ASEAN Guidelines on the Regulation, Use, and Trade of Biological Control Agents (BCA)

Implementing Biological Control Agents in the ASEAN Region: Guidelines for Policy Makers and Practitioners

ASEAN Guidelines on the Regulation, Use, and Trade of Biological Control Agents (BCA)

The Regional BCA Expert Working Groups on Application[#] and Regulation*

And

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Under Commission of the ASEAN Sectoral Working Group on Crops (ASWGC) on Behalf of ASEAN

And

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Summary

These *Guidelines* summarise the work of the 'ASEAN Regional BCA Expert Groups on Regulation and Application', which was supported by the project 'ASEAN Sustainable Agrifood Systems (ASEAN Biocontrol)' funded by the Federal Republic of Germany. It has two primary goals:

- To form a framework for the better implementation of biological control agents (BCA);
- To provide a template for harmonisation of regulations and thus stimulate regional trade in BCA.

Experts from the ASEAN Member States (AMS) met several times in 2013 to present their experiences with regard to the regulation of BCA and biocontrol methods against major pests in certain key crops (in particular: rice, vegetables and fruits). These national understandings were compared with proposed international regulation and scientific data. The *Guidelines* therefore constitute a harmonised opinion of ASEAN Experts.

BCA are most applicable in the context of appropriate Integrated Pest Management (IPM) strategies that emphasise preventative pest management: with regular observation of the crop and timely, targeted intervention only where required. It follows that a range of BCA must be made readily available to farmers as required; this is most likely to come about by providing an appropriate regulatory environment and technical support to the small and medium-sized enterprises (SME) that have a reputation for providing these products.

For practical purposes, BCA have been grouped into four product categories:

- Microbial control agents (microbials or MCA),
- Macro-organisms (macrobials),
- Semiochemicals (mostly pheromones, kairomones, etc.),
- Natural products (plant extracts or 'botanicals', fermentation and other products)

Of these, microbials and many 'natural products' are often termed as 'biopesticides'; however, a number of fermentation products have been covered by chemical pesticide legislation and are not included in this edition of the *Guidelines*. Microbials may have special application needs and, as with other BCA, include a range of organisms with varying properties and requirements for manufacture, specification and regulation. With macro-organisms, a distinction is drawn between introduced predators and parasitoids (often for 'classical' biological control) and indigenous species. Semiochemicals are characterised by extremely low application dosage and risk of toxicity; they may be used in conjunction with conventional insecticides in traps, thus limiting their environmental impact. Regulation of botanicals poses certain difficulties, because they commonly consist of complex mixtures of active substances, where separate toxicities cannot be determined.

Biological control is not universally appropriate for all pest management situations and there remains an evident and continuing role for chemical pesticides: nevertheless with an increasing proportion of natural products and their analogues. There are a number of systems that use biocontrol as a principal component of pest management strategy, including the critically important

rice, vegetable and fruit crops, for which case studies are described. Individual biological control agents are, by their very nature, limited to a restricted number of target pests and cannot be compared with ‘block-buster’ chemicals.

It is therefore vital to provide a regulatory environment that encourages development by SME producers: with measures to simplify, harmonise and minimise the cost of procedures rather than adding regulatory burdens. These *Guidelines* provide a set of minimum data requirements for registration of products such as microbials and botanical pesticides. Harmonised data requirements are also an important prerequisite to improve trade of BCA within ASEAN and beyond. Furthermore, it is incumbent on Registration Authorities to provide scrutiny of (i) the product label, which is the primary point of communication between the producer and users (farmers or their advisors) and (ii) the post-registration processes that ensure maintenance of product quality and thus the continued relevance and reputation of BCA as tools for pest management.

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Glossary

AI*[1]	Active ingredient (sometimes AS: active substance)
BCA	Biological Control Agent(s) (see section 1.1.1)
Biocontrol	Abridgment of 'biological control'
Biopesticide	Biological pesticide (see section 1.1.1)
Biorational	"Any type of [pesticide] active against pest populations, but relatively innocuous to non-target organisms, and, therefore, non-disruptive to biological control" (04) (68)
Botanical	Natural (unmodified) plant extracts (see section 2.4)
BPH	Brown plant-hopper of rice, *Nilaparvata lugens* (Stål)
Bt	*Bacillus thuringiensis*
CFU	Colony Forming Unit (an estimate of viable bacterial or fungal cells)
CMR	Carcinogenicity, Mutagenicity, Reproductive toxicity
DAT	Day after transplanting
DBM	Diamondback moth, *Plutella xylostella*
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
IPM	Integrated Pest Management (see section 1.2)
IU	International Unit: a standardised measure of dosage for *Bt* products
MCA	Microbial Control Agent(s) (see section 2.1)
MSDS	Material Safety Data Sheet
PCR	Polymerase Chain Reaction (for identification of micro-organisms)
SCLP	Straight-chained lepidopteran pheromone
sp.	Species (plural spp.)

Organisations, etc.

APPPC	Asia and Pacific Plant Protection Commission
ASEAN	Association of Southeast Asian Nations (http://www.asean.org/)
- ABC	ASEAN Biocontrol for Sustainable Agrifood Systems
- AIFS:	ASEAN Integrated Food Security Framework
- AMS:	ASEAN Member States
- ASWGC	ASEAN Sectoral Working Group on Crops
BCPC	British Crop Production Council
CropLife	CropLife International (http://www.croplife.org/)
DOA	Department (or appropriate, equivalent Ministry level) of Agriculture
EU	European Union
EWG	Expert Working Group
FAO	Food and Agriculture Organization of the United Nations (http://www.fao.org/)
- IPPC	International Plant Protection Convention

[1] Formulation names (including AI) all conform to the *CropLife* two-letter convention, now adopted by FAO and other international organisations (see section 2.5)

GIZ/GTZ	Deutsche Gesellschaft für Internationale Zusammenarbeit (http://www.giz.de)
IBMA	International Biocontrol Manufacturers' Association (http://www.ibma-global.org)
MAQIS	Malaysian Quarantine and Inspection Services
OECD	Organisation for Economic Co-operation and Development (http://www.oecd.org/)
SME	Small and Medium-sized Enterprise(s)
US EPA	United States Environmental Protection Agency
WHO	World Health Organization

Preface

In order to meet the food needs and expectations of a global human population, that is projected to increase to 9 billion by around 2050; crop production will have to increase by some 70–100% during the 21st century (01). In Southeast Asia, 618 million people (11.7%) currently live in 3.3% of the World's land area[2]. Attempting to address this global issue, a number of recent, high profile, multi-author, scientific and policy papers have identified the need for a holistic approach to a broad range of issues, including soil conservation, water availability and the need for sustainable and improved pest and disease management practices (02) (03). With changes to market policy, rural development, low producer prices and increased costs of agricultural inputs, food production in the ASEAN countries can barely keep up with increasing demand: especially in the cities. Contamination of food with residues of pesticides, together with their impact on the environment in the rural areas, is a matter of increasing concern in this region and elsewhere.

In Southeast Asia, food supply is commonly based on smallholder structures, especially for important staple foods such as rice or soya. Furthermore, many cash and export crops such as oil palm, cocoa, or tropical fruits are grown by small farmers: often then supplying the processors of large plantations. The various technologies of the 'Green Revolution', including high-responding varieties tied to inputs of chemical pesticides and fertilisers, brought about increases in yield per hectare for many crops, but due to low and even declining producer prices, did not always increase income for rural families. This increased dependence of farmers on expensive chemical inputs, which sometimes was compounded by pesticide resistance and pest resurgence caused by the impact of broad-spectrum insecticides on natural enemies (see section 3.1).

Government extension services, aided by international programmes and often supported by the FAO, promoted IPM from the 1990s onwards. Manufacturers of BCA inputs often only have scattered distribution networks, resulting in a lack of availability of suitable biological control agents for farmers. In contrast, manufacturers of chemical pesticides have a well-developed distribution and supply networks and frequently make excessive promises on improvements of yield. However, most farmers are insufficiently trained in the selection and use of pesticides. Application techniques are usually poor and there is a deficit of knowledge among both farmers and pesticide salesmen; this knowledge gap may also adversely affect the successful implementation of biocontrol products or biopesticides (see section 2.5.3).

These *Guidelines* summarise the work of AMS experts, who met in the region several times during 2013 (09), in response to a request of the ASEAN Working Group on Crops (ASWGC) to the ASEAN Biocontrol for Sustainable Agrifood Systems Project. It is implemented by GIZ on behalf of the German Federal Ministry for Economic Cooperation and Development (BMZ). In order to prepare Southeast Asian countries for the challenges of the ASEAN Economic Community (AEC), which is scheduled for 2015, the Member States are working together on the ASEAN Integrated Food Security

[2]excluding Antarctica

(AIFS) Framework), which will strengthen their ability to provide sufficient food for the region as well as coping with the ever increasing demands of international commodity markets.

The document describes ways to improve sustainable crop protection through more extended use of BCA in concert with the principles of “integrated pest management”; probably because of its pivotal role, this term has inevitably had a multiplicity of interpretations by different stakeholders. A working definition, focusing on BCA within the context of internationally-recognised IPM narratives, was needed for the purposes of agreed Guidelines (see Chapter 1, section 1.2). BCA encompass a wide range of products and a brief overview is given in Chapter 2. It is acknowledged that they are not applicable to all pest management situations, so specific case studies, where application appears effective and feasible, are described in Chapter 3. Chapter 4 examines regulations and how they might develop in future, with necessary improvements, rationalisation and harmonisation. Chapter 5 provides suggestions for improvement that integrate aspects of regulation and use of BCA.

The purpose of the *Guidelines* is to provide an agreed framework for future development of BCA: specifically creating a regional blueprint for national regulation and implementation strategies. In addition, harmonisation of registration requirements would make regulation of BCA easier, less costly and promote their trade between AMS. After approval by the ASWGC, the *Guidelines* would become an ASEAN recommendation: consequently to be incorporated into national regulations and, most importantly, policies.

1 Introduction

1.1 Project history, terminology & stakeholders

Commercial biological control agents (BCA) are becoming increasingly important in modern, sustainable agriculture. They have gained attention of developing and emerging country agricultural administrations because of their relatively low toxicity to man and environment, potential for local production, and compatibility with smallholder farming, which is the predominant form of agricultural production in Southeast Asia.

The present text builds upon and refers to previous efforts undertaken by various stakeholders to work towards increased application of BCA and regulatory harmonisation in AMS. Reference is made to:

- The “Commercialisation of Biopesticides in Southeast Asia” programme of the German International Cooperation (GIZ), which developed guidelines for data requirements for BCA from 2007-2010 in collaboration with government representatives (DOA) from Thailand, Indonesia and Vietnam. With regard to microbials and semiochemicals, comments by the participating countries on the relevance of specific requirements are also included.
- A project conducted under guidance of FAO, which developed guidelines for harmonisation of registration requirements for biopesticides among seven Southeast Asian countries (Cambodia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand, and Vietnam). Besides minimum data requirements for botanical pesticides and microbial control agents, the document also provides guidance on administrative procedures.

With consumer and environmental pressures resulting in an intensified regulatory environment, the crop protection landscape appears now to be changing rapidly. For example, the European Commission has implemented new regulations (Plant Protection Product Regulation EC/1107/2009, Sustainable Use Directive, Water Framework Directive) that “could result in the withdrawal of some chemical pesticides currently available and in mandatory application of IPM techniques as from 2014” (10). This heightened regulatory pressure is a direct consequence of early inappropriate use of pesticides; the subsequent political trends can be said to date back to Rachel Carson’s *Silent Spring* (05), but have been increasingly intense over the last two decades. Although there has been widespread enthusiasm for the use of BCA in ASEAN countries, widespread use (and misuse) of synthetic chemical pesticides continues to dominate agricultural production.

The ASEAN Biocontrol for Sustainable Agrifood Systems Project has brought together experts from nine AMS, who have presented their experiences with regard to the regulation of the various BCA types with regard to biocontrol methods against major pests of rice, vegetables and fruits. These national experiences were compared and amended in light of other international regulations and scientific data. One of the objectives of the project has been to stimulate discussion among AMS and set a framework for implementation of BCA and, if possible harmonisation of regulation (Chapter 4). We also look beyond regulation to trade issues and pest management policies: all of which have an impact on the distribution and use of BCA. The role of the private sector in production and distribution of BCA is also emphasised.

1.1.1 *Biological Control Agents (BCA): categories and terminology*

The term ‘biopesticide’, a contraction of biological pesticide, has come to mean many things, even though the term has historically been associated with biological control - and by implication - the manipulation of living organisms. In other regions, regulatory positions have been influenced by public perceptions, thus:

- in the EU, biopesticides have been defined as “a form of pesticide based on micro-organisms or natural products” (10)
- the US EPA states that they “include naturally occurring substances that control pests (biochemical pesticides), micro-organisms that control pests (microbial pesticides), and pesticidal substances produced by plants containing added genetic material (plant-incorporated protectants) or PIPs” (11).

The US terminology therefore includes three categories, including ‘biochemical pesticides’ which are characterised by a non-toxic mode of action that may affect the growth and development of a pest, its ability to reproduce, or pest ecology. They also may have an impact on the growth and development of treated plants including their post-harvest physiology. They include (i) plant growth regulators, (ii) insect growth regulators, (iii) organic acids, (iv) plant extracts, (v) pheromones, (vi) minerals/other substances.

Given that the toxophores of several chemical pesticide modes of action are of natural origin (e.g. pyrethroids from pyrethrum, diamides from ryanodine) and major agrochemical companies are promoting naturally occurring fermentation products (e.g. avermectins, spinosyns), many products lie in a substantial ‘grey area’ between truly biological and chemical control agents. There are also legal implications to the terminology used: ‘growth regulators’, ‘biostimulants’, ’plant strengtheners’, etc., which often carry less onerous (or no) regulatory burden in comparison with products described anywhere as ‘(bio)pesticides’. The arguments used are often specious, but may have enormous cost implications. Decisions on what to include or exclude, of course matter for national Regulatory Authorities, but the authors of these guidelines recommend that decisions are made on a scientific evidence basis. These are often difficult decisions involving a pay-off between efficacy and environmental impact. For example, the decision to exclude certain fermentation products in the 5th edition of the *Manual of Biocontrol Agents* (12) has not been taken lightly and based, at least in part, by studies on non-target organisms published in referred journals (13) (14).

In order to avoid the confusion around the term ‘biopesticide’ and accommodate living as well as non-living active agents and ingredients, the ‘ASEAN Biocontrol for Sustainable Agrifood Systems’ Project and other agencies[3] classify BCA into four product categories:

- Microbial control agents (MCA or microbials),

[3] *E.g.* OECD, International Biocontrol Manufacturers’ Association (IBMA): now harmonised with the British Crop Production Council (BCPC) *Manual of Biocontrol Agents*

- Macro-organisms (macrobials),
- Semiochemicals (mostly pheromones, kairomones, etc.),
- Natural products (plant extracts or 'botanicals', fermentation[4]and other products)

This categorisation is market-oriented rather than following a strict scientific reasoning, and it explicitly includes products that are not regarded 'classical' biological control agents.

1.1.2 *Farmers and other stakeholders*

Farming systems in developed and developing countries are fundamentally different, with predominantly mechanised large-scale agriculture in the former and smallholder farming in the latter case. Also in Southeast Asia, smallholder farming is the dominant form, which still provides for the livelihoods of the majority of the rural population. Although agriculture in industrialised countries is often characterised as 'modern', it evolved and is maintained today on a basis of enormous inputs and subsidies (particularly in Europe and the US) that raises concerns regarding the competitiveness and sustainability of this approach. As ASEAN countries aim to strengthen food security in the region, the questions arises: what is the most appropriate approach here for agriculture in general and pest management strategy in particular?

Promotion of biocontrol techniques often has been promoted by governments in Southeast Asia: as part of their strategy to increase levels of food safety (i.e. the reduction of chemical residues in food) and reduce contamination of the environment. The constraints to the broad adoption of biocontrol techniques can be related to a lack of: (i) commercially available biocontrol products for a substantial range of pest problems, (due to their 'niche' status); (ii) awareness of the importance of beneficial insects in pest management; (iii) awareness by producers of the risks of residues in food and, more generally, pesticides in the environment., (iv) an easily perceived 'knock-down' with non-synthetic pesticides. The application of biocontrol products (as opposed to 'classical' biological control) may also be more complex than the use of chemicals: involving the need for substantial training of farmers to understand better the true costs and benefits of the various options: not least the health and safety of farm workers.

To date, farmers are practically never held liable for environmental and other damage caused by their operations, partly because it has proved difficult to monetise the environmental and health benefits of sustainable agriculture. Biocontrol can most easily been turned into money from the consumer, by paying more for food, when produce has been labelled as 'organic'. The scope for sustainable, biorational pest management techniques is more than this and other certification schemes[5] appear to be growing. The FAO stated "For (the farmers) to benefit, higher food prices would need to be transmitted through the entire value chain all the way to the small producer." The means by which appropriate and innovative technologies can be brought to rural areas involve

[4] In the 5th Ed., fermentation and other products will be included in a new section - currently called 'others' in the USA - these may include naturally-occurring 'biorational' active substances and products.

[5] Including FairTrade, Rainforest Alliance, UTZ Certified. Most organic certifiers are affiliated to International Foundation of Organic Agriculture Movements (IFOAM).

comprehensive, monetised initiatives and cannot be solved just by the transfer of improved technology.

The farmer is naturally the major stakeholder, but there are other players. To adapt an observation by Hamilton & Crossly (15), summarising the situation at the international level, other stakeholders include:

- The Major Agrochemical (now often called Life Sciences) industry: principally the half dozen multinational research-based companies which have invested hugely in new technologies (and wish to protect their investments with patents and confidentiality). They provide governments with regulatory data to show that their products are safe and effective. It may be significant that in the past decade, most of these companies have bought up a number of …
- Small and Medium-sized Enterprises (SME): dedicated to the production of biological pesticides.
- Companies producing "generic" pesticide products are seen by many to benefit farmers by pushing down the prices of agrochemical products when patents expire ('off-patent' compounds). In some countries, they are owned or supported by governments. It is not always appreciated by the general public that their interests (and those of their respective sales people) may be different to those of research-based companies.
- Consumer groups and activists who voice concerns, which are often shared by the general public, but which may be taken out of context. It has been argued that they need "regular exposés of unsafe residues in food to maintain their profiles."
- The media are interested in selling newspapers or television time, with priority given to colourful and sensational stories. It is debatable whether it is in their interests to provide a completely objective balance to such stories, but presenters often guide the debate.
- National Governments (and increasingly, international bodies such as the European Union): have to balance the various interests and provide an appropriate legislative framework for the various players involved. They emphasise that this decision making must be 'evidence-based' and are also a major source of support to ...
- Research Scientists: who "seek research grants [and] may try to influence research funding bodies by carefully-timed and purpose-designed press releases or may overemphasise a safety concern in order to secure funding". In Asia, a number of research institutes have had a history of setting up production facilities to encourage the use of BCA.

This stakeholder profile certainly also applies to Southeast Asia, although the roles and importance of the different actors may vary. National governments have been the driving force in the advancement of research and use of BCA in agriculture in ASEAN: notably Thailand, Indonesia, the Philippines and Malaysia, with Vietnamese research institutes also active in BCA development.

1.2 Role of BCA in IPM

The spectrum of pest management options available to farmers is changing, yet too few truly implement IPM: which is generally agreed to be an essential factor in sustainable crop production. The EU only recently proposed that IPM become mandatory in all Member States in 2014, even though its principles had long been declared as a mainstay of modern agriculture. Unfortunately, as in economics, IPM is subject to a variety of interpretations with differences in emphasis from the various interest groups. Originally, the IPM concept was a reaction to the early overuse of synthetic pesticides and clearly proposed their reduced application (04). This was followed by the subsequent politicisation of pesticides; which can be said to date back to Rachel Carson's *Silent Spring* (05), but has been increasingly intense over the last two decades. In Southeast Asia, rampant misuse of synthetic pesticides and failures in controlling pests such as the brown plant hopper in rice, led to several area-wide IPM programmes in 1980s and 1990s (06). Unfortunately, the momentum that IPM gained during this period could not be maintained and although the concept still appears in government policies, support for it is currently very low. Pest management in Southeast Asia is confronted with a sharp decline in productivity of active ingredients, which results in constantly increasing demands for further inputs (07). Recent international studies have shown that, especially in rice and vegetables, reduction or removal of synthetic pesticides can even increase yields, turning an old paradigm upside down (08).

