesticides**							
34.1.	***Establishing procedures for re-evaluation of registered pesticides on a regular cycle or based on harmonized guidelines***							

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