The Food and Agriculture Organisation of the United Nations (FAO) currently defines IPM as "an ecosystem approach to crop production and protection that combines different management strategies and practices to grow healthy crops and minimize the use of pesticides. FAO promotes IPM as the preferred approach to crop protection and regards it as a pillar of both sustainable intensification of crop production and pesticide risk reduction. As such, IPM is being mainstreamed in FAO activities involving crop production and protection." (21).

The fact remains that chemical pesticides predominate and cannot be ignored. The industry body representing research-based pesticide companies, *CropLife* (22), influences farmers and policy makers, and emphasises the role played by pesticides. IPM is interpreted as follows: "… a system of managing pests designed to be sustainable. IPM involves using the best combination of cultural, biological and chemical measures for particular circumstances, including plant biotechnology as appropriate. This provides the most cost effective, environmentally sound and socially acceptable method of managing diseases, insects, weeds and other pests in agriculture". The plant science industry has endorsed IPM practices for many years, and has publicly declared its commitment to promoting IPM. All *CropLife* International member companies support and abide by the FAO definition of IPM in its International Code of Conduct on the Distribution and Use of Pesticides (Article 2).

IPM strategies consist of three basic components:

- Prevention of pest build-up through use of appropriate crop cultivation methods.
- Observation of the crop to monitor pest levels, as well as the levels of natural control mechanisms, such as beneficial insects, in order to make the correct decision on the need for control measures.
- Intervention where control measures are needed.

Inevitably, the various stakeholders (above) are likely to place different emphasis on the meaning of IPM. In contrast to the *CropLife* approach, came the idea in the late 1980s and 1990s that IPM should be essentially "biological control on a grand scale" (23), with biopesticides at their most useful when they recycle (like a parasitoid) rather than following a 'chemical model' of efficacy. However, there are also dangers in this extreme, with the risk of deskilling farmers in useful techniques.

Since the crop protection markets appear to be 'weighted' in favour of chemical products, members from ABC participating states proposed the following working definition:

"**IPM is a preventive strategy of crop protection that uses biocontrol as a main pillar and integrates various other methods. Specifically, acting synthetic pesticides can be used as a last option. IPM is cost effective and prioritises human and environmental safety. IPM also considers farmers' local knowledge and practices, and the need for an appropriate level of education**."

1.3 Sustainability: who will develop BCA products?

Commercial microbials have been around since 1948, when the first microbial product for control of the Japanese beetle based on the bacterium *Paenibacillus popilliae* was registered in the US (62). Since that time various microbials have been identified and developed, and for a couple of products, new companies were formed that later disappeared again. A lot of the original research was carried out in the public domain: that is universities, governmental research institutes and alike. Only in few cases, among them *Bacillus thuringiensis*, research, production, and commercialisation reached the industrial level.

Although the interest of multinational industry is now again focusing on certain BCA, there was a long period, in which the BCA market was mainly supplied with products from small and medium-sized companies with a strong research base in biocontrol. This meant that a relatively small group of BCA suppliers had to compete with a much larger chemical plant protection market, which resulted in a very small percentage of market share for BCA in the plant protection sector. Currently, however, this share is rising.

Besides commercial products, there is also a history of BCA that are directly produced by growers or farmers themselves. This concept has been promoted on a larger scale: for instance, within the farmer-field-school (FFS) programmes of FAO and other development institutions (65). Cuba is a country that has diverted its national plant protection system entirely to the mass production of BCA at the governmental and at the farmers' level: a strategy which has proven successful in meeting the food security demands of this nation (63). Among ASEAN Member States, Thailand, Indonesia and the Philippines for instance have developed BCA production systems under government control that are disseminated to farmers and where farmers are part of the production process themselves.

So, who should develop and mass-produce BCA: farmers or commercial enterprises? The answer is both, but it depends on the products in question and whether high quality mass production is required. Discussions among experts from AMS showed that there is broad agreement that the quality of BCA needs to be substantially improved to be competitive in the plant protection market. It was also agreed that only a proper commercial approach through the private sector could guarantee the quality and quantities required in the agricultural market. This is especially true for various microbials, botanicals, and semiochemicals. On the other hand, it is also regarded a useful approach for reducing their dependency on synthetic pesticides, if farmers directly produce certain BCA for their own use and benefit. Furthermore, 'classical' biological control strategies involving the import and release of invertebrates for insect control (67) or the augmentation of native beneficial organisms (which usually attract no commercial interest) are typically tasks for government agencies which promote techniques among farmers and growers.

Some biological control authorities have questioned whether BCA should be developed too closely along a pesticide-like paradigm. Biological control encompasses much more than just pesticidal agents, given the whole range of natural enemies and antagonists in the agro-ecosystem (23). Especially at the farmers' level, more training and information is needed on the practical use of the various facets of biocontrol, and in the broader context of agro-ecological engineering.

Agricultural policies that promote biological control will provide new avenues for the private sector to develop and market BCA. Although demand for certain BCA is rising significantly, availability of good quality products is still very limited. There is a significant danger that continued supply of poor-quality products could severely hamper the implementation of biological control. In ASEAN, lack of private sector investment and technical knowledge for local production is one of the reasons. Once medium and long-term national and regional pest management policies open up access to new biocontrol markets, this situation can be expected to improve.

2 BCA profiles

This is an overview of the general role, safety and efficacy for each category of BCA, with special reference to the situation in ASEAN. For specific information on control agents and products, reference can be made to the ABC database (see Appendix I) and the BCPC *Manual of Biocontrol Agents* (12). To date, there are 720 registered products included in this database (October 2013): the most prominent of which is *Bacillus thuringiensis* (*Bt*). Also predominant are a large number of fermentation products that include avermectins (about 35% of products including abamectin, milbemectin and emamectin benzoate), other macrocyclic lactone insecticides such as spinosins and various fungicidal and bactericidal antibiotics (mostly validamycin, but also ningnanmycin, streptomycin, etc.). In addition, plant growth regulators are listed that include auxins, brassinolide, cytokinins, gibberellic acid, etc.; strictly speaking, these are not plant protection products.

Some AMS regard such substances as BCA, while others list them under conventional pesticides; macrocyclic lactone insecticide products in particular are often covered by chemical pesticide legislation and have not been included in the 5th edition of the *BCPC manual*. It was agreed among regional experts to not categorise them as 'typical' BCA and avermectins were specifically excluded since they may exhibit synthetic pesticide-like broad-spectrum activity and pose certain environmental risks (e.g. relatively high aquatic toxicity). Thus, there remain 471 registered products (as of October 2013: see Table 1 below). The numbers demonstrate that the market for BCA has significantly expanded, compared with the situation at the start of the millennium (24).

Table 1: Categories of BCA[6] and number of products available in ASEAN (Source: ABC database)

BCA category	Indonesia	Lao PDR	Malaysia	Philippines	Singapore	Thailand	Vietnam	Total
Attractant	9						9	18
Botanical	16	1	8		3	2	60	90
Growth stimulator		2					47	49
Microbial	31	6	35	9	7	23	62	173
Natural product		2	2		1		79	84
Other	1	7				1		9
Product Mix	4	3	1				39	47
Semiochemical	1							1
Grand Total	62	21	46	9	11	26	296	471

2.1 Microbials

Micro-organisms dominate the commercial BCA product portfolio. They are living organisms that are often applied through standard pesticide application equipment. In the ASEAN region, interest in microbials (also alternatively termed 'microbial control agents' or MCA) to date has been dominated by bacteria and fungi, although protozoa, nematodes and viruses have also been developed for practical use, for instance by government research programmes in Thailand (25).

Historically, microbials have been as much about values as commerce and product development, with needs to be driven by highly motivated scientists and research groups (26). From a commercial point of view, there have been three phases in the development of the now highly successful insecticidal bacterium *Bacillus thuringiensis* (*Bt*): with decades passing between early (scientist driven) development and the second stage in the late 1980s, when more optimised products were marketed. Finally in the third phase, the well-known but still controversial technology for expressing truncated forms of *Bt* genes in crops (27), provides highly targeted delivery of the protein to pests at their most susceptible stage (young larvae). However, genetically-modified microbials will not be covered by the *Guidelines*.

2.1.1 ***Bacteria***

Bacillus thuringiensis (*Bt*) is by far the most important BCA to date, both globally and in the ASEAN region (where for example, 69 products have been recorded for control of *Plutella*). Globally, isolates in various sub-species belong to 3 different functional sub-groups, specific to: Lepidoptera (*Bt* [sero]var *thuringiensis, Bt* var *morrisoni, Bt* var *kustaki, Bt* var *aizawai*); Coleoptera (*Bt* var *tenebrionis*) and Diptera (*Bt* var *israelensis*). In recent years, there has also been considerable interest by industry in other *Bacillus* species (e.g. *B. subtilis, B. pumilus*) for disease control. *Bacillus* spp. are commercially and operationally attractive because they have the advantages of ease of production and stability with storage. However, pests are subject to long-documented insecticide resistance to *Bt* toxins (28).

[6] 'plant growth stimulators'/regulators include: auxins, brassinolide, cytokinins, gibberellic acid; 'others' include oils *etc.*

Bt has the capacity to kill insects by the pathogenicity of the bacterium itself, and proteinaceous (*cry*) toxins that form bi-pyramidal crystals inside each bacterium and constitute the main activity of products, can also act as stomach poisons to insect pests. Because of the complexity of action (which might also include a third endotoxin factor), the International Unit (IU) was developed based on bioassay measurements against a standard, although there can be some confusion about their absolute quantitative values (29). Using the IU as a standard for dosage, *Bt* must be applied regularly and in the correct quantity like a chemical insecticide.

With formulation developments and other privately-funded improvements, a range of *Bacillus* formulations are available, with a large number of proprietary commercial products. *Bt* formulations typically have a low toxicity and, having long been compared with chemicals, have usually been assigned as Class III (moderate risk: caution) in the WHO/EPA toxicity classifications (30). In Southeast Asia, the majority of the *Bt* products are imported from the major agrochemical companies, but there are also local manufacturers.

2.1.2 ***Fungi***

According to the ABC database, entomopathogenic fungi (EPF) in the genera *Metarhizium* and *Beauveria* have been developed and used on a localised basis in a number of Southeast Asian countries for various pests including insects in the Hemiptera, Coleoptera and Diptera. The antagonistic fungi *Trichoderma* spp., including *T. harzianum*, has been used in several AMS for management of soil-borne diseases.

Cases of successful biological control with fungi have been a driver for phylogenetic research on several important genera, using molecular techniques that frequently reveal a diversity that is remarkably greater than older classifications based only on morphological characteristics (e.g. the old 2 'varieties' of *Metarhizium anisopliae* are now known to represent at least 9 different spp. (33). The species in *Beauveria*, *Lecanicillium* (five species that were previously '*Verticillium lecanii*') and *Trichoderma* have likewise been revised.) Correct identification of fungal isolates is essential since we now understand that individual species may 'target' pests: often at the family level or more specifically. Inexperience with genetic characterisation and lack of technology are currently major obstacles in AMS to raise the quality of fungal BCA through proper identification and formulation. Future efforts to improve the situation should especially include the producers in the private sector. Improved characterisation of isolates or strains also will be beneficial to the regulators.

Although pest management, based on fungi such as *Beauveria* and *Metarhizium*, has a century-long history of efficacy and safety, it must not be assumed that all fungal isolates are safe; for example, individual isolates in certain species of *Trichoderma*, *Isaria* (previously *Paecillomyces*) and even *Metarhizium* have been shown to produce secondary metabolites that may be risky to human health. Promising 'new' isolates and species must be identified accurately, and a toxicology profile prepared before advanced product development takes place. This was carried out for *M. acridum,* and products were developed for environmentally-sound locust and grasshopper control in the international LUBILOSA (34) Programme: which placed a range of 'enabling technologies' in the public domain for turning potentially beneficial fungi into useful, stable, practical products.

Rigorous quality control in production and formulation is especially crucial for EPF even in an 'appropriate technology' context (35). In particular, minimisation of moisture from preparations of fungal spores is vital for storage stability (36). Some poor-quality formulations have caused blockages in application equipment and rigorous particle size specifications are needed.

2.1.3 *Protozoa*

Only a few BCA products worldwide are based on protozoan parasites, including *Nosema* species against certain insect pests. The reasons for that are manifold, but primarily include difficulties with production and life cycles with sexual stages that pose problems regarding regulator's demands for genetic stability of isolates.

In ASEAN, one successful example of a commercial product based on a protozoan BCA is *Sarcocystis singaporensis*, a cyst-forming parasite that naturally infects rodents (rats of the genera *Rattus* and *Bandicota*) and a boid snake: the reticulated python. S. *singaporensis* has been developed for rodent control in Southeast Asia (37), with a product which is now available in at least three AMS (Thailand, Indonesia, Lao PDR; it also has been registered in Vietnam). This product was deliberately developed and commercialised locally, because it was realised early on that the use of a native BCA could be advantageous with regard to effectiveness, economics of production (these parasite are grown in live hosts), and the regulatory hurdles to be overcome (being a pathogen of mammals). It is a good example of how an idea, having first being scientifically conceived, was developed further by international development cooperation (German government, DOA of Thailand and Indonesia), and finally commercialised through technology transfer to the local private sector (25) (37).

Sarcocystis singaporensis was examined more than 20 years with regard to host specificity, a point that was crucial to determine that the micro-organism is highly specific for its target hosts and safe for humans and non-target animals, in particular other mammals. Because rats are sensitive to certain infection doses even if they are infected naturally, this is a powerful example of how a naturally evolved host-parasite relationship can be exploited for effective pest management. Application of *S. singaporensis* is especially effective in combination with the establishment of barn owls, which are unaffected by the protozoan (38). This approach has become increasingly attractive for rodent management in oil palm plantations of Southeast Asia: environments which are highly challenging for rodent management as number of rats can reach several hundred per hectare.

2.1.4 *Insect viruses and entomopathogenic nematodes*

Whereas insect viruses and nematodes hold a strong position in the product portfolios of BCA in Europe, the US, and other developed countries, there is currently only one NPV (nuclear polyhedrosis virus) product registered in Vietnam according the ABC database. Nematodes are actually not micro-organisms but may be treated as such from an operational point of view. From a regulatory perspective, they have been treated as macro-organisms in the EU - with very little regulatory burden – hence their relative commercial success.

However, pilot production plants for baculoviruses and nematodes have been established at the DOA in Thailand, and products of both types have been elevated to the commercial level in collaboration with local companies or research institutes (25). For instance, the baculoviruses against key lepidopteran vegetable pests in Thailand (*Spodoptera exigua*, *S. litura*, and *Helicoverpa armigera*) are currently mass-produced by the research institute BIOTEC and have evolved to high quality products. Yet, market penetration is still limited due to stiff competition with synthetic pesticides and a still limited commercial distribution system. This example outlines the importance of approaching development and commercialisation of BCA from a demand-driven perspective, which should engage the private sector in the early phase of development.

2.2 Macrobial agents

These include insects and mites that are most commonly mass-reared before release as inundative/augmentative biological control agents. Other modes of deployment include conservation control (using native predators and parasitoids) and 'classical' biological control (introductions of natural enemies, often from the centre of origin of an invasive pest) (39). Only in the latter approach is regulation required: with successful introductions depending on extensive preliminary studies (that require up to 10 years) to gain a comprehensive understanding of the biology and ecology of the pest and natural enemy complex. Analyses are made of the environments from which they originate and have subsequently colonised, or into which they would be released. Concern about the risk which introduced biological control agents might pose to natural, non-agricultural ecosystems did not become a major issue until recently. However, the most successful 'classical' biocontrol campaigns have had among the highest cost–benefit ratios of any pest management practice.

Examples of species used in Southeast Asia in the two categories are:

- In Malaysia, *Trichogramma* sp. was produced locally in 1995 to control sugar cane borer (*Diatraea saccharalis*) and *Diadegma semiclausum* was used against *Plutella xylostella* on crucifers in organic farms (78).
- In Thailand and Indonesia, an outbreak of *Heteropsylla cubana* (Homoptera: Psyllidae) was controlled by 2 species of predators and 1 species of parasitoid. The predators were *Curinus coeruleus* and *Olla abodominalis*, introduced from Hawaii and Saipan. The parasitoid, *Psyllaephagus yaseeni* (Hymenoptera: Encyrtidae), was also introduced from Hawaii to Thailand for the same purpose, later it was introduced from Thailand to Indonesia (73) (74).
- Locally produced *Cotesia flavipes* (Hymenoptera: Braconidae) was used to control sugarcane stem borers (75) and *Diadegma semiclausum* was used against diamondback moth or *Plutella xylostella* in Thailand.
- A recent example (2012) includes the successful release of the wasp *Anagyrus lopezi* introduced from Benin to control the pink cassava mealybug *Phenacossus manihoti* in Thailand (76). Biological control reduced the infested area from 170,000 ha in 2010 to 64,000 ha in 2011, and just 3,300 ha in 2012 (Rojanaridpiched et al. 2012 cited in (40)).

ASEAN Member States follow FAO guidelines: usually restricting regulatory controls only to the import of alien organisms for biocontrol. The issue of regulation of macrobials was strongly related to cross-border trade. In the case of a native species, augmentation in the same country is not usually a problem; but what about inter-island supply of macrobials? Should a species be regarded foreign in a country when it is imported from neighbouring countries that are located in a region of similar ecology or environments? More concretely, should we regard a *Trichogramma* species from Malaysia as a foreign species in importing to Indonesia, although the species is also available naturally in the importing country?

2.3 Semiochemicals

Semiochemicals are biochemical molecules or mixtures that carry specific messages between individuals of the same or different species. In crop protection, semiochemicals are often used as insect attractants (pheromones), but may also act as repellents. Most of the semiochemical products used worldwide are pheromones used for monitoring pest populations: usually in conjunction with a trap mechanism (e.g. sticky boards, water).

Pheromones can be considered as the active substances of plant protection products, if they are used for sexual confusion or mass trapping rather than monitoring. If the pheromone is added to attract insects which are then killed by an insecticide, the pheromone can be considered as an adjuvant in a formulation where the active ingredient is the insecticide. In this case, even where highly active pesticides (such as pyrethroids or fiproles) are used, their deployment is highly targeted: so that impact on the environment and non-target organisms is negligible.

The basic regulatory requirements require chemical identification, physicochemical properties, toxicological and eco-toxicological profiles, proof of air concentrations (in case of volatile application), and proof of user safety (for handling and disposal). ASEAN Member States may seek guidance from existing regulations in the EU, US, and by OECD: with simplified requirements (in comparison to synthetic pesticides). These include scientifically-based waivers for specific groups of semiochemicals (e.g. straight-chained lepidopteran pheromones, or SCLP), and general guidance for the evaluation and adequate rationales for other semiochemicals. A "reduced-risk" approach (linked to a fast-track registration) is upheld by the US EPA (especially with regard to SCLP), where the following criteria apply:

- Low toxicity and impact on non-target organisms;
- Very low rates of use.

Although some data requirements are listed in the FAO (2012) guidelines (41), these are not specific to this group of products and contain no guidance on reducing risk. The potential risks associated with the use of semiochemicals could include exceeding the prescribed air concentrations due to improper application, unspecific attraction of non-target or beneficial species, ineffectiveness when used under inappropriate conditions, or the hazard potential of the accompanying 'killing' or formulating agent. However, semiochemicals are usually treated as 'reduced-risk' pesticides and regulation can be handled faster than conventional chemicals.

The regulatory situation for semiochemicals in ASEAN is unclear, sometimes complicated and reflects the fact that semiochemicals themselves have a non-toxic mode of action. While some countries (e.g. Thailand, Indonesia, Philippines) have received applications to register semiochemicals, this has proved to be difficult, because efficacy testing cannot be compared to chemical pesticides (i.e. killing agents). Therefore, applicants have had to declare their crop protection claims very carefully; the complexity of field testing protocols increases with the following sequence of claims:

Trapping efficacy → Pest population reduction → Crop damage reduction → Crop yield improvement

Consequently, only "trapping efficacy" was proposed as the main objective for field testing, while other parameters (such as population reduction, damage reduction, or yield improvement) should remain an issue between BCA supplier and farmer, and their testing ought not to be part of the registration procedure. To help applicants in ASEAN and to foster mutual recognition of dossiers, harmonised field testing protocols should be made available[7].

In Thailand, semiochemicals are declared as industrial chemicals, with much lower regulatory requirements (only a MSDS). In addition, there are much lower taxes on industrial chemicals than on pesticides. Indonesia has a considerable number of BCA registered as semiochemicals, but possibly this regulatory classification needs revision, for example, in the case of synthetic attractants or repellents (there is no repellent product registered for agricultural use in ASEAN, only for household use). In Malaysia, semiochemicals are widely used commercially throughout the country and also exported to Indonesia. Malaysia does not require registering semiochemicals, and therefore there are no semiochemicals used as "pesticides". In other AMS, semiochemicals are at the research phase and not commercially available, or information is still lacking (cf. Minutes of the 3rd work meeting of the ASEAN BCA expert groups).

2.4 Natural (botanical and other) products

Natural plant extracts, often known as 'botanicals' include a wide variety of substances with different properties and biological activity. Registered products which appear to be widely used in Southeast Asia include various extracts of the Indian neem tree (effectively azadirachtin: the leading botanical active ingredient), natural pyrethrum, ginseng extract, saponin, rotenone, capsaicin, garlic and various oil extracts. With 60 different botanical products, Vietnam shows the highest number of registrations in this category (Table 1). The importance of botanicals is further underscored by the fact that many unregistered products are circulating in the market, often produced by research institutes, small private manufacturers, or even by farmers themselves. Useful details of manufacturers and references are included in the ABC database, the *BCPC Manual* and *Biopesticides of Plant Origin* (42), respectively.

Internationally recognised lists of 'safe' botanicals exist, which include those considered of minimum risk and should not need further toxicological testing. These are categorised as 'reduced-risk' or have a history of 'safe-use'. However, the botanical group includes substances such as rotenone - a WHO/EPA toxicity class II compound – so as with microbials, it is important not to

[7] See Minutes of the 3rd EWG meeting and Appendix III

assume that plant extracts are safe. Likewise, compounds such as pyrethrum are subject to insecticide resistance (or cross-resistance with synthetic pyrethroids) and may be toxic to bees.

A major obstacle for commercialisation and wider availability of botanical products in the region is the inability of local manufacturers and the regulatory system to properly address characterisation and risk assessment of plant extracts with multiple active ingredients. This is also a problem at the international level. A seminar on botanical extracts was organised by the OECD BioPesticides Steering Group (BPSG) (43); in their summary, key issues to be addressed included the following statements:

- "It is clear that the term 'botanical' covers a very diverse group of compounds therefore, depending on the characteristics of an active substance, flexibility and consideration on a case-by-case may be needed."
- "It is also clear that the issue of specification for 'botanicals' is more complex than for conventional chemicals and there are problems of how to provide technical specifications. Plant extracts are complex mixtures of a wide range of chemical compounds and biological activities. Various approaches are under evaluation including:
  (i) the biomarker approach in which the key compounds of the bioactive plant extract are determined. This approach can be used for quality assurance but it is unclear how this is related to the efficacy of the substance/product.
  (ii) Biocide 'whole extract' approach, but this may lead to 'variability issues'
  (iii) Blending (technical mixture of active substances) may be an option[8]."
- "It is still unclear how to deal with synthesised analogues or mimics, which are nature identical but synthesised versions. Should they be treated as 'conventional chemicals'? In this respect it should also be mentioned that radio-labelling techniques are impossible to use for plant extracts. A more balanced approach is needed."

ASEAN regulatory experts worked together to define "Minimum data requirements for botanicals' (Appendix II) that consider some of the points mentioned above. In the meantime, while the present document was under preparation, the EU has issued an updated guidance on the regulation of botanicals (79), which could serve as a valuable source to develop further the issues discussed above.

It was proposed in the work meetings that botanicals should not be compared directly with synthetic pesticides when it comes to measuring effectiveness in the field. Botanicals degrade quickly in the environment and are less rain-fast than synthetic products, which may result in lower short-term performance and require different application tactics; this should be acknowledged by regulators and users as well. The value of plant extracts is most apparent during early growing stages, at low pest pressures and against young larvae rather than adult insects. These principles are documented in a field testing protocol that was jointly developed by the regional BCA expert group (Appendix III).

[8] But such an approach would hardly result in "natural products"

2.5 Formulations, quality control, and application techniques

2.5.1 *Formulations of microbials*

Formulation improves the properties of active control agents (be they biological or chemical) for handling, storage, application and may substantially influence effectiveness and safety. However, regulatory authorities should be aware that with several microbial and even some modern chemical pesticides[9], the mammalian toxicity of the formulating ingredients may exceed that of the active control agent.

Formulation terminology follows an internationally recognised two-letter convention; unfortunately, many manufacturers still fail to follow these industry standards, which can cause confusion for users. Regulators should insist that all producers describe BCA with the easily recognisable formulation descriptors (and thus appropriate specifications) listed by *CropLife* (31) and FAO/WHO (32).

The most frequently used products are formulations for mixing with water then applying as sprays, with older formulations such as wettable powders (WP) still in use. From the 1980s, conventional products such as emulsifiable concentrates (EC) were slowly replaced with formulations having reduced or no use of hazardous solvents and improved stability. Examples include suspension concentrates (SC) and water dispersible granules (WG) that are easier and safer to handle by the operator and have been used for microbial products such as *Bt*.

In all cases, the formulation scientist seeks to minimise the rate of settling of particulate suspensions of microbials in the formulation bottle and sprayer tank, by minimising particle size. The rate of settling is governed by Stokes' formula, whose most important factor is particle size: the only squared parameter in the equation. For microbials, particle size obviously cannot be less than that of a single propagule (colony forming unit), but there are likewise advantages in minimising constituents that do not exceed this size (to avoid nozzle blockage, etc.) As discussed in section 2.5.3, from a practical application point of view, one of the most important features of microbials is that they must be delivered to the target as particles: usually suspended in a liquid and dispersed as spray droplets. At a much more basic level, it is important that there are no large particles in the formulation which risk clogging filters and nozzles of spray equipment.

The specific requirements for quality control of microbials will be heavily dependent on the nature of the organism and may be species-specific. Important specifications usually include:

- Limits for contaminants (e.g. no human pathogens detected in 10,000 CFU sampled)
- Viability at packing; viability profile over time (usually temperature dependent) …
- ... for fungi, this affected by moisture content (see below)
- Particle size specifications (formulation dependent: as above)

[9] Microbials, plant extracts, fermentation products and relatively specific (non-neurotoxic) chemicals can be collectively termed 'biorational pesticides'

2.5.2 *Quality control and labelling of BCA*

The product label provides the means of communication between the producer, the regulator and the farmer (or his/her advisor). As such, labels are crucially important and must therefore be a key part of regulatory scrutiny. National regulators have labelling policies and labels must always be written in the appropriate local language(s), but international advice is available on harmonising label formats, which has similarities to those of standard pesticides. An example (from *CropLife*) is given in Figure 1.

Because of their nature that is frequently different from conventional chemicals, BCA should have appropriate and as comprehensive instructions on application as possible. For microbials, the following information must be included:

- Isolate used (implies virulence)
- Number of CFU/IU (or other unit) per gram
- Expiry date

It is incumbent on regulators to check on whether the information on quantities/concentrations, together with the application instructions, is compatible with encounter of the microbials by the target pest and thus the probability of efficacy (see below).

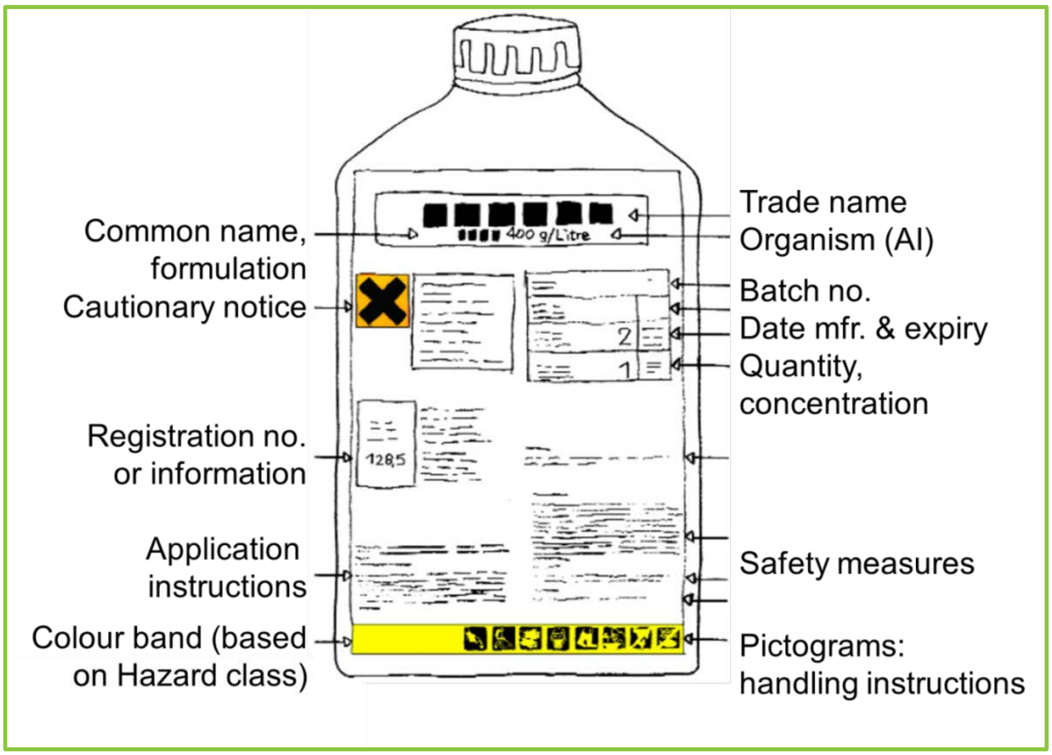

Figure 1: Important components of a pesticide label (courtesy *CropLife* International)

2.5.3 *Application techniques*

Because BCA encompass quite a variety of different products and active agents, which fall into different categories with different modes of action, guidance on proper application techniques has to acknowledge this product diversity. The group that shows the greatest similarities with synthetic pesticides in terms of application technique is the microbials, which also explains to a large extent their greater success in the market compared with other BCA.

Nevertheless, also microbials show peculiarities that distinguish them from common pesticides. In general, handling and application of BCA will be influenced or determined by one or more of the following factors:

- Nature of the agent: e.g. microscopic or macroscopic, living and self-replicating, particulate, biochemical or volatile compound, etc.
- Mode of action: delayed killing effect, antagonistic or competitive behaviour (not killing), attractant, repellent, etc.
- Specificity: usually high or higher than common pesticides' target specificity
- Shelf life & biodegradability: many BCA have reduced shelf lives and biodegradability in the environment is higher compared to common chemical products.

Practical advice on how to apply microbials and botanicals was attached to the field testing protocols that were developed in the course of making these *Guidelines* (for the protocols, see Appendix III). This and more useful information is contained in Cornell University's Resource Guide for Organic Insect and Disease Management (69), which is a valuable source for hands-on experience and knowledge regarding the application of BCA. It is available at http://www.nysaes.cornell.edu.

In order to achieve success in the field with many microbial applications, spraying techniques are of crucial importance. Some farmers regret the withdrawal of older chemical pesticides: which were often cheaper than the substituted, 'biorational' products. Crude application methods, that were adequate for chemicals with a long persistence or fumigant action (now unacceptable) is often inadequate for many biological products (and some modern chemicals). There has been a convergence in need for more targeted application methods for chemicals, microbials and other biologically-based control agents (44). Applying less, by applying more efficiently, should be a fundamental maxim in IPM (whether using BCA or conventional chemicals), yet pesticide application practices have not improved over recent decades in many countries: in some, standards have actually gone down. A contributing factor may have been overzealous implementation of IPM programmes that sometimes has precluded the use of pesticides altogether, making their use an 'unofficial' activity and effectively deskilling (or at least not training) farmers in better techniques.

Optimising efficacy in the field with BCA usually requires a 'delivery system' approach involving appropriate formulations and careful selection of application equipment (45). Because of their particulate nature, microbial formulations often have special application requirements. There is (i) usually a clear relationship between number of particles and biological efficacy and (ii) an essential need to keep the organism alive. If a microbial is to be delivered as a spray, the propagules must be suspended and distributed so that they have a reasonable chance of reaching the target site. In the development of a new microbial product, a careful analysis is needed of the numerical distribution of particles: in the formulation bottle, sprayer tank mix, spray droplet spectrum and the fate of those droplets. With dissolved or nano-particulate active substances, botanical extracts and fermentation products can be treated functionally as similar to chemical pesticides in this respect, but all biorational pesticides will benefit from careful attention to dose-transfer efficiency. Improved delivery systems are most unlikely to revive a poorly performing BCA, but the performance of a good control agent (as with a chemical pesticide) will be severely reduced by poor delivery systems.

FAO provides *guidelines on the minimum requirements for agricultural pesticide application equipment* (46), but unfortunately in any visit to sprayer stores or farmers in the region, it can be difficult to find equipment that complies with these requirements. For portable equipment (as used by most farmers and especially smallholders), specifications are given for sprayer tanks, pumps, etc., with specific requirements on nozzles. These include:

- "Nozzles supplied with or recommended for a sprayer should be manufactured to international standards (ISO)[10]."
- "The sprayer manufacturer should include in the sprayer manual, information on: nozzle flow rates, characteristic spray patterns and spray angles … "

Spray quality matters, but it appears increasingly that locally available sprayers are fitted with variable cone nozzles which are impossible to calibrate and produce an infinitely variable range of droplet size spectra and flow rates (47). A relatively small number of large droplets may represent a large proportion of the spray volume (that could have been turned into a large number of more efficient small droplets). These larger droplets are highly likely to run off leaves, fall back onto the ground ('run-off' or exo-drift) and be wasted. This can be a contributory factor to poor or variable efficacy.

3 Crops: Case studies

3.1 Rice

Rice is the primary staple food in the region and therefore a key target crop for development. In the context of the ABC project, experts decided to focus on brown plant hoppers (BPH: often included together with white-backed plant hoppers, *Sogatella furcifera*), various species of stem borers (*Scirpophaga* and *Chilo* spp.) and rice blast (*Magnaporthe grisea*). However, sheath blight is important in some areas: especially the Vietnamese summer crops, prompting the widespread marketing of validamycin (from the fermentation of *Streptomyces hygroscopicus*) and a range of other antibiotic-type products.

Information on pests and diseases has been based on the considerable amount of literature published by IRRI, which historically made extensive use of cumulative damage data. However, such data did not always reflect the actual variability of damage in an agro-ecosystem and were often

[10]ISO 10625:2005 specifies system of colour coding for identification of standard hydraulic spray nozzles (e.g. flat fan, deflector and single component cone nozzles)

obtained under intense pesticide regimes, making the data unhelpful for determining biocontrol strategies. Nevertheless, current knowledge of the rice environment suggests that insect pests are in many cases of lesser importance when compared to weeds or rodents, for instance. It also appears to be commonly acknowledged among the scientific community that BPH usually only achieves pest status after repeated application of broad-spectrum insecticides. However, action thresholds for BPH must be lowered if the virus diseases grassy-stunt and ragged-stunt are present. It is also necessary to distinguish between three different rice habitats: lowland irrigated, rainfed lowland and upland (dry land) rice, which often show contrasting pest and disease complexes.

3.1.1 *Member States' experience, scientific evidence, market information (ABC database), and results from field trials*

Only Indonesia and Vietnam presented field application details for entomopathogenic fungi against **brown plant hopper** (BPH). Thailand provided some references to published studies mainly dealing with effectiveness of local isolates of entomopathogenic fungi under laboratory and semi-field conditions. Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, and Vietnam listed IPM measures that deemed useful against BPH (see below). Based on internationally published scientific studies, the main BCA that appear to be effective against BPH are entomopathogenic fungi, namely certain isolates or strains of *Beauveria* spp. and *Metarhizium* spp. (53) (54) (55). Isolates or strains that showed high levels of effectiveness were applied in the field at rates ranging from 5 x 10^{12}, 6 x 10^{12} to 7.5 x 10^{12} conidia per ha based on experiences from the Philippines, Vietnam, and Korea, respectively. Dry mycelia of *B. bassiana* can also be applied at rates equivalent to 200 g per ha in a formulation with 5% LiquaGel® (56).

The ABC database identifies several commercial BCA recommended for use against BPH in Vietnam, Indonesia and Malaysia (see Appendix I). The available products are based on neem or entomopathogenic fungi; however, only Vietnam lists entomopathogenic fungi as specifically registered for use against BPH. Furthermore, the action thresholds for starting a fungal treatment have not yet been fully established. One source (70) recommends starting treatment at a density of 3 BPH per tiller, or about 1000 per m^2. A minimum pest population level appears to be necessary for the secondary cycling (horizontal transmission) of entomopathogenic fungi. In this regard, it is recommended by various publications not to spray fungal products preventatively (i.e. when the target pest is completely absent).

Besides use of BCA, the following IPM measures were proposed by AMS and found common acceptance:

- Use of resistant varieties
- Synchronous timing of planting
- Use of fallow periods
- No use of chemical pesticides if pest under threshold, at least until 40 days after transplanting (DAT), unless virus diseases are present in the area, in which case, targeted application (of biorational agents) may be warranted
- Monitoring of natural enemies and pest incidence

- Balanced use of nitrogen fertiliser (avoid overuse)
- Reduced seedling density
- Sanitation measures

Rice stem borers are reported as widespread; however they rarely cause significant crop loss in the common short-duration varieties. Where control is needed (e.g. in long duration, premium varieties), the main biocontrol approach favoured by AMS includes *Trichogramma* spp. In principle, timing of control is very important for rice stem borer, as this pest is most damaging during the panicle initiation stage. However, availability of BCA appears to be very limited, with state sponsored production of these insects in decline. As with other insect natural enemies, their effectiveness is hindered by widespread overuse of broad-spectrum insecticides.

It is important to stipulate how *Trichogramma* use could be promoted in the future - and which species are actually to be used (therefore more effort put into identification and characterisation). Other BCA against stem borer include botanicals and pheromones. The ABC Project will address the latter with the descriptions of field demonstrations of mass trapping with sex pheromones; the results are not included here, because the demonstrations were still ongoing when this text was written. Large-scale experience with pheromone-based mass trapping has been described from India (58). The changes in practice recommended for brown plant hopper (e.g. the 40 DAT pesticide moratorium) would also help manage stem borers and other insect pests, because preservation of natural enemies would increase the crop's natural pest control function. Commercially available and registered products against rice stem borer according to the ABC database only include botanical products based on plant extracts of *Croton tonkinensis* (Matrine) in Vietnam, and on root extracts of *Sphora flavescens* (Oxymatrine) in Cambodia (see also Appendix I).

The scientific evidence available reflects quite well the recommendations of AMS. There exist various studies on the application of *Trichogramma* species against rice stem borers. All of them arrive at an effective release rate of around 100,000 adult parasitoids per ha, applied two times as in Indian field trials (57). The published data emphasise that, in the case of macro-organisms, it is important to exactly identify the species of *Trichogramma,* since they performed differently against various pests in the field.

Species-specific sex pheromones are the second major biocontrol approach that has been tested successfully for stem borer control, particularly in India and Bangladesh. A study from 2008 in India compared use of rice stem borer mass trapping (employing sex pheromones) with synthetic pesticides and farmer's practice (58). The economic analysis also included other input costs (e.g. herbicides, fertiliser etc.) and revealed that pheromone application can indeed replace chemical pesticides in terms of effectiveness and economy.

Rice blast, *Magnaporthe grisea*, an ascomycete fungus, is also known as rice blast fungus, rice rotten neck, rice seedling blight, blast of rice, etc. is a plant-pathogenic fungus that causes an important disease affecting rice. It is now known that *M. grisea* consists of a cryptic species complex containing at least two biological species that have clear genetic differences and do not interbreed.

Complex members isolated from the tropical grass *Digitaria* have been more narrowly defined as *M. grisea*. The remaining members of the complex isolated from rice and a variety of other hosts have been renamed *Magnaporthe oryzae*. Confusion about which of these two names to use for the rice blast pathogen remains, as both are now used by different authors.

Management of rice blast includes use of resistant varieties, seed treatment with systemic fungicides, balanced use of fertiliser, use of compost, and sanitation were recommended. Available BCA include *Trichoderma* spp., *Bacillus subtilis, Corynebacterium* sp. and chitosan. Although *Trichoderma* spp. and *B. subtilis* (Indonesia), and *Trichoderma* spp. and Chitosan (Vietnam) are commercially available in the respective AMS, they appear not to be particularly registered for application against rice blast (according to the ABC database).

Box 1: Application of *Trichoderma harzianum* for management of rice blast

Field trials to test the effectiveness of *Trichoderma* species in controlling rice blast were jointly planned in the Regional BCA Expert Group on Application and implemented in Lao PDR (under supervision of the Plant Protection Centre in Vientiane) and in Cambodia in four provinces: Prey Veng, Kampong Chnang, Battambang and Kandal (under supervision of the DOA). Although not all data could be evaluated at the time of writing this document, preliminary results from Battambang in Cambodia were highly encouraging.

Four treatments (with four replicates) were compared: T1) negative control without composting, T2) negative control with composting, T3) treatment with *Trichoderma harzianum* added to compost, T4) *T. harzianum* added to compost and sprayed on leaves four times. While moderate infestations with rice blast were recorded in T1, none were seen in the other treatments. Great differences were observed in rice yields at harvest: While composting alone (T2) doubled average yields from 2 (T1) to 4 tons ha^{-1}, application of *T. harzianum* further increased yields to averages of 5.5 tons ha^{-1} (T3) and 6.1 (T4) tons ha^{-1}. While T3 and T4 were not significantly different, all other pairwise comparisons of treatments were statistically different. An economic evaluation is under preparation. Apparently, application of compost alone already controlled rice blast infection. Importantly, the fungal treatments visibly improved root growth of the rice plants confirming earlier studies that *Trichoderma* has a positive impact on the overall plant nutritional status besides disease control.

The lesson learnt from this trial is that proper nutrient management and biocontrol can go hand in hand for achieving optimal results. An important publication that provides a good overview over the properties and functions of *Trichoderma* fungi was published in the year 2000 already, but is still relevant today (77).

The positive effects of biocontrol with *Trichoderma* could be directly observed by the Regional BCA Expert Groups in vegetable fields during the excursion that was linked to the Project Partner Meeting in Cambodia on 13 March 2014. The field trip was hosted and directed by Dr. Kean Sophea of the DOA, Cambodia, who had arranged demonstration plots in tomato, cucumber and other vegetables. Generally taller and healthier plants could be observed in treated fields and local farmers were content with the results.

3.1.2 *Conclusions: development of BCA in rice production*

During discussions with regional experts, the role and use of BCA in rice is predicated on:

- Relieving rice farmers from the 'treadmill' of continuous synthetic pesticide use.
- Disavowing farmers of the belief that pesticide use necessarily increases yield.
- Avoidance of broad-spectrum insecticide use within the first 40 days after transplanting.
- Promoting the combination of cultural measures and BCA use, especially for seed treatment and against early stages of pest insects.
- Observing the actual relevance of pests, weeds, diseases, rodents, etc., and taking appropriate measures only when necessary.

With regard to management of **BPH**, BCA based on entomopathogenic fungi appear to be the most promising, but quality aspects need to be emphasised in the future, such as isolate or strain characterisation (genetics, biology, target specificity), in view of selection of the most effective products. Furthermore, formulations have to be improved and action thresholds in the field need to be confirmed for designing reliable application protocols. Although commercial products based on entomopathogenic fungi do already exist in some AMS (Appendix I), most of them are not registered for use against BPH. Therefore, private companies producing entomopathogenic fungi should be encouraged and supported to implement these improvements and further expand their portfolio especially for application in rice and against BPH.

The application of parasitoids of the genus *Trichogramma* against **rice stem borers** appears to be straightforward and well elaborated in the field. Yet a broader application of this approach would require significantly reduced or no broad-spectrum pesticide applications in the future. The technological know-how to mass-produce *Trichogramma* is established in some AMS (e.g. Philippines, Thailand, and Indonesia); thus, the revival or extension of local production is feasible. Mass trapping based on pest species-specific pheromone lures appears to be another promising approach, which has been elaborated and field-tested in India. Large-scale applications (to increase efficacy and reduce costs for the farmer) should be field-tested in ASEAN to see whether the good experiences from India can be confirmed under Southeast Asian conditions. However, BCA-based IPM approaches require careful economic evaluation over several years, because the pest status of stem borers appears to be overrated at times and field experience indicates that removal of pesticide inputs alone could raise profitability for the farmer.

To date, fungal diseases such as **rice blast** or sheath blight are still perceived to be difficult to treat by farmers and plant pathologists. The ABC database appears to reveal that rice blast is not 'targeted' by many BCA, despite its widely cited importance in AMS. However, solutions that work for managing fungal diseases in rice have been developed already: for instance, FAO has worked out management options for rice blast within its farmer-field-school programmes in Southeast Asia. Experiences from Vietnam indicated that rice blast usually could be managed with the use of resistant rice varieties coupled with careful nitrogen management and optimised seeding rate (59). BCA could complement this IPM approach by providing the necessary tools once the strategy above would not be sufficient to fend off disease. In particular, the field trials that were conducted by ABC with its partners in AMS while developing these *Guidelines* have revealed that the application of *Trichoderma harzianum* is a useful tool not only to control disease but to improve general plant health. Based on a low cost (local) production, *Trichoderma* should be made widely available to farmers and could become a mainstay for disease and nutrition management of rice. Making *Trichoderma* spp. and other BCA available for rice blast management in ASEAN could also include the extension of existing registrations for active agents to new crops. Finally, new products based on *B. subtilis* should be also tested for their potential to control rice blast.

Biocontrol of fungal diseases using antagonistic fungi like *Trichoderma* spp. or microbials like *B. subtilis* could become important in the area of food safety in the future. Aflatoxin is a highly toxic compound of the fungus *Aspergillus flavus* that grows on a variety of food commodities, including rice. Aflatoxin has been linked to liver cancer worldwide, but hepatocellular cancer prevalence in developing countries is 16-32 times higher than in developed countries (71). Pre-harvest interventions in the field have been highly effective by using biocontrol with antagonistic fungi to reduce infestation of crops with toxigenic *Aspergillus flavus* (72). Thus, with appropriate governmental support and private sector cooperation, biocontrol may become an important component of Aflatoxin reduction strategies.

3.2 Vegetables

Vegetables are widely grown, especially by smallholder farmers in the region, both for family food consumption and as fast-growing cash crops. Three major pests include diamondback moth (DBM: *Plutella xylostella*), flea beetles (*Phyllotreta* spp.), and fungal diseases caused by *Fusarium* spp.

3.2.1 *Member States' experience, scientific evidence, market information (ABC database), and results from field trials*

Diamondback moth (DBM) was stated as a major pest in cabbages and other vegetables by almost all AMS, inflicting high percentages of damage, and causing complete crop loss in certain areas. It appears that season and climate affects severity of attack: Vietnam finds DBM to be more of a problem in the cooler north of the country while Indonesia observed more damage in the dry season.

Biocontrol using macro-organisms appeared to be a highly recommended strategy by Indonesia, Malaysia, and the Philippines, including the use of parasitoids like *Cotesia plutellae* and *Diadegma semiclausum*. Application of *Bt* was recommended by all AMS as a main component or supplement to other control approaches. Vietnam also mentioned the usefulness of various botanicals against DBM. Crop rotation is generally regarded as effective, but only strongly by two AMS, whereas pesticides were recommended (on an action threshold basis) by six AMS.

Specific government strategies and programmes to reduce synthetic pesticides have commenced in some AMS. For instance, Brunei Darussalam is currently considering how its GAP scheme can be used as a suitable platform for biocontrol products. Indonesia (Ministerial Decree) and the Philippines (Organic Act) cited changes in legislation as a potential path to promote more environmentally friendly inputs in pest management. Singapore highlighted training courses for pesticide operators as an entry point for education on biocontrol products.

Indonesia and the Philippines presented detailed instructions on how to produce and apply parasitoids for use against DBM based on governmental production facilities' experiences. However, no details on the cost of such programs were provided. Malaysia highlighted the use of monitoring (specific threshold levels for DBM) as a decision support tool for determining whether *Bt* or synthetic pesticides would be used against DBM. Singapore detailed on the application of nets to keep out DBM, highlighted crop rotation with non-cruciferous crops, applied sex pheromone traps at recommended densities, and cited the use of abamectin and *Bt* as biocontrol strategies at higher DBM levels.

Early scientific studies (1980s and 1990s) established the use of parasitoids as an effective means against DBM in Southeast Asia (mainly in Indonesia and Malaysia). Already during that time, it was recommended to combine *Bt* and parasitoids, and this was further consolidated in a review from 1993 (60), which identified DBM as a "difficult to control pest worldwide" due to recurring synthetic pesticide resistance. However, development of resistance has also occurred with *Bt*, therefore requiring an integrated resistance management (IRM) strategy that includes *Bt.* Other tools recommended by science include a close-season for brassicas, plant resistance, cultural controls, pheromones, and other microbials (e.g. *Beauveria* spp.) and botanicals (e.g. neem). In a recent review, (61) it was concluded that DBM still remained the main pest of brassicas worldwide and that the potential of using parasitoids could become realised only if use of broad-spectrum synthetic insecticides was abandoned.

The ABC database shows an availability of a total of 141 registered biocontrol products against DBM (October 2013; excluding avermectins). This is currently the largest product range against an insect pest in the database, which is certainly due to the importance of DBM. This includes:

69 *Bt*-based products
27 Azadirachtin-based products
12 Ginseng products
8 Rotenone-based products
4 Pyrethrins
7 Spinosad products and others

For the control of DBM, experts of the AMS mainly recommended the use of parasitoids, *Bt*, and pheromones as major BCA. This is not fully in line; however, with what is available on the market (*Bt* and neem products). A problematic point is the use of beneficials like *Diadegma semiclausum*, which have been proven to be highly effective (and cost-efficient) for area-wide DBM management in the past, but do not play a significant role anymore, because widespread pesticide applications have greatly reduced their existence. These BCA could only gain importance again, if conventional pesticide use is reduced or completely avoided (see our conclusions below).

There exist no well-established, scientifically-derived approaches to control **flea beetles** yet, which led the experts to the conclusion that more research and product testing is needed. In consequence, trials to test different management approaches for flea beetle were planned in Brunei

Darussalam, Singapore, Thailand, and other AMS, whereby results were available from Thailand by the time of writing of this document. A brief summary is given in Box 2.

Box 2: Field trial on management of flea beetle with biocontrol agents

A replicated field trial to evaluate the effectiveness of two BCA against flea beetles, namely the nematode ***Steinernema carpocapsae*** (produced by DOA, Thailand) and the beetle-specific microbial ***Bacillus thuringiensis*** **var** ***tenebrionis*** (Valent BioSciences), was conducted during the dry season in a Chinese cabbage field of about 0.2 ha in a vegetable growing area of Chiang Rai, Thailand. This area was under the management of the Royal Project Foundation, and the field trial was implemented as cooperation between the Royal Project, the DOA, and the project 'ASEAN Sustainable Agrifood Systems (ASEAN Biocontrol)'. Farmers had reported that his area shows heavy infestations with flea beetles: this was confirmed as high numbers of flea beetles (here: *Phyllotetra striolata*) were already present when the cabbage seedlings were planted in the field. The main purpose of the trial was to compare larvicidal treatments (both BCA target the larvae of the flea beetle and are applied to the soil) with farmers' practice, which consisted of the application of broad-spectrum synthetic pesticides that targeted the adult beetles only. While synthetic pesticides were applied six times (and as a mix of various active ingredients) during the 1.5 month-long growing period, nematode and *Bt* var *tenebrionis* applications were restricted to four and three applications, respectively. Untreated plots served as true negative controls.

The results of the trial showed that both BCA significantly improved root development (weight) of Chinese cabbages during the early weeks of growth, while total plant weight was similar in all treatments. However, once the plants' biomass extended beyond 600 g, development of the negative control plants significantly lagged behind when compared to the other treatments. Damage to cabbage leaves was high across all treatments due to the fact that adult beetles were highly mobile and able to fly to neighbouring plots. At harvest, Chinese cabbages grown on the negative control plots showed a significantly higher proportion of undeveloped heads (loss) and a significantly lower mean total weight of marketable cabbages when compared with plants treated with BCA or synthetic pesticides. Furthermore, in the two marketable cabbage categories 1 and 2 BCA-treated plots produced significantly more heads than those treated with synthetic pesticides. Cost-benefit analysis revealed that application of *Bt* var *tenebrionis* was economical in comparison to synthetic pesticides. In the case of the latter total input costs (including fertiliser) were too high, which generated a loss of income during that season. The trial was replicated in the wet season. Because flea beetle numbers and the associated damage were much lower than in the dry season, insect management was generally uneconomic. Profits at harvest could only be realised under the conditions of the negative control, i.e. by avoiding inputs for insect management (and reducing fertiliser inputs).

In conclusion, both BCA applications helped farmers to achieve better harvesting results when compared to no pest control and synthetic insecticides in the dry season. These experiences also underline the necessity to keep an eye on the economic aspects of farming. Because farmers in that area plant cabbage in a row most of the time, they maintain high levels of the insect pest, particularly in the dry season. Better crop rotation would certainly improve the situation while further reducing input costs.

With regard to infections with ***Fusarium*** species, cultural and physical management techniques described so far need to be further developed and field tested in the future. Various microbial BCA that have been identified as effective in international scientific reports are actually also available on markets in ASEAN, including *Trichoderma* spp., *Bacillus* spp., and *Streptomyces lydicus* (the latter is registered in Vietnam; see Appendix I). However, because many of these products are not registered for use in vegetables, we recommend extending existing registrations to vegetables, after field testing has confirmed the usefulness of these products in relevant crops. Additionally, the use of BCA as seed treatments should be evaluated in the future.

3.2.2 *Conclusions: development of BCA in vegetable production*

AMS' experts ranked the feasibility of implementation of the proposed biocontrol approaches for vegetables as:

> DBM >> fungal diseases > flea beetle, while management of DBM using *Bt* was regarded a good starting point.

Because **DBM** is a worldwide – and one of the most recognised - insect pests, it has attracted a high number of pesticidal products in ASEAN, and is also the number one target for BCA (Appendix I). A biocontrol-based IPM strategy appears to be readily feasible for certain vegetables given the relatively high variety of tools at hand. Just if one considers *Bt*-based products alone, these are available in at least seven AMS (see Appendix I).

Whether or not parasitoid wasps could (again) become an effective tool against DBM will especially depend on the extent to which synthetic broad-spectrum pesticides can be reduced or avoided in areas where a release is considered. This is a topic where governments would need to become involved and take over responsibility for the management of interventions, also because mass production of beneficial insects is not a commercially attractive business to date. Certainly, areas with organic farming would be suitable for release or re-introduction of parasitoids, provided the areas are big enough; or some other kind of agricultural zoning would be required to be implemented in protecting these BCA. Promotion of parasitoids needs not necessarily come along with calls for environmental protection: rather, there are solid economic reasons to rely on biological control using beneficial arthropods. Benefit-to-cost ratios are among the highest in pest management (67). We think that the combination of a parasitoid like *Diadegma semiclausum* with other BCA could become a truly sustainable management approach for DBM and other lepidopteran pests.

Bt is generally a useful tool for control of **important lepidopteran pests**. A broader use is therefore highly recommendable, provided that the issue of resistance management is considered in future promotional activities. But there still exist other BCA: in Thailand, highly effective baculovirus preparations have been developed against important pests of vegetables (25). Although these products are mass-produced under high quality standards (at BIOTEC), they are not registered. Therefore, their market distribution is limited. In other AMS (e.g. Lao PDR, Vietnam), there exist only few registered baculovirus products. Thus, there is still a high potential for the safe and highly effective baculovirus agents to enter the regional vegetable markets of ASEAN. Local production of baculoviruses should be expanded and marketing channels developed. There is a variety of commercial products already available from sources in Europe or India; yet, these are not available in ASEAN.

Although, as indicated above, control of **flea beetles** using BCA was seen as problematic, the field trials conducted by the Project testing *Bt* var *tenebrionis* and entomopathogenic nematodes have shown encouraging results. In particular, with regard to *Bt* var *tenebrionis,* there exist high quality products on the international market; yet, this microbial has been only registered in Vietnam to date (see Appendix I). Nematodes are produced by the DOA in Thailand and sold by few private companies, but are not broadly available in AMS. Both BCA appear to be at least as effective against flea beetles as common chemical compounds and merit broader promotion and application. The Project 'ASEAN Sustainable Agrifood Systems' will repeat the trials in a bid to develop an effective IPM strategy against flea beetles, frequent damage by which could be confirmed in cabbages by recent observations in Cambodia, Vietnam, Brunei Darussalam and Thailand.

Two factors will determine the future of **neem**-based products for control of vegetable pests: (1) availability of high quality products that are properly registered (many regulatory issues remain for botanicals, which should be resolved); (2) since neem and other botanicals usually exhibit a lower efficacy than synthetic pesticides, their use requires application strategies that target young pest stages at higher frequencies. Such adaptation of application methods must be effectively conveyed to farmers; quite often wrong application results in underperformance or failure of plant extracts (see section 2.4). Nevertheless, despite the quality and application issues, it remains a fact that neem extracts (and its AI azadirachtin) are quite commonly available in AMS (see Appendix I). So there apparently exists a demand for neem. We suggest that the use of neem could be expanded significantly once the aforementioned problems are addressed adequately and its effectiveness in a biocontrol-based IPM strategy can be demonstrated.

3.3 Fruits

3.3.1 *Member States' experiences, scientific evidence, market information (ABC database)*

Fruits are considered to be important cash crops, besides providing local food for large number of smallholders in Southeast Asia. Fruit-fly pests (*Bactrocera* spp.) significantly reduce both the quality and quantity of production of various kinds of fruits. In many cases, the losses can reach up to 100%; thus this pest is declared by all of the AMS as the most destructive pest in fruits in the region. All AMS agreed that the term 'fruit-fly' will relate to the genus *Bactrocera* spp. only.

Due to the high variety of species and the various references given by AMS for fruit fly identification, it is suggested to harmonise the identification method by using the same identification aid, e.g. Lucid Key or other online resources.

Various control methods have been practised by the AMS in order to reduce the losses due to the fruit fly in the region as follows:

- Bagging of the un-infested fruits with plastic, cloth or paper
- Field sanitation, especially collecting the infested fruits; then bury them properly
- Cultural practices such as pruning
- The use of sterile insect technique
- Monitoring and mass trapping by using attractant including (1) the male pheromone [methyl eugenol (ME): 4-allyl-1, 2-dimethoxybenzene-carboxylate]; Cue lure: 4-(p-Acetoxyphenyl)-butan-2-one (2) food lure (protein bait-based products)
- Soil application of entomopathogenic fungi (e.g. *Metarhizium*) against fruit-fly larvae
- The use of parasitoids e.g. Braconidae (*Diachasmimorpha longicaudata*, *Biosteres* spp. and *Opius* spp.)
- Application of selective insecticides

Among the various methods mentioned above, the use of attractant (both male attractant and food lure) is apparently most commonly practised in the region; natural enemies (parasitoids and entomopathogenic fungi) and sterile insect techniques appear not to be commonly used. Attractants are reported to be especially effective when integrated with other approaches: especially field sanitation and wide-area cultural practices that avoid immigration from neighbouring, untreated (often non-commercial) areas. The participation of farmer groups and the other stakeholders, working together, is an important factor for the success of fruit-fly management over suitably large areas.

The ABC database revealed that only Indonesia and Vietnam have registered products for fruit-fly management. Methyl eugenol and protein bait-based products appear to be available in the two countries, whereby abamectin is only registered for use against fruit fly in Vietnam. However, it was confirmed by the other AMS that attractants were also available in the other countries but registered as industrial chemicals (but sold as plant protection products).

- Male attractant including methyl eugenol [4-allyl-1, 2-dimethoxybenzene-carboxylate], and Cue lure [4-(p-Acetoxyphenyl)-butan-2-one]: The male attractants were used both for monitoring and mass trapping. With regard to mass trapping, Indonesia recommended to use 16 traps/ha for orange and 20 traps/ha for mango. In many cases, selected insecticides are also applied inside the trap or put onto a wooden block surface to kill the flies immediately. The attractant is applied throughout the year over as many years as needed to reduce the populations of fruit fly to very low levels. To maintain the effectiveness of ME, ME blocks are replaced with fresh ones every 2-3 months, while ME liquid (applied with cotton rolls as carrier) is replenished every two weeks. The attractant can be placed in Steiner traps or traps crafted out of common plastic bottles. If the lure has to be placed high inside trees, ME blocks are nailed onto the trunk.
- The success of mass trapping depends strongly on the time of application. Since mass trapping is a prophylactic tool, it is recommended to start mass trapping when the population is low. Therefore, the threshold level concept that is usually applied in the context of chemical pesticides is not applicable here. Besides trap density and timing of mass trapping, it is also important to consider the appropriate placement of traps: for example, the most effective height of traps can vary depending on the crop in question. Trap design may be another important factor.

- To measure trapping success, it would be useful to correlate damage reduction with the reduction of the fruit fly population. It is recommended that additional traps be set up for monitoring purposes. Monitoring traps can be placed every 5-6 ha inside the farm area as well as at border areas surrounding the fruit orchard. Fruit-fly populations are monitored weekly in order to calculate the number of flies trapped per day (FTD):

$$FTD = \frac{\text{Total No. fruit flies collected in traps}}{\text{No. traps}} \text{ x No. days}$$

- Total No. fruit flies trapped/No. traps x No. days. An area can be considered free of the pest if the FTD is 0. An FTD between 0.1 and 1 means that the population is suppressed, while an FTD >1 warrants for continued control efforts. The success of fruit fly control can be further determined by observing the percentage of fruits that are infested. Fruit samples are taken randomly and placed individually in 'rearing' boxes (room temperature) to check whether or not fruit flies will emerge after about two weeks. The number of infested samples versus the total number of samples indicates the proportion of infestation.
- Food lure (protein bait): Protein bait is applied as spot spraying on 3-4 spots per tree. About 25 ml of bait is sprayed on each spot. Fruits should not come in contact with the bait, which can reduce their quality due to stains. The average dosage for a protein bait application is 1 litre/ha. In practice, protein bait can be mixed with selected insecticides (e.g. malathion, fipronil), which would classify this approach as a 'lure and kill' system. Applications are carried out during the morning hours (e.g. 08.00 to 10.00) and usually start at the beginning of fruit formation once about 75% of the trees on the farm have reached this stage. They are continued on a weekly basis until harvesting time. It is estimated that about 18-20 applications are needed in a growing season, depending on the type of fruit. Protein bait can also be applied as a mass trapping tool, in combination with ME block. Because protein bait attracts females while ME attracts males, the number of ME blocks can be reduced to 7-9 units per ha.

3.3.2 *Conclusions: development of BCA in fruit production*

The correct identification of fruit fly species is crucial to design proper strategies for control. Current control methods include cultural practices, use of attractants for mass trapping and attract and kill systems, fruit bagging, sanitation, the potential use of natural enemies and other biocontrol agents.

An important requirement for success is an **area-wide control approach** covering areas larger than just a single fruit orchard. Additionally, locations outside the fruit growing area should be considered as potential sources for fruit fly and checked accordingly. Applications of control techniques should be done simultaneously throughout the target areas. This also requires that farmers cooperate and are properly informed about the advantages of a community (area-wide) approach. Successful fruit fly control can be maintained over many years, but only after the awareness of farmers and others living in the target area has been increased to a level that results in effective cooperation.

4 Regulatory requirements

4.1 Towards a regulation for BCA in ASEAN

Wherever possible, these *Guidelines* are consistent with those of the Food and Agriculture Organization. FAO has assisted and supported Southeast Asian countries in the implementation of legislation to regulate the use of pesticide products since 1982. A key achievement has been preparation of the *International Code of Conduct on the Distribution and Use of Pesticides* within Asia and the Pacific region. FAO recognises that a major constraint for member countries is enforcement of legal provisions due to political and economic developments that started during the early 1970s and lasted until the 1990s, creating a wide range of private sector activities in the field of pesticides. Synthetic pesticides started to be formulated and distributed in various Southeast Asian countries and they became an increasingly important economic trade factor creating psychological and economical dependencies among growers and other users of pesticides. (24)

Guidance on the regulation of BCA, in their diversity that we encounter today, was not available until around 2007 (apart from an early FAO guidance document on micro-organisms from 1988). The regional GTZ programme 'Commercialisation of Biopesticides in Southeast Asia' made an attempt, in collaboration with three AMS (Thailand, Indonesia, Vietnam), to develop and update data requirements for MCA and semiochemicals based on international guidance published by OECD. This also included an information exchange with and a visit to the OECD BioPesticide Steering Group at that time.

At the end of 2012 the regional GIZ project 'ASEAN Biocontrol for Sustainable Agrifood Systems', under the framework of which the present *Guidelines* were written, invited AMS to establish a 'regional BCA expert group on regulation' to develop guidelines for all four major categories of BCA with regard to data requirements and procedural aspects of regulation, also including aspects of trade. The work was discussed with FAO, who had just completed a technical cooperation project on regulatory harmonisation of pesticides in the region and welcomed a concerted effort to focus on the regulation of BCA as an important product group with great potential for the development of sustainable agriculture in the region (51).

The work of the expert group, which precipitated in the present *Guidelines*, also resulted in tables of 'Minimum data requirements' for microbials and botanicals (given in Appendix II). These *Guidelines* concentrate on formulated products and are structured on an FAO template. A tiered system is proposed (see section 4.3). In addition, for the first time there is now available guidance for regulators on field testing of microbials and botanicals (Appendix III).

4.2 National frameworks

The current regulatory situation for BCA in ASEAN was intensively discussed with AMS during the work meetings of the BCA expert group on regulation. Before this group started its work at the end of 2012, FAO had conducted a first assessment on 'biopesticides' and found that most of the countries in Southeast Asia had to varying degrees data requirements and procedures in place that related to the folders: identification/characterisation (A), toxicology (B), bio-efficacy (C), residue data (D), human health exposure/environmental fate and effects (F), and additional data requirements (G). However, harmonisation in the sense of availability of a basic set of identical or closely matching data requirements among AMS was not apparent. It was noted that "Harmonized pesticide registration in the region would…allow for the application of similar requirements and quality standards. 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." (49)

In 2013, the ASEAN group of regulatory experts examined in detail the status of the regulatory situation, focusing on the four major categories of BCA outlined in Chapter 1. A brief overview that synthesises the analyses of FAO (during an APPPC Workshop for Enhancement of Regional Collaboration in Pesticide Regulatory Management in November 2012) and the ASEAN experts is given in the list below. Please refer to Table 1 for the number of registered products in some countries and to Appendix I for registered active ingredients and their target pests and diseases.

- **Brunei Darussalam**: Products containing azadirachtin, citronella oil, methyl eugenol and *Bt* have been approved to be imported into the country (under Ministry of Health and DoAA) – mainly for government trials. However, the approval procedures of these products followed those of chemical pesticides; application would be handled case by case; a MSDS is required.
- **Cambodia**: The recent law on Management of Pesticide and Fertilizer was promulgated in early February 2012. There were five main regulations under this law that have been developed and approved in 2013 for implementation, particularly the regulations on the procedure and standard requirements for the registration of pesticides/fertilizers; the pesticides list of the Kingdom Of Cambodia; the procedures of Pesticides and Fertilizers Trade. Now, the trade activity of pesticide products is fully enforced, with a set of obligations for the trader's implementation, including registration of products, import license, formulations/repackage license, distribution license, and where registration and wholesale/retail permits are required. Post-registration activities are monitored and controlled by the primary and the pre-distribution inspection. Department of Agricultural Legislation and the Provincial Office of the Ministry of Agriculture, Forestry and Fisheries (MAFF) are working as judicial police in law enforcement for all activities related to pesticide/fertilizer trades and uses. With regard to BCA management, its terminology and the lawful term of pesticides was already stated in the law on Pesticide and Fertilizer. Cambodia will further develop the regulations on the procedure for BCA trade and use them later after the ASEAN *Guidelines* have been endorsed.
- **Indonesia** has a new institution for pesticide regulation since 2010 which involves a Pesticide Committee (under the Ministry of Agriculture - MOA) consisting of various experts. Different types of usage of pesticides include crop protection, household, forestry, fisheries, etc. Registration is required for local production and use; export is regulated specifically. Other institutions involved are the Ministry of Trade; quarantine is under MOA. Usually, they do not analyse AI, even not for local products (supporting documents are required only). There are around 200 applications for products per year.
- **Lao PDR**: Registration of products is done through the DOA in Vientiane. No characterisation and testing are done locally; if necessary, this is conducted abroad following FAO standards.

- **Malaysia**: Regulation of pesticides is under the Pesticide Act 1974 (amended in 2004). She follows a notification system and distinguishes between commodity and proprietary (new AI) registrations. Only full registrations are allowed, no other types. Registrations are valid for a 5-year period. A completeness check of the dossier is done by the registration office for content and composition of the product with regard to the 'claim' by the producer. The staff of the registration laboratory includes mostly "chemists". There are around 12 applications for BCA per year.
- **Myanmar**: a law on pesticide registration was enacted in May 1990 (no BCA-specific regulation). A pesticide board exists since 1992 and constitutes the highest authority, which oversees various technical committees. Currently, there is only the import of pesticides, which requires different types of registrations: provisional (5 years), full (10 years), amended (5 years). The minimum data requirements include identity, efficacy, toxicology, human health, environmental fate, etc.
- **The Philippines**: The FPA (Fertilizer and Pesticide Authority of DOA) issues full (3 years) and conditional (1 year) registrations. An experimental use permit is issued for experiments by standard protocols for efficacy testing. Biorational products include microbials (with reduced requirements) and biochemicals; for pheromones, only provision of specifications is required. Genetically modified products are also categorised under biorationals. A regulatory guidance is available. There exists an institutional dichotomy with regard to regulation of BCA: since the 'Organic Act', BCA used in organic agriculture are regulated by the Bureau of Agriculture and Fisheries Standards (BAFS) of the DOA. Testing is done outside of the agency; the assessment and validation of the tests is done in the Fertilizer and Pesticide Authority's lab. There are around 50 applications per year. Requirements are quite complicated and demanding, but waivers are possible.
- **Singapore:** The Agri-Food and Veterinary Authority of Singapore (AVA) regulates agricultural pesticides including BCA used in the commercial cultivation of plants in Singapore under the Control of Plants Act and the Control of Plants (Registration of Pesticides) Rules. Pesticide products meant for use in the agricultural farms are required to be registered with AVA. AVA has on average 10 applications for registration of pesticide products per year. So far, there was no application for registration of BCA products in the last 2 years.
- **Thailand**: A new registration procedure for pesticides is in place since 2009. Major changes include the fact that toxicology has to be done by GLP labs (which do not exist in Thailand) with regard to synthetic pesticides (for BCA, by national laboratories). One formulation cannot be associated with more than 3 trade names (per applicant). There exist specific data requirements for microbials, botanicals, and pheromones. Exempted from toxicological evaluation are *Bt*, NPV, nematodes, *Sarcocystis singaporensis*, and saponin. The data requirements for BCA are aligned towards OECD and the EU since 2009. Amended rules can be expected by 2015. Pesticides are regulated under the Hazardous Substance Act, whereby the Hazardous Substance Committee includes a pesticide registration sub-committee and a biopesticide data evaluation working group. Registration includes the following steps: submission of dossier, quality and efficacy testing, general evaluation, presentation of results, and decision by sub-committee. She relies on external experts for the assessment of dossiers. There are around 13 BCA applications per year (2012), mostly for imported products. In comparison, there are around 3000 applications per year for synthetic pesticides and a very high number of current products (approximately 30,000). In order to control illegal trade, she has limited entry points into the country to five, conducts inspection of factories and shops including taking samples, reports violations to the police, and requires labels in Thai language. The private sector in Thailand dealing with

pesticides is supported by the Thai Crop Protection Association and the Thai Agricultural Business Association.

- **Vietnam**: the first pesticide law was implemented in 2001, followed in 2010 by a law on pesticide management, which was due for renewal in 2012. The Pesticide Board of the Ministry of Agriculture and Rural Development (MARD) includes the Plant Protection Department (PPD; pesticide management), the National Pesticide Advisory Committee (9 members), and a Technical Committee on Bio-efficacy (7 members). The PPD is responsible for checking dossiers, for licensing import & manufacture of pesticides, and for inspection. She follows the general policy of 'one manufacturer/one applicant; one pesticide/one trade name'. The types of registration include field trial, full (5 years), supplementary, and renewal. 'Biopesticides' require large-scale efficacy trials. BCA and chemicals have the same data requirements. Vietnam does not have a separate guideline for BCA yet. That shall be established following to the ASEAN *Guidelines* development process. Capacity development for expanding expertise on BCA is required. There are around 200-300 pesticide applications per year, of which <10% are BCA (including abamectin and related products, with very few microbials).

4.3 Harmonisation

How might 'regulatory harmonisation' work in the ASEAN region? As indicated above, harmonisation can encompass a variety of elements, which might include:

- a common set of data requirements
- a standardised regulatory procedure
- agreed ways or mechanisms on how to achieve mutual agreements, and communicate and advance regulatory issues across AMS

A relatively high degree of sophistication in harmonising regulatory efforts has been reached in the EU with a positive list of active ingredients (the so-called 'Annex 1'; based on a joint risk assessment), which Members States then acknowledge and include in their national regulatory procedures (see Box 1). This example shall just highlight a possible direction of development: whether this is feasible and desirable for Southeast Asia may be a subject of discussion in the future.

A common set of data requirements for microbials and botanicals (currently the dominating products in markets of the region) has been developed by the ASEAN BCA expert group on regulation and is a major backbone of these *Guidelines*. These 'Minimum data requirements' have been prepared for formulated products and list a data set for a full registration. They were structured on an FAO template. A tiered system is proposed, whereby tier 1 requirements constitute the 'minimum' or basic requirements, and the rest of the requirements would be requested under tier 2, if certain 'triggers' make that necessary. Tier 1 requirements include biological/chemical characteristics, toxicological evaluation, bio-efficacy, as well as packaging and labelling. Tier 2 requirements are on residue data, human health exposure, environmental fate and effects data, and additional data as required.

In certain technical details, both data requirement lists stand out from common regulatory texts in that they emphasise BCA-specific information requirements that were developed and proposed by expert panels under OECD and others. The two most important points shall be named here:

- Microbials: risk assessment of micro-organisms is not appropriate and remains inconclusive if one applies tools of 'classical' toxicological analysis only. Instead, the major determinants for examining the risk that these organisms might pose are infectivity, host specificity, and pathogenicity. Having defined host specificity properly, this would answer another host of questions that commonly has its bearing during the 'ecotoxicological' phase of assessment.
- Botanicals/plant extracts: to date, regulators treat plant extracts as compounds of a single active ingredient. However, common water-based or alcoholic extracts can contain dozens of ingredients, each of which may or may not exhibit certain activities and toxicological properties. Inexperience of regulators with this circumstance is a major regulatory hurdle for botanicals. The characterisation of such 'soups' is challenging, but possible, and approaches for this have been devised by OECD and the EU, which are now annotated in ASEAN's minimum data requirements.

Additionally, it is recommended that consideration is given to the history of safe use for these two groups of BCA; lists of 'low risk' substances and microbials have been published internationally.

With regard to the import and release of macro-organisms for biocontrol, the AMS agreed to apply the procedures proposed by FAO in 2005 (52). But how should regulators deal with native macro-organisms? Would they need to be regulated at all? Almost all Member States agreed that if they were used as commercial products, regulation would be somehow required, irrespective of their origin. In this regard, Indonesia and the Philippines, both countries consisting of a patchwork of islands, remarked that due to different ecological zones, it would be recommendable to regulate the movement of native organisms, too. There exist bio-safety committees that deal with such questions already. However, given the fact that there is little interest of the private sector in this BCA group in ASEAN while the still rare applications are mostly dealt with by the government sector, there is probably no urgent need for a new regulation.

Regulatory aspects for semiochemicals were presented in Chapter 2. Similarly, regulatory inexperience with how to deal with botanicals effectively inhibits their wider distribution. This is revealed by the ABC database which just lists one registered product (as of 2012), although its use is probably significant, particularly in the plantation sector of Southeast Asia.

Experts from the AMS agreed that the following registration steps would be logical and agreeable to regulators:

Typical Registration Steps
✓ Pre-registration meeting (limited dossier)
✓ Application form with instructions (Tiered approach to data requirements)
✓ Issue of acknowledgement
✓ Check list for completeness of documents
✓ Technical and scientific evaluation
✓ Risk assessment and risk management evaluation
✓ Preparation of summaries and conclusions
✓ Registration decision
✓ Publication and dissemination of registration decision

Figure 2: Typical registration steps for BCA

The pre-registration meeting was included as a new element, which most of the AMS found useful because it could provide orientation for the applicant as well as the regulator. However, no consensus was reached as to what exactly should be discussed in that meeting and whether or not a binding agreement, for instance, on data waivers or procedural changes was acceptable.

The above steps largely mirror the FAO guidelines on harmonisation of biopesticides regulation, which elaborate on the administrative aspects of the registration process (48), starting with the submission of a registration dossier. The process continues with evaluation by the regulatory authority, and is usually terminated by a decision of the regulatory body on whether or not registration (and permission to sell) is granted. Registration can be unconditional or conditional, whereby in the latter case, additional data, studies, or action by the registrant may be required. The process is concluded by issuance of a registration certificate along with the approved label bearing a unique identification number.

It would be helpful also to assign unique numbers to exempted products for which there has been a process of notification. Without such numbers, growers get offered products and they cannot judge if they are really exempt.

Technical evaluation of the registration dossier would include verification of the data provided, waiver of data in certain instances, and verification of specifications by analytical methods and test protocols on test samples provided by the registrant and evaluation of the applicants conclusions. It can further include inspection of the manufacturing process. There must be a mechanism for the applicant to notify if they change production method, source material or formulation, and a mechanism to determine how much of a change is allowed before a new application is needed. Producers regularly change/optimise their methods and significant difference to the registered product may occur.

In terms of organisational requirements on the side of the regulator, a division solely dedicated to BCA should be established within a pesticide registration department to ensure that BCA would be treated appropriately and proportionally. Specific time periods for completion of registration are normally prescribed by registration authorities, provided that all relevant data have been submitted by the registrant. To promote use of BCA, special fast-track services should be offered (probably involving a BCA specialist regulator and an online system), reducing registration time significantly.

The regulatory authority will issue a validity period of a registration for each type of registration (see above). Once the validity period ends, re-registration should be granted to the original registrant after review of the previous data as well as any new data generated after a previous registration, provided that the registrant has complied with the regulatory provisions, in particular, with regard to consistency of the specifications of the product or active ingredient (registration standard) and that any changes in, such as production method and formulation are addressed.

In order to promote mutual, cross-border acceptance of products, the ASEAN BCA experts on regulation indicated that data such as field test evaluations could be accepted if these were appropriate for local situations in terms of crop, climate, and pest or disease. With regard to toxicological/infectivity data, it was proposed that companies should be encouraged to share dossiers.

Box 3: What might regulatory harmonisation mean?

One of the goals of these *Guidelines* is to stimulate discussion among ASEAN Member States (AMS) on regulatory harmonisation of BCA. It is important to consider what ‘harmonisation’ would actually mean.

Common guidelines might enable AMS to ‘speak a common language’ when it comes to registering BCA (data requirements, policies, etc.), but national registrations remain unique processes of neighbouring Member States. Such an approach would certainly be beneficial to the cause of BCA. However, could ‘harmonisation’ go even further and mean closer integration of processes among AMS?

Taking the EU as an example of a regional regulatory framework: regulation in the EU is still complicated for BCA and cannot be recommended to be adopted as a whole, but the most valuable harmonisation aspects might be considered:

Regulation of BCA in the EU makes use of **positive lists**. Active ingredients of BCA are registered EU-wide, and if approved (usually by one ‘rapporteur’ country that consults with the other Member States), the BCA is included in a positive list, called Annex 1. In practice, it means that all data that have been generated for inclusion in Annex 1 and basic data (toxicity studies, environmental risk assessments, etc.) will be accepted by all EU Member States.

The registrant has then to proceed with national registrations (in those countries with a suitable market), but data requirements are reduced substantially to only additional, country specific points (e.g. local efficacy, etc.)

Therefore, development and mutual acceptance of positive lists could effectively bring about ‘harmonisation’.

4.4 The need for simplification

We remind readers that individual biological control agents are, by their very nature, limited to a relatively small number of target pests and cannot be compared with 'block-buster' chemicals. It is vital to provide a regulatory environment that encourages development by SME producers: this means measures to simplify, harmonise and minimise the cost of procedures rather than adding regulatory burdens.

For example, the FAO guidelines on registration of biopesticides proposed that import and export could be subject to the legal provisions of the "Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade 1998". However, BCA are evidently not among the hazardous or banned pesticides and other chemicals listed (and by their inherent environmentally friendly properties, they certainly do not belong there). It is therefore inexplicable why this suggestion was made, since even the most toxic plant-derived substances such as rotenone would not be regulated under PIC.

4.5 Post-registration issues and quality control

Once registration is complete and a certificate has been issued, processes must be put in place to monitor compliance of the registrant with the specifications stipulated by the registration documents and the product label. The methods and frequency of checks for compliance with product specifications is best determined in detail by specialists (for each class of BCA) in Member States.

This is a crucial aspect of the regulatory process: quality issues that currently plague various countries in the region threaten the future viability of some BCA.

However, it is not usually the purpose of registration to provide for, or even guarantee 'product quality'. This is the responsibility of the manufacturer. The main purpose of regulatory monitoring is to make sure that a product adheres to the standards of safety and effectiveness documented by the specifications, which have been agreed upon between the registrant and the regulatory authority.

In practice, monitoring parameters should be reduced to aspects that are really operationally relevant. Samples must be collected by random at sales points and during inspections of the manufacturing facilities. Examples of how specifications of BCA can be monitored, and which technical facilities, equipment and methodology are useful and necessary, are described in the FAO guidelines (49).

4.6 Trade of BCA products within ASEAN

Lack of international harmonisation in enabling regulations is perhaps the most important barrier to the wider implementation of biological control; in some circumstances, 'gatekeeper' regulations place barriers in the way of efficient introduction and application of BCA.

The Secretariat of the International Plant Protection Convention (IPPC), of the Food and Agriculture Organization of the United Nations (FAO), has published a revised International Standard for Phytosanitary Measures (ISPM No. 3) on *Guidelines for the export, shipment, import, and release of biological control agents and other beneficial organisms* (50), which should also help AMS to solve some of the problems and increase transboundary trade in BCA. The OECD recommendations on data requirements of invertebrate biocontrol agents (IBCA) and microbials also cover trade issues. It is suggested that with native or long-established IBCA, exemption or substantially reduced information requirements may be appropriate. However, both of these guidelines only refer to living organisms (e.g. self-replicating micro-organisms, macro-organisms including arthropods). Trade in non-living control agents (botanicals, semiochemicals, etc.), is not covered.

A majority of the AMS impose an import tax on BCA similar to conventional pesticides, irrespective of the origin of the product. Some AMS actively encourage commercial production of BCA locally. Reduced trade barriers in the advent of the ASEAN Economic Community could perhaps mean that local production could benefit from this and that trade of BCA inside ASEAN could be stimulated. It could be also considered to tax BCA differently as they come along with much less of the negative externalities attributed to conventional pesticide use. It has recently been proposed to impose an environmental tax on synthetic pesticides and at the same time encourage the use of non-chemical alternatives (07).

Finally, it is important to recognise the activities of national institutions involved in trade of BCA (e.g. the phytosanitary and regulatory departments, biosafety commissions, ministries of trade and industry, etc.) within the AMS. Below is a list of relevant agencies and, where available, steps involved in the import and export of BCA:

- **Brunei Darussalam**: For import, a ‘Poison License’ must first be obtained from the Ministry of Health, which coordinates with DoAA (Ministry of Industry and Primary Resources) as Agrochemical Experts for approval and Agrochemical Import Permit. Taxation and declaration of goods are dealt with by Customs and Excise Department under the Ministry of Finance.
- **Cambodia**: Import; once registration of a product has been successful, the form ‘import’ has to be completed. An import license is then issued by MAFF (Department of Agricultural Legislation - DAL).
- **Indonesia**: Import and export of product is within the framework of the Indonesia National Single Window (INSW) of the Ministry of Trade. Import is dependent on the recommendation from the BCA committee under the quarantine agency. Precondition is the registration, which is issued by the MoA based on the evaluation of the Pesticide Committee. Export also requires a registration with the MoA.
- **Lao PDR**: The DOA is responsible for import and export of pesticide products. The DOA issues registration certificates, import and export licenses. The Department of Trade under the Ministry of Industry & Trade is responsible for regulating manufacturers and their buildings. Taxation is dealt with by the Department of Customs under the Ministry of Finance.
- **Malaysia:** Import licenses are issued by the Pesticide Board or Plant Biosecurity Division (whichever relevant). Customs and MAQIS check the product at the entry point. For export, the requirements of the importing country have to be observed.

- **Myanmar:** Import requires registration by DOA and a license issued by the Ministry of Commerce. For export, the provisions of the importing country must be observed and a license issued by the Ministry of Commerce is required.
- **The Philippines:** The import and export of imported or local BCA is under the Biodiversity Management Bureau of the Department of Environment and Natural Resources (DENR). Also the Fertilizer and Pesticide Authority (FPA) issues permits, depending on the product involved. They may offer tax exemption if needed. The Bureau of Customs (Department of Finance - DOF) is responsible for the import or export clearance and collects tax.
- **Singapore:** The import of biological control agent is regulated by AVA under the Control of Plants (Plant Importation) Rules. A "biological control agent" (BCA) is defined as a natural enemy, an antagonist or a competitor of a pest, or any other self-replicating biotic entity, used for pest control. AVA will conduct an Import Risk Analysis (IRA) on the organism to be imported. Import will be granted only when the risk is considered acceptable. Export of BCA is currently not regulated.
- **Thailand:** Import requires a registration and license issued by the DOA. Living micro-organisms need approval from the quarantine office (a pest risk analysis is required). The customs is responsible for clearance. Quality is checked through random sampling. Export requires an export license from the DOA, while the product must be registered in the destination country.
- **Vietnam:** Import is regulated by the MARD and the MOF (Ministry of Finance). If a product is registered in Vietnam, no license is required for import. If a product is not registered, an import license is needed. Export must be in compliance with the requirements of the importing country.

We emphasise that BCA are most likely to be competitive with simplified and harmonised regulatory procedures. As simple as this seems, harmonisation of paperwork and formats could be highly effective: having first agreed on a single standard. Because AMS show significant differences with regard to technical and human resource capabilities, it will also be important that countries help each other to remove the barriers to successful implementation of biological control. Further harmonisation, information exchange, mutual recognition of data requirements and dossiers would all be steps in the right direction.

5 Strategy for Improvement of Regulation and Use

5.1 Needs for the ASEAN Region

During the meetings of the ASEAN Regional BCA expert groups on regulation and application, participants identified a number of areas in which ASEAN *Guidelines* could be of assistance[11], which can broadly be summarised to include:

- Development of appropriate national regulations
- ASEAN regional cooperation and networking on biological control

[11] Summary, minutes and conclusions of 1st, 2nd and 3rd meetings; ASEAN Sustainable Agrifood Systems (Biocontrol)

- Training and awareness for farmers and extension officers (role in IPM, resource material for farmer-field-schools)
- Use for agricultural certification (including 'organic' production)
- Participation of the private sector
- Developing protocols for BCA efficacy studies
- 'Good manufacturing practices' and testing of quality
- Resource material that can easily be translated and used for making leaflets, posters, etc.
- Influencing policy on IPM, R&D, etc.
- Promoting trade of BCA among AMS

Primary overall objectives must therefore include the creation of conditions where the private sector can see sustained profitability for high quality BCA products (with accompanying advice to farmers and growers). This requires:

(a) effective but minimal regulation;
(b) formulation of mutual goals and good communication between governments and the private inputs sector. In practice, this could be approached through designation of policies that actively encourage or even mandate the use of BCA and other sustainable crop management approaches. Introduction of biology-based IPM principles into ASEAN GAP protocols would be a good start.
(c) incentives for the commercialisation of products in research;
(d) identification of further needs and resources to provide appropriate BCA;
(e) improvement of access by farmers and growers to the premium markets for high quality food.

In Chapter 3, a number of pest management situations were identified in which BCA have a strong and immediate potential role in key agricultural crops. These can be summarised as:

- Pest management in crop ecosystems where misuse of conventional pesticides is known to be deleterious (e.g. resurgence of rice BPH);
- Pest management where conventional pesticide application techniques have been vitiated by high cost, pesticide resistance or poor efficacy (e.g. control of *Bactrocera* species complex and *Plutella xylostella*);
- Crops with a high risk of pesticide residues (especially vegetables and fruit);
- The limited but high-value 'organic' sector.

Besides biology-based private companies and their associations, national governments and public research institutes continue to play their role as knowledge hubs and producers and distributors of BCA. As discussed among the ASEAN regional BCA experts, exemplary government initiatives include:

- Mass production and release of parasitoids and other beneficial organisms: Thailand (e.g. *Diadegma semiclausum*, *Anagyrus lopezi*), the Philippines (e.g. *Trichogramma* sp.), Lao PDR (e.g. *Trichogramma* sp., *A. lopezi*), Malaysia (e.g. *Asecodes hispinarum)*, Vietnam (e.g. *A. lopezi*);
- Area-wide pest management: Indonesia (fruit fly mass trapping programmes), Vietnam (e.g. fruit fly mass trapping and baiting).

5.2 Availability

An important early step is identifying key markets (i.e. crops and their pests) that might benefit most from biology-based IPM. BCA are, by their very nature, limited to a limited number of target pests and cannot be compared with 'block-buster' chemicals that have large markets. It is vital to provide a regulatory environment that encourages development by SME producers: with measures to simplify, harmonise and minimise the cost of procedures rather than adding regulatory burdens.

Removing the barriers to development and distribution of effective BCA products must be accompanied by 'weeding out' poor products that risk damaging the reputation of biological control. It is important therefore to ensure that rigorous (and therefore possibly expensive) quality control procedures are maintained for these products, while convincing the private sector of the potential profitability of biocontrol and motivating investment. National, or preferably a regional professional association would be a useful driver for BCA production and could also broker mutual recognition of national regulations.

Production of certain BCA by the farmer himself has been promoted in many countries through farmer-field-schools programmes and is also practiced in Southeast Asia. The regional BCA experts concluded that mass production in farmers' hands, although certainly beneficial, would not guarantee the quality and quantity of commercial BCA that is actually required. With microbials, the level of rigorous quality control required (35) usually precludes local production, with the possible exception of very vigorous *Trichoderma* isolates. Public BCA producers frequently have not managed to acquire registration for their research products or a reasonable commercialisation. It was therefore acknowledged that the private sector will play a key role in the sustainability of production when it comes to large-scale manufacture.

5.3 Reliability

It is incumbent on Registration Authorities to provide scrutiny of the post-registration processes that ensure maintenance of product quality and thus the continued reputation of BCA as useful tools for pest management. As discussed above, it is not usually the role of regulators to carry out quality controls, but they can demand and check that appropriate standard operating procedures (SOP) have been put in place for manufacturing and distribution: to internationally acceptable standards.

The product label, which is the primary point of communication between the producer and the users, must be clear and accurate. It is crucial to ensure that:

- The contents of BCA products are 'what they say on the bottle';
- Concentrations, expiry dates, etc. as appropriate are clearly shown;
- Specific and appropriate advice is given on product application.

5.4 User Knowledge

It can be argued that the responsibility of Regulatory Authorities should end with checking the information on the label for the 'users': be they farmers or their advisors. It is normally understood that in practice, farmers rarely read labels as carefully as they should and that support and extension is needed to reinforce label information.

The need for capacity development among farmers has long been recognised and put into practice in the form of farmer field schools and similar programmes. The extension units of governments also provide valuable outreach mechanisms, but extension infrastructure is often understaffed and underfunded. The practical reality in many AMS is that most pest management advice to farmers and growers comes from dealers of pesticides and other chemical inputs. If IPM actually means reduction of pesticides, this appears to inevitably conflict with the business interests of the pesticide industry (20).

One of the main target groups for policy change should be farmers and growers themselves. Although the use of BCA has been associated with organic agriculture, it is conventional farming practice that needs reform in ASEAN and actually holds many opportunities for the introduction of a biology-based IPM. Contrary to popular belief, studies on the adoption of environmentally friendly technology by farmers have clearly shown that it is not necessarily the price of a technology but the level of education and knowledge of the farmer that are mostly determining the degree of adoption (16) (17) (64). IPM success appears to depend on regular crop monitoring, and an ability to understand complex systems (66). Psychological and practical product dependencies ('path dependency') that govern farmers' perceptions must be considered as well, in order to promote adoption of new technologies (18) (19).

5.5 Perceptions of efficacy

In Chapter 1, we emphasised the need for an appropriate IPM framework which emphasised preventive approaches rather than over-reliance on 'chemical models' that frequently assume curative control of pest 'outbreaks'. However, there are also dangers of denying the role of chemical pesticides in the 'real world': not least in terms of resources for product support.

There are two approaches to the regulation of efficacy of plant protection products:

- A view that 'the market will decide' about efficacy and that the primary role of regulation is to ensure safety. This is considered appropriate in the USA and elsewhere, with farmers often benefiting from sophisticated agricultural extension support networks. Effectively, maintenance of brand reputation is thought to be sufficient.
- More 'interventionist' policies (e.g. as in Europe): where toxicology studies are likewise emphasised, but companies must also demonstrate efficacy against key target pests in order to obtain registration.

The view in most AMS is that farmers will be supported with advice on effective products, often via government research and extension agencies. Such agencies have typically been keen to promote

BCA and IPM, but have little experience in scaling-up and commercialisation, so a successful model (worldwide) has been to carry out the basic research and development (e.g. identification of active control agents, laboratory assays and trials) then to transfer the know-how to 'spin off' or other companies prepared to invest in further technology.

Since BCA are often fairly specific, with limited markets, they are likely to be developed by SME with limited funding. Light-touch regulation is therefore essential at this stage, even though more promising products and enterprises may subsequently been bought up by major life sciences or important national/regional companies. This could possibly be seen as an **ultimate measure of success for BCA**, resulting in further product development and helping to overcome many of the financial and promotional constraints identified in this document.

5.6 The 4th plenary meeting of application and regulation experts: a way forward

Throughout these *Guidelines* we have emphasised the need for evidence-based policy making, streamlined regulation and practical implementation of policies for strengthening the biocontrol component in IPM/GAP. During the 4th plenary meeting of application and regulation experts, it was agreed that strategies for improvement should focus on measures that enhanced availability and reliability of BCA products. In addition, greater understanding of critical issues is needed at various levels, with transfer of internationally acceptable standards to national policies. This requires capacity building for regulators, specialist scientists and the private sector BCA producers, together with a substantial interaction between these stakeholders.

Some of the points that were discussed in the 4th expert meeting are presented here in more detail in order to help to develop a future strategy for improvement. Regarding the question of **how and where the ASEAN *Guidelines* could help AMS to improve regulation and use of BCA**, the responses of the experts are summarised below:

Cambodia sees the value of the *Guidelines* in that it can be used to develop a national regulation, including the procedures and information requirements that are proposed in it. The categorisation of BCA was found to be useful, in particular for better understanding among regulators and to clarify the identity of products. The Cambodia representative would still wish to see more explicit statements or categorisation of the hazardous potential of BCA.

Indonesia emphasised the importance of harmonisation and joint collaboration; the text of the *Guidelines* itself could be useful in the future. The representative added that registrations should be simplified, and that the experts should make a plan how networking and training can be maintained.

Lao PDR commented that the *Guidelines* will help the country to define a regulatory framework. The representative looked forward to learning more from the other AMS: exchanging experiences and information.

Malaysia sees the *Guidelines* helpful for defining the data requirements for registration of BCA at a national level.

The Philippines see the *Guidelines* as giving direction in development of a BCA regulatory system. The representative also pointed out that on the national level, it will be very helpful to bring the regulators, academics (experts), and the private sector together.

Thailand values the new experiences gained during collaboration with the other AMS, and sees the *Guidelines* becoming a platform for exchange of knowledge and experiences between AMS. The *Guidelines* will help to refine the scope of data requirements for registration and provide clear and practical advice in the application of BCA at national level.

Vietnam mentioned that the *Guidelines* provide suggestions on the proposed special policy for BCA. They will also be helpful to set up the regulatory framework for BCA in Vietnam.

On the second day of the meeting, regulators and application experts formulated topics for an action programme in each country that should be further developed and implemented in the second phase of the ABC Project.

With regard to application, it was proposed that parts of the IPM strategies proposed in the *Guidelines* should find their way into good agricultural codes of practice that have been or are being developed in AMS. In Thailand, for instance, the use of BCA is already considered under the Thai GAP scheme; however, there is still potential for improvement of biology-based pest management strategies. In Indonesia, BCA are included and actively promoted under GAP by the government. The Philippines are considering the inclusion of BCA into good agricultural codes of practice once the supply can be secured. Supply and availability are issues where the ABC database on BCA can be particularly helpful in the future.

The following table summarises some of the future actions proposed by participating experts:

Table 2: Future actions proposed by ASEAN experts for regulation and use of BCA

Country	Regulation	Application
Brunei Darussalam	Better coordination between government, importers, and distributors; raising public awareness; training for government and the private sector on proper labelling;	Integrating the *Guidelines* into national IPM or GAP plans/programmes; adopting the field protocol to conduct further research and trials on BCA; developing Demo Plots for training purposes (DoAA officers, extensionists, and eventually farmers).
Cambodia	Inform and encourage producers and distributors (collaboration between government and private sector); training of government departments (e.g. law);	Raising public awareness through mass media; field trials; collaboration with NGOs and the private sector; link to other projects (e.g. ADB, USAID);
Indonesia	Training of the Pesticide Committee, university experts and	Support of association of BCA producers and distributors;

	other government units; installation of post-registration monitoring system;	
Lao PDR	Promotion of better collaboration between importers and regulators by training measures;	Translation of the *Guidelines* into Lao language; raising public awareness; increasing research activities including field trials; specific training courses for government officials and farmers;
Malaysia	Make changes to the current regulation; inform and discuss with the pesticide board and private companies; develop training for dossier evaluation;	Raising public awareness; implementing field studies; targeting extension officers and farmers; collaboration with other AMS (e.g. Brunei Darussalam, Indonesia)
Myanmar[12]	Discuss the *Guidelines* with the Pesticide Registration Board and the private sector. *Guidelines* require approval by DOA.	Translation of *Guidelines* to Myanmar language; raising public awareness; implementing research trials; conducting training courses for extension staff of DOA, the private sector and farmers;
Philippines	Discussing the ASEAN *Guidelines* within DOA-attached agencies (Bureau of Plant Industry, Bureau of Agriculture and Fisheries Standards and the Fertilizer and Pesticides Authority) and the DENR – Biodiversity Management Bureau; collaboration with the technical boards of companies; potential tax exemption for BCA;	Inform relevant government departments; develop business models for distribution (e.g. onion farmers and BCA producers); develop promotional material for different target groups;
Thailand	Inform BCA producers and the public; training for government officers and the private sector;	Translate the *Guidelines* into Thai; distribute and discuss the *Guidelines* with relevant institutions (recommendations to be submitted to ministerial level); produce short versions of the *Guidelines* for different target groups;
Vietnam	Include guidance into legislation; targeting government institutes and the private sector; potential formation of a BCA association;	Training of government and sellers (producers, distributors), the latter forming the link to the farmers;

[12] The proposals by experts from Myanmar were presented on the occasion of the 5th EWG meeting on 12 March 2014 in Phnom Penh, Cambodia.

Appendix I Products

In this section, information retrieved from the Project's database on biocontrol agents (BCA) registered in ASEAN Member States is presented. For ease of use within the limited space of this document, the information is limited to lists of pests and diseases and the corresponding active ingredients/agents for control from eight AMS (no trade names are included). For Indonesia, Malaysia, the Philippines, Singapore, Thailand, and Vietnam, these lists contain all registered BCA as of October 2013, while in the case of Cambodia and Lao PDR, the data were updated in April 2014. Abamectin and related compounds are largely excluded; they are only mentioned when contained in product mixes. This exclusion is related to the circumstance that these compounds are not categorised as BCA in some AMS; see also the introductory part of Chapter 2 for further explanation. Note that the categorisation of BCA in the following lists largely follows "The Manual of Biocontrol Agents" (12). The category 'natural products' usually includes products derived from plants, but 'botanicals' are listed here as a separate group just to make numbers better visible.

Against which pest and diseases are BCA used (registered) in ASEAN? General target profile of the active agents/ingredients from six AMS:

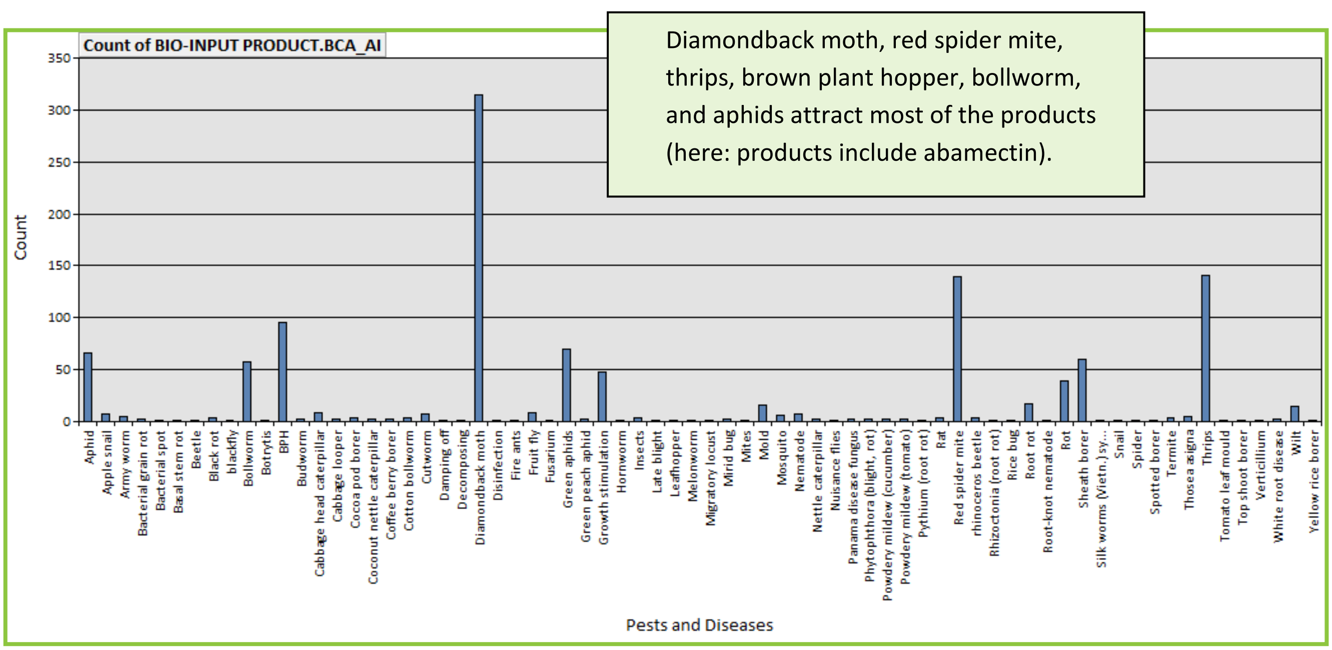

Figure 3: Target pest and disease profiles of BCA registered in ASEAN

Indonesia: Pests & diseases against which BCA have been registered (Status: October 2013)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Aphid	Eugenol	Attractant
Apple snail	Saponin	Botanical
Army worm	Acetate and Alcohol	Other
	Bacillus thuringiensis Berliner var. kurstaki Serotype 3a, 3b Strain SA - 11 : 6,4 %	Microbial
Basal stem rot	Bacillus subtilis: 4.55 x 10^5 cfu/g Trichoderma viridae: 1.05 x 10^5 cfu/g Trichoderma harzianum ; 450 x 10^5 cfu/	Product Mix
Brown Plant Hopper (BPH)	Curcumin, Piperine, Azadirachtin	Product Mix
Budworm	Bacillus thuringiensis var. aizawai strain GC-91 : 3.8 %	Microbial
	Bacillus thuringiensis var. kurstaki strain HD-7 : 16,000 iu/mg	Microbial
Cabbage head caterpillar	Bacillus thuringiensis	Microbial
	Bacillus thuringiensis Berliner var. Kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
	Bacillus thuringiensis var. Aizawai strain GC-91 : 3.8 %	Microbial
	Bacillus thuringiensis var. kurstaki strain HD-7 : 16,000 iu/mg	Microbial
	Bacillus thuringiensis varietas kurstaki serotype HD-1: 16.000 IU/mg (25%)	Microbial
	Bacillus thuringiensis, varietas aizawal serotype H-7 : 200 g/l	Microbial
	Bacillus thuringiensis, varietas aizawal serotype H-7 : 86 x 10^9 spora/gram	Microbial
	Saponin	Botanical
Cabbage looper	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
Cocoa pod borer	Beauveria bassiana	Microbial
	Beauveria bassiana : 2.6 x 10^6 spora/ml	Microbial
	Delta endotoxin Bacillus thuringiensis var. kurstaki serotype H-3 a, 3 b, Strain Z-52 (b.a): 16 %	Microbial
	Hexadekatrienil acetate : 60 % hexadekatrienol : 40 %	Semiochemical
Coconut nettle caterpillar	Bacillus thuringiensis, varietas aizawai serotype H-7 : 200 g/l	Microbial
	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
Coffee berry borer	Beauveria bassiana : 1.005 x 10^9 spora / gram	Microbial
	Ethanol	Attractant
	Ethanol : 250 g/l	Attractant
Cotton bollworm	Bacillus thuringiensis var. Aizawai strain GC-91 : 3.8 %	Microbial
Cutworm	Azadirachtin	Botanical
	Bacillus thuringiensis var. Aizawai strain GC-91 : 3.8 %	Microbial
	Curcumin, Piperine, Azadirachtin	Product Mix
	Metarhizium anisopliae : 3.5 x 10^8, spora/ml Bacillus thuringiensis: 2.4 x 10^7 spora/ml	Product Mix
Damping off	Piperine, Eugenol	Product Mix
Diamondback moth	Bacillus thuringiencis var. kurstaki strain EG. 7841 : 2.5 %	Microbial
	Bacillus thuringiensis	Microbial
	Bacillus thuringiensis var. aizawai serotype (H-7) : 20 %	Microbial
	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
	Bacillus thuringiensis subsp. aizawai: 10.30%	Microbial
	Bacillus thuringiensis var kurstaki serotype 3 abc: 2%	Microbial
	Bacillus thuringiensis var. aizawai serotype 7: 7500 lu/mg	Microbial
	Bacillus thuringiensis var. aizawai strain GC-91 : 3.8 %	Microbial
	Bacillus thuringiensis var. kurstaki strain HD-7 : 16,000 iu/mg	Microbial
	Bacillus thuringiensis varietas Kurstaki serotipe HD-1: 16.000 IU/mg (25%)	Microbial
	Bacillus thuringiensis, varietas aizawal serotype H-7 : 200 g/l	Microbial
	Bacillus thuringiensis, varietas aizawal serotype H-7 : 86 x 10^9 spora/gram	Microbial
	Delta endotoxin Bacillus thuringiensis var. kurstaki serotype H-3 a, 3 b, Strain Z-52 (b.a): 16 %	Microbial
	Saponin	Botanical
Fruit fly	Capsaicin	Botanical
	Methyl Eugenol	Attractant
	Protein hidrolisa: 79.91 g/l	Attractant
Green peach aphid	Azadirachtin	Botanical
	Methyl Eugenol	Attractant
Late blight	Azadirachtin	Botanical
Leafhopper	Azadirachtin	Botanical
Migratory locust	Metarhizium anisopliae var. acridum Strain FI-985 : 300 g/l	Microbial
Mirid bug	Azadirachtin	Botanical
	Beauveria bassiana	Microbial
	Beauveria bassiana : 2.6 x 10^6 spora/ml	Microbial
Mosquito	Bacillus thuringiensis	Microbial
	Citronella oil	Botanical
Nettle caterpillar	Bacillus thuringiensis var. aizawai serotype 7: 7500 lu/mg	Microbial
	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
Panama disease fungus	Azadirachtin	Botanical
	Bacillus subtilis: 4.55 x 10^5 cfu/g Trichoderma viridae: 1.05 x 10^5 cfu/g Trichoderma harzianum ; 450 x 10^5 cfu/	Product Mix
	Trichoderma koningii : 5,000,000 spora/g	Microbial
Rat	Sarcocystis singaporensis	Microbial
Rhinoceros beetle	Metarhizium anisopliae var . Major : 1 %	Microbial
Rice bug	Beuvaria bassiana 4.5 x 10^10 spora/g	Microbial
Root rot	Gliocladium spp Min. 15 x 10^6 spora/g	Microbial
Root-knot nematode	Azadirachtin	Botanical
Spotted borer	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
Thosea asigna	Bacillus thuringiensis serotype 3a 3b strain HD-1 : 17,600 IU/mg	Microbial
Thosea asigna	Bacillus thuringiensis	Microbial
	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
	Bacillus thuringiensis var. aizawai serotype 7: 7500 lu/mg	Microbial
	Bacillus thuringiensis var. kurstaki strain HD-7 : 16,000 iu/mg	Microbial
Thrips	Methyl Eugenol	Attractant
Tomato leaf mould	Eugenol	Attractant
Top shoot borer	Bacillus thuringiensis Berliner var. kurstaki serotype 3a, 3b strain HDI : 16.000 IU/mg : 3,2%	Microbial
White root disease	Trichoderma koningii : 5,000,000 spora/g	Microbial
	Trichoderma koningii	Microbial
Yellow rice borer	Curcumin, Piperine, Azadirachtin	Product Mix

Malaysia: Pests & diseases against which BCA have been registered (Status: October 2013)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Brown Plant Hopper (BPH)	Azadirachtin	Botanical
Diamondback moth	Azadirachtin	Botanical
	Bacillus Thuringiensis Subsp. Aizawai	Microbial
	Bacillus Thuringiensis Subsp. Kurstaki	Microbial
	Bacillus Thuringiensis Subsp. Kurstaki (3A, 3B) Strain Hd-1	Microbial
	Bacillus Thuringiensis Subsp. Kurstaki (3A, 3B) Strain Z-52	Microbial
	Bacillus Thuringiensis Subsp. Kurstaki (3A, 3B, 3C)	Microbial
	Spinosad	Natural product
Insects	Bacillus Thuringiensis Subsp. Kurstaki (3A, 3B, 3C)	Microbial
	Clarified Hydrophobic Extract Of Neem Oil + D-Limonene	Product Mix
	Metarhizium Anisopliae Var. Majus (St-01)	Microbial
Rhinoceros beetle	Metarhizium Anisopliae Var. Majus (St-01)	Microbial
	Metarhizium Anisopliae Var. Majus (St-01)	Microbial
	Metarhizium anisopliae var. Major	Microbial
Spider mite	Azadirachtin	Botanical
Western Flower Thrips	Azadirachtin	Botanical
Whitefly	Azadirachtin	Botanical

Philippines: Pests & diseases against which BCA have been registered (Status: October 2013)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Anthracnose	Bacillus subtilis strain QST713	Microbial
Aphid	Beauveria bassiana strain GHA	Microbial
Army worm	Bacillus thuringiensis var. aizawai	Microbial
Black Sigatoka	Bacillus subtilis strain QST713	Microbial
Bollworm	Bacillus thuringiensis var. kurstaki	Microbial
Cabbage looper	Bacillus thuringiensis var. kurstaki	Microbial
Cutworm	Bacillus thuringiensis var. kurstaki	Microbial
Decomposing	Trichoderma spp.	Microbial
Diamondback moth	Bacillus thuringiensis var. aizawai	Microbial
	Bacillus thuringiensis var. kurstaki	Microbial
Mealy bugs	Beauveria bassiana strain GHA	Microbial
Mosquito	Beauveria bassiana strain GHA	Microbial
Nematode	Paecilomyces lilacinus strain 251	Microbial
Phytophthora (blight, rot)	Trichoderma spp.	Microbial
Psyllids	Beauveria bassiana strain GHA	Microbial
Rot	Trichoderma spp.	Microbial
Thrips	Beauveria bassiana strain GHA	Microbial
Tomato fruit worm	Bacillus thuringiensis var. kurstaki	Microbial
Whitefly	Beauveria bassiana strain GHA	Microbial

Singapore: Pests & diseases against which BCA have been registered (Status: October 2013)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Blackfly	Bacillus thuringiensis var israelensis	Microbial
Mosquito	Bacillus thuringiensis var israelensis (H-14)	Microbial
	Bacillus thuringiensis var israelensis	Microbial
Nuisance flies	Bacillus thuringiensis var israelensis	Microbial
Powdery mildew (cucumber)	Garlic	Botanical
Powdery mildew (tomato)	Garlic	Botanical

Thailand: Pests & diseases against which BCA have been registered (Status: October 2013)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Army worm	Bacillus thuringiensis var. kurstaki	Microbial
	Bacillus thuringiensis subsp. aizawai	Microbial
Cabbage looper	Bacillus thuringiensis var. kurstaki	Microbial
	Bacillus thuringiensis subsp. aizawai	Microbial
Cotton bollworm	Bacillus thuringiensis var. kurstaki	Microbial
	Bacillus thuringiensis subsp. aizawai	Microbial
Cutworm	Bacillus thuringiensis var. kurstaki	Microbial
	Bacillus thuringiensis subsp. aizawai	Microbial
Diamondback moth	Bacillus thuringiensis Berliner subsp. aizawai	Microbial
Hornworm	Bacillus thuringiensis var. kurstaki	Microbial
Melonworm	Bacillus thuringiensis var. kurstaki	Microbial

Vietnam: Pests & diseases against which BCA have been registered (Status: October 2013)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Aphids	Abamectin 2g/kg (35.5g/l), (53g/l) + Bacillus thuringiensis var.kurstaki 18g/kg (0.5g/l),	Product Mix
	Azadirachtin	Botanical
	Bacillus thuringiensis var.kurstaki 1.6% + Spinosad 0.4%	Microbial
	Ginseng extract (Matrine)	Botanical
	Pyrethrins	Botanical
	Rotenone	Botanical
	Rotenone	Botanical
	Rotenone 2.5% + Saponin 2.5%	Product Mix
	Spinosad (min 96.4%)	Natural product
Bacterial grain rot	Streptomyces lydicus WYEC 108 1.3% + Fe 21.9% + Humic acid 47%	Microbial
	Streptomyces lydicus WYEC 108	Microbial
Bacterial spot	Streptomyces lydicus WYEC 108	Microbial
Beetle	Cnidiadin	Botanical
Black rot	Chitosan (Oligo - Chitosan)	Natural product
	Chitosan 2% + Oligo - Alginate 10%	Product Mix
	Eugenol	Attractant
	Trichoderma spp 10^6 cfu/ml 1% (1%), (1%) + K-Humate 3% (3.5%),(4%) + Fulva	Product Mix
Bollworm	Azadirachtin	Botanical
	Bacillus thuringiensis var.aizawai	Microbial
	Bacillus thuringiensis var.kurstaki	Microbial
	Bacillus thuringiensis var.kurstaki 16.000 IU + Granulosis virus 10^8 PIB	Microbial
	Beauveria bassiana Vuill	Microbial
	Celastrus angulatus	Botanical
	Ginseng extract (Matrine)	Botanical
	Oxymatrine	Natural product
	Rotenone	Botanical
Botrytis	Streptomyces lydicus WYEC 108	Microbial
Brown Plant Hopper (BPH)	Azadirachtin	Botanical
	Beauveria 10^7 CFU/g + Metarhizium 10^7 CFU/g	Product Mix
	Beauveria bassiana 1 billion spore/g + Metarhizium anizopliae 0.5 billion spore/g	Product Mix
	Beauveria bassiana Vuill	Microbial
	Ginseng extract (Matrine)	Botanical
	Metarhizium anisopliae var. anisopliae Ma5 10^11 - 10^12 spore/g	Microbial
	Pyrethrins	Botanical
	Rotenone	Botanical
	Spinosad (min 96.4%)	Natural product
Diamondback moth	Abamectin 0.9% + Bacillus thuringiensis var.kurstaki 1.1%	Product Mix
	Abamectin 1g/kg + Bacillus thuringiensis var.kurstaki 19g/kg	Product Mix
	Abamectin 2g/kg (35.5g/l), (53g/l) + Bacillus thuringiensis var.kurstaki 18g/kg (0.5g/l),	Product Mix
	Abamectin 3.5g/l (36g/l) + Azadirachtin 0.1g/l (1g/l)	Product Mix
	Abamectin 6g/l + Azadirachtin 1g/l + Emamectin benzoate 5g/l	Product Mix
	Azadirachtin	Botanical
	Bacillus thuringiensis var. 7216	Microbial
	Bacillus thuringiensis var. aizawai	Microbial
	Bacillus thuringiensis var.aizawai 32000IU (16000 IU) + Beauveria bassiana 1x10^7 spo	Microbial
	Bacillus thuringiensis var.kurstaki	Microbial
	Bacillus thuringiensis var.kurstaki 1.6% + Spinosad 0.4%	Microbial
	Bacillus thuringiensis var.kurstaki 16.000 IU + Granulosis virus 10^8 PIB	Microbial
	Beauveria bassiana Vuill	Microbial
	Celastrus angulatas	Botanical
	Citrus oil	Botanical
	Ginseng extract (Matrine)	Botanical
	Oxymatrine	Natural product
	Pyrethrins	Botanical
	Pyrethrins 2.5% + Rotenone 0.5%	Product Mix
	Rotenone	Botanical
	Rotenone 2.5% + Saponin 2.5%	Product Mix
	Spinosad (min 96.4%)	Natural product
	Virus 10^4 virus/mg + Bacillus thuringiensis var.kurstaki 16000-32000 IU/mg	Product Mix
Disinfection	Bacillus thuringiensis var.tenebrionis	Microbial
Fruit fly	Abamectin 1.8g/kg + Bacillus thuringiensis 20g/kg (10^10 bt/g)	Product Mix
	Methyl eugenol 85% + Natural gum 10% + Synthetic adhesive: Poly (propylene amide	Attractant
	Protien thuy phan (Protien hydrolysis)	Attractant
Fusarium	Streptomyces lydicus WYEC 108	Microbial
Green aphids	Abamectin 0.5% + Azadirachtin 0.3%	Product Mix
	Abamectin 35g/l (54g/l) + 1g/l (1g/l) Azadirachtin	Product Mix
	Azadirachtin	Botanical
	Bacillus thuringiensis var. T36	Microbial
	Bacillus thuringiensis var.kurstaki	Microbial
	Celastrus angulatas	Botanical
	Ginseng extract (Matrine)	Botanical
	Pyrethrins	Botanical
	Pyrethrins 2.5% + Rotenone 0.5%	Product Mix
	Rotenone	Botanical
	Rotenone 2.5% + Saponin 2.5%	Product Mix
Growth stimulation	Alpha - Naphthyl acetic acid	Growth stimulator
	Auxins 11mg/l + Cytokinins 0.031mg/l + Gibberellic	Growth stimulator
	Brassinolide (min 98%)	Growth stimulator
	Chitosan (Oligo - Chitosan)	Natural product
	Cytokinin (Zeatin)	Growth stimulator
	Fulvic acid	Growth stimulator
	Gibberellic acid	Growth stimulator
	Oligo - Alginate	Growth stimulator
Mold	Bacillus subtilis	Microbial
	Chitosan (Oligo - Chitosan)	Natural product
	Citrus oil	Botanical
	Cucuminoid 5% + Gingerol 0.5%	Product Mix
	Eugenol	Attractant
	Ginseng extract (Matrine)	Botanical
	Pseudomonas fluorescens	Microbial
	Streptomyces lydicus WYEC 108	Microbial
	Streptomyces lydicus WYEC 108 1.3% + Fe 21.9% + Humic acid 47%	Microbial
	Trichoderma spp 10^6 cfu/ml 1% (1%), (1%) + K-Humate 3% (3.5%),(4%) + Fulva	Product Mix
	Trichoderma viride	Microbial
	Validamycin (Validamycin A) (min 40%)	Natural product

Cambodia: Pests & diseases against which BCA have been registered (Status: April 2014)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Aphid	Rotenone 5%	Botanical
Army worm	Oxymatrine 4%	Botanical
Cabbage looper	Oxymatrine 4%	Botanical
Diamondback moth	Oxymatrine 4%	Botanical
Fungal infection	Thymol (plant extract), Oleic Acid	Botanical
Rice leaffolder	Oxymatrine 4%	Botanical
Soil conditioner	Bacillus subtilis subsp. subtilis	Microbial
Spider mite	Rotenone 5%	Botanical
Thrips	Rotenone 5%	Botanical
Western Flower Thrips	Rotenone 5%	Botanical
Yellow rice borer	Oxymatrine 4%	Botanical

Lao PDR: Pests & diseases against which BCA have been registered (Status: April 2014)

Pests & Diseases	Biocontrol Agent_AI	BCA Category
Disinfection	Chaetomium cupreum	Microbial
	Paecilomyces lilacinus	Microbial
	Streptomycin sulfate	Other
Fungal infection	Ningnamycin	Other
	Validamycin A	Other
Insects	Abamectin 0.9%; Bacillus thuringensis 1.1%	Product Mix
	Azadirachtin	Botanical
	Bacillus thuringiensis	Microbial
Plant growth regulator/stimulator	Effective microorganism	Growth stimulator
Plant growth regulator/ stimulator	Seaweed Extract	Growth stimulator
Rat	Sarcocystis singaporensis	Microbial

Appendix II Data Requirements for Registration

The two sets of data requirements below, for microbials and botanical pesticides (botanicals), propose information requirements for a **formulated product** and a **regular registration** (as opposed to provisional or supplementary registrations). In the case of micro-organisms, it was seen advantageous to distinguish between AI and the formulation as a whole at certain information points, so that in these cases requirements are extended to the AI.

Both sets of data requirements make use of a template 'data requirements for harmonized registration of biopesticides' which was published by FAO in 2012 (Guidance for Pesticide Regulatory Management in Southeast Asia, FAO Regional Office for Asia and The Pacific, Bangkok). The ASEAN regulatory experts agreed that the aspect of harmonisation could be reflected in a 'minimum' data requirement set (folders A-D) or tier 1 information package, while additional information requirements (folders E-G) would be treated under tier 2.

Abbreviations: R = Required, NR = Not required, C = Conditional

IIa Microbials

No.	Folder	A.I.	Formulation
Tier 1 Requirements			
	A. Biological and Chemical Characteristics		
1	Systematic name (genus and species)		R
2	Strain/or isolate name of active agent		R
3	Common name (if available)		R
4	Source or origin, host range, and mode of action of active agent ➢ Mode of action: e.g. non-toxic mechanisms, infection of target, competitive or antagonistic behaviour, etc.	R	
5	Specification of product (Set of requirements to be satisfied by product)		R
6	Composition of the product		R
7	Manufacturing process	R	R
8	Test procedures and criteria for identification ➢ Including method(s) of analysis/biological assay	R	R
9	Impurities & Contaminants	R	R
			Tier 2: further tests if data/results of tier 1 warrant this
10	Shelf life claim		R
11	A sample for verification		R
	B. Infectivity & Pathogenicity or Toxicity to Non-Target Organisms		

12	Infectivity, pathogenicity and host specificity (living micro-organism) ➢ Including relevance for human health and other non-target organisms ('ecotox')	R	Tier 2: if reasons for concern (e.g. contaminants, toxic properties of formulating compound, etc.)
13	Toxicity (secondary metabolites of micro-organisms) <u>Remark</u>: Metabolites (biochemical compounds) of micro-organisms could be also treated as 'Natural Products', which would classify them as chemical compounds that undergo classical toxicological analysis.	R	Tier 2: as above
	C. Bio-Efficacy		
14	Field studies ➢ Based on 'draft efficacy test protocol' for microbials (see Appendix III). <u>Remark</u>: Amenable to data waivers if extensive field experience exists		R
15	Laboratory studies ➢ Including confirmation of claims of target specific action and potency		(R)
	D. Processing, Packaging, and Labelling		
16	Process of formulation		R
17	Usage and storage information		R
18	Labels and leaflets		R
Tier 2 Requirements			
	E. Residue Data ➢ Only relevant if residues of the active agent of any kind are likely and to be expected on food or feed items. ➢ Substances used for formulation must not produce residues on feed or food items. This must be documented by relevant references.	C	
	<u>Remarks</u>: • Based on the available experience and evidence to date, it is assumed that by their nature microbial pest control agents do not produce chemical residues in food. • Microbial metabolites, although effective, are usually readily biodegradable. • The persistence of micro-organisms intentionally introduced into agro-ecosystems (though they will normally not persist on or in the food items) is a matter of host range. In many cases, the micro-organisms introduced as biocontrol agents may already exist in the environment, and application may lead to transient changes in the composition of the (soil) microflora.		

	However, this cannot be considered as a "residue".		
	F. Human Health Exposure/Environmental Fate and Effects Data ➢ If any results from tier 1 suggest further risk assessment	C	
	Remarks: • Extrapolation to human health can be done from mammalian testing if the microbial pest control agent is in any category of concern. Identification as a true (i.e. excluding results from immuno-compromised individuals) human pathogen means rejection of the active agent. • Up to date, no micro-organisms used for biocontrol worldwide have shown CMR effects (carcinogenicity, mutagenicity, reproductive toxicity). • Results from monitoring programs and health surveys of 'worker's safety' at the production site must be used to assess general human health risks. • Usually no need for investigation of degradation and movement within and between compartments, if the risk of spread is tested earlier with host range, infectivity, etc. Technically, tracing micro-organisms in the open can be accomplished using genetic diagnostic methods (e.g. PCR) employing markers specific for the BCA and its target.		
	G. Additional Data Requirements	C	

IIb Botanical Pesticides

No.	**Folder**	**A.I.**	**Formulation**
Tier 1 Requirements			
	A. Biological and Chemical Characteristics		
1	Systematic name (genus and species of plant)		R
2	Common name		R
3	Source or origin (locality and conditions of growth; may become part of identity of product)		R
4	Specification of product (nature, purpose, and usage)		R
5	Characterisation of the product (analytical approach optional) ➢ Active ingredient(s) ➢ Biomarker linked or unlinked to activity ➢ Gross constituents	C	R

6	Manufacturing process (extraction, formulation, etc.; may become part of identity of product)		R
7	Test procedures and criteria for identification		R
8	Impurities ➢ Toxic metabolites apart from actives (substances of concern) ➢ Inactive metabolites ➢ Microbial & process impurities (methods of removal)		R
9	Shelf life claim		R
10	A sample for verification		R
	B. Toxicological evaluation		
11	Minimum risk check: plant extract/product (internationally) recognised as: ➢ Minimal risk pesticide ➢ Part of pharmacopoeia ➢ Food grade ➢ History of safe use	C	R
12	Toxicological testing (method based on degree of characterisation of active compounds) ➢ Standard toxicology for active ingredient(s) ➢ 'Tox' of biomarked active fraction (actives unknown) ➢ Toxicological testing of whole extract (biomarkers and actives not known)		C
13	Environmental safety testing (ecotoxicology)		C
	C. Bio-Efficacy		
14	Field studies ➢ Based on 'draft efficacy test protocol' for botanical pesticides (see Appendix III) <u>Remark:</u> Amenable to data waivers if extensive field experience exists		R
15	Laboratory studies		NR
	<u>Remarks:</u> • Bio-efficacy of botanicals is naturally lower than that of synthetic pesticides, which requires efficacy categories different to synthetics. Consequently, efficacy testing of botanicals is often not comparable with synthetic pesticides as positive standards.		

	• Lower efficacies could be acceptable as long as a potential product generates the (economic) benefits as claimed.		
	D. Packaging and Labelling		
16	Packaging process and storage information		R
17	Labels and leaflets		R
Tier 2 Requirements			
	E. Residue Data		C
	Remarks: • Botanicals usually do not generate residues, because they rapidly degrade in the environment. • Plant extracts cannot be radio-labelled for tracing purposes (like synthetic pesticides can) • Check for residues only, if they could be suspected due to the nature of the plant extract. Certain thresholds (triggers) have been proposed (e.g. European legislation) and could be considered on a case-by-case basis.		
	F. Human Health Exposure/Environmental Fate and Effects Data ➢ If any results from tier 1 require further (tier 2) risk assessments		C
	G. Additional Data Requirements		C

Appendix III Efficacy Test Protocols

Two efficacy test protocols are attached here that are based on a template developed by FAO and were discussed and modified by the Regional BCA Expert Working Group on Application. Both protocols are identical regarding most of the text, but contain specific changes here and there, so that both are included here.

The designation as 'draft' indicates that the documents may serve as templates for possible future versions that would be updated once more application experience accumulates in AMS.

Both protocols were distributed to regulatory and application experts of AMS; they originally included as attachment, some notes on the safety, effectiveness, and practical application of selected BCA. That text is not reproduced here, because it encompasses published information, the most important sources of which are referenced below.

Microbials

DRAFT EFFICACY TEST PROTOCOL

1. EXPERIMENTAL CONDITIONS

1.1 Selection of Crop and Cultivar, Test Organisms

This test protocol is concerned with the efficacy evaluation of microbial pest control agents 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. and 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) (usage of chemical pesticides). Cultural conditions (e.g. soil type and pH, fertilisers, 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 for the relevant pest or disease should be carried out in different locations with distinct environmental conditions over an entire growing period of the crop (e.g. about 2 trials in 2 locations or seasons). The timing, amount and method of irrigation, if applied, should be recorded.

Trials can be done under semi-field conditions (e.g. outdoor, but in protected environment or cages) or involving larger scales in farmers' fields. Generally, highly mobile pests require larger scales than less mobile pests.

The relevant conditions of the plot and crop should be adequately described like sowing or planting date, row spacing, cultivation measures, crop condition and pest/diseases densities etc.

1.3 Design and Layout of the Trial

1.3.1 Treatments

Test product(s), and untreated control are to be arranged in a randomised 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 and any additional remarks)

In the case of on-farm trials, it is recommended to include a negative control, farmers' practice and the microbial product under question.

1.3.2 Plot Size and Replication

Net plot size: Use an optimum plot size (e.g. 15-20 m^2); however, this will depend on the type of crop/pest and disease/product under study and location of trial. Highly mobile pests might require larger plot sizes for evaluation (e.g. 60-80 m^2 or larger).

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 into account pest dispersal and possible drift of pesticides.

Replications: should be 4 per treatment (provided the error or residual degrees of freedom are at least 12). More replications are recommended, in particular, if one wants to account for an expected higher variability of the negative control plots which might show higher pest/disease pressures and crop damage.

2. APPLICATION OF TREATMENTS

2.1 Test Product(s)

The product(s) under investigation should be the named formulated product(s).

2.2 Mode of Application

All applications should comply with good experimental practices.

2.2.1 Method of Application

The method of application (e.g. spray, broadcast, soil application, etc.) will normally be specified on the (proposed) label/leaflet.

Different microbial products show different modes of action and require different environmental conditions. Accordingly, there exist specific recommendations for application. A selection of examples is listed in the Annex of this protocol.

2.2.2 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%. Other application techniques, different to spraying, will also need proper description.

Precaution should be taken to avoid drift between plots, where relevant, by holding a screen around the plot being treated.

2.2.3 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).

As specified in the Annex, many microbials should be used in a preventative manner rather than curative; that means these products are applied when pest/disease incidence is in the lower range and insect stages are young, for instance. Different modes of action when compared with synthetic pesticides usually result in a longer reaction time between application and the observation of visible effects. Thus, proper timing of application is crucial for success.

2.2.4 Doses and Volumes Used

The product should be tested at a dose range that accommodates for environmental and target pest variability. The recommended application dose would be recommended based on the results of the official field testing. 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 (litre/ha) should also be given. The spray volume (litre/ha) will be appropriate to the stage of the crop.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1 Characterisation of the location

Characteristics of the location are presented here, including coordinates, elevation, climatic zone, etc.

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 or by percentage of damage or percentage of infection per unit area of plant parts on selected plants in the trial.

3.2.2 Time and Frequency

Microbial pesticide assessments are adjusted to the mode of action of the product under question, the type of plots, and the biology of the pest population. Because microbials show also long-term effects, it is recommended to observe during a whole cropping season.

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 including major symptoms of pesticide 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.

3.4 Quantitative and/or Qualitative Recording of Yield

If the proposed label claims an effect on yield then yield should be included in the field evaluation of the product. Quantitative and/or qualitative yield should be recorded where relevant in each treatment and should preferably be converted into 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, organisational aspects, methodology, results, discussions and conclusions).

5. REFERENCES

- Lace L.A. & Kaya H.K., eds. (2007) Field Manual of Techniques in Invertebrate Pathology. Application and Evaluation of pathogens for control of insects and other invertebrate pests. Springer, Dordrecht, Netherlands
- Caldwell, B. et al. (2013) Resource Guide for Organic Insect and Disease Management. Cornell University.

ANNEX

Microbial products show different modes of action and require different environmental conditions compared with synthetic pesticides. General application guidelines that contain many practical tips and include notes on the safety and the effectiveness of various microbials can be found in Caldwell et al. 2013:

Freely available under: http://web.pppmb.cals.cornell.edu/resourceguide/pdf/resource-guide-for-organic-insect-and-disease-management.pdf

Botanical Pest Control Products

DRAFT EFFICACY TEST PROTOCOL (based on an FAO template and modified by EWG)

1. EXPERIMENTAL CONDITIONS

1.1 Selection of Crop and Cultivar, Test Organisms

This test protocol is concerned with the efficacy evaluation of botanical pest control agents 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. and 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) (usage of chemical pesticides). Cultural conditions (e.g. soil type and pH, fertilisers, 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 for the relevant pest or disease should be carried out in different locations with distinct environmental conditions over an entire growing period of the crop (e.g. about 2 trials in 2 locations or seasons). The timing, amount and method of irrigation, if applied, should be recorded.

Trials can be done under semi-field conditions or involving larger scales in farmers' fields (depends on BCA under evaluation and purpose/claim of product).

The relevant conditions of the plot and crop should be adequately described like sowing or planting date, row spacing, cultivation measures, crop condition and pest/diseases densities, etc.

1.3 Design and Layout of the Trial

1.3.1 Treatments

Test product(s), and untreated control are to be arranged in a randomised 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 and any additional remarks)

In the case of on-farm trials, it is recommended to include an untreated control, farmers' practice (preferred over chemical standard) and the botanical product under question. In all cases, the length of the observation time should be appropriate for the botanical under consideration. Pest or disease levels should be considered together with achieving an economic benefit to the user.

1.3.2 Plot Size and Replication

Net plot size: Use an optimum plot size (e.g. 15-20 m^2); however this will depend on the type of crop/ pest and disease/product under study and location of trial. Highly mobile pests might require larger plot sizes for evaluation (e.g. 60-80 m^2 or larger).

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 4 per treatment (provided the error or residual degrees of freedom are at least 12). More replications are recommended, in particular, if one wants to account for an expected higher variability of the negative control plots which might show higher pest/disease pressures and crop damage.

2. APPLICATION OF TREATMENTS

2.1 Test Product(s)

The product(s) under investigation should be the named formulated product(s).

2.2 Mode of Application

All applications should comply with good experimental practices.

2.2.1 Method of Application

The method of application (e.g. spray, broadcast, soil application, etc.) will normally be specified on the (proposed) label/leaflet.

Different botanical products show different modes of action and require different environmental conditions. Accordingly, there exist specific recommendations for application. A selection of examples is listed in the Annex of this protocol.

2.2.2 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%. Other application techniques, different to spraying, will also need proper description. It is important to optimize volume application rates, especially when treating foliage.

Precaution should be taken to avoid drift between plots, where relevant, by holding a screen around the plot being treated.

2.2.3 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).

2.2.4 Doses and Volumes Used

The product should be tested at a dose range that accommodates for environmental and target pest variability. The recommended application dose would be recommended based on the results of the official field testing. 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 (litre/ha) should also be given. The spray volume (litre/ha) will be appropriate to the stage of the crop.

3. MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1 Characterisation of the location

Characteristics of the location are presented here, including coordinates, elevation, climatic zone, etc.

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 or by percentage of damage or percentage of infection per unit area of plant parts on selected plants in the trial

3.2.2 Time and Frequency

Botanical pesticide assessments are adjusted to the mode of action of the product under question, the type of plots, and the biology of the pest population. Because botanicals show also long-term effects, it might be considered to observe during a whole cropping season.

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 including major symptoms of pesticide 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.

3.4 Quantitative and/or Qualitative Recording of Yield

If the proposed label claims an effect on yield then yield should be included in the field evaluation of the product. Quantitative and/or qualitative yield should be recorded where relevant in each treatment and should preferably be converted into 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, organisational aspects, methodology, results, discussions and conclusions).

5. REFERENCES

Caldwell et al. (2013) Resource guide for organic insect and disease management. Cornell University, New York.

ANNEX

Botanical pesticides show different modes of action and require different environmental conditions compared with synthetic pesticides. General application guidelines that contain many practical tips and include notes on the safety and the effectiveness of various botanicals can be found in Caldwell et al. 2013. Products like neem, pyrethrum, and rotenone are covered in depth. Additionally, useful categories for efficacy evaluation of botanicals are proposed and extensive target pest lists are presented:

Freely available under: http://web.pppmb.cals.cornell.edu/resourceguide/pdf/resource-guide-for-organic-insect-and-disease-management.pdf

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