International Symposium on Biopesticides for Developing Countries

Proceedings
CATIE, Turrialba, Costa Rica
October 28-30, 2003

Ulrich Roettger and Reinhold Muschler, editors.

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Preface

This document presents the valuable contributions of the international symposium on biopesticides that was organized jointly at Turrialba, Costa Rica, in October 2003 by the Center for Tropical Agriculture on Training and Research (CATIE), the CATIE/GTZ regional Project on the promotion of Biopesticides, the private sector related to Biopesticides from various countries and researchers especially from Latin America. This symposium brought together 34 experts from the public and private sectors from 14 countries around the world to share their experiences with Biopesticides regarding all stages from production and formulation through registration and marketing all the way to their final application in the field.

We organized the 31 contributions to this volume in four thematic sections. The first section of eleven papers discusses underlying definitions and concepts related to Biopesticides as an evolving group of more natural and less toxic pest control options. This section also presents the development and relevance of Biopesticides from the perspectives of the public and private sectors. Two papers focus on the potential roles of Biopesticides as substitutes for chemicals that have been banned or restricted under international conventions. The final paper in this group reviews experiences of the German Agency for Technical Cooperation with supporting Biopesticides initiatives through international technical cooperation.

The second section groups eight contributions, which focus on innovations, production and application of Biopesticides in different countries. Following a comparison of industrial versus home-scale production of antagonistic and entomopathogenic fungi, the authors summarize advances with and constraints for Biopesticides using examples from Cuba, the Dominican Republic, Colombia, Africa and Thailand.

The third group of seven papers presents relevant issues from the regulatory frameworks developed in the USA, Europe and Peru, and provides an overview of three important information systems focusing on Biopesticides: the CATIE/GTZ information system, relevant websites of the US's EPA, and the website on non-chemical pest management developed by the German branch of the Pesticide Action Network.

The final section with five documents provides an outlook on Biopesticides in the future. This section provides regional assessments of Biopesticides markets and use, production capacities, and limitations from Central America, Southeast Asia, and Africa. The volume concludes with a tabular summary of the main conclusions of the working groups which were in session during two days of the symposium. We believe that many of the points raised by the working groups provide useful directions for designing future development activities.

Finally we would like to thank all the financial supporters, our support staff, and all the participants of the symposium for their manifold contributions during the sessions and working groups. A particular warm appreciation goes to those authors who have collaborated with us during the sometimes difficult editing process of this volume. Undoubtedly, the final quality of this volume gives testimony to the great motivation of the people involved in developing and promoting Biopesticides as emerging tools for pest and disease control in environmentally more benign agricultural systems of the future in developed and developing counties.

R. G. Muschler and U. Röttger
Turrialba and San José, Costa Rica
December 2004

Section 1

Definitions, Concepts and Relevance

What are Biopesticides?

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Abstract
Biopesticides have a range of definitions all of which include reference to the natural or biological origin of the active ingredients. This article summarizes definitions from different countries and organizations world-wide and discusses reasons, constraints and prospects for using biopesticides in the future.

Introduction

Biopesticides or Biological Pesticides are, as the name implies, biologically derived agents for pest management. Although, as discussed below, there is no single definition for biopesticides, one of their principal attributes is that they are not chemically derived pesticides. Consequently, they are widely regarded as more environmentally acceptable. However, the name pesticide, even when associated with biological or "natural" methods of pest management tends to give an impression of being a derivation of chemical pesticides, even though they have a completely different mode of action. Care must, therefore, be taken in presenting the unique characteristics of biopesticides so that their environmental benefits receive the full recognition they deserve. Parting from the various definitions of biopesticides, this chapter reviews the opportunities and constraints that affect the production and use of these agents.

Definitions

Although the word "biological" provides the root for the term biopesticide, most of the internationally used definitions focus on the attributes required for the registration of chemical pesticides in each country. There is, therefore, a tendency to apply the concepts associated with chemical pesticides, which has been referred to as the chemical paradigm (Gelernter & Evans, 1999). Great care should be taken to avoid an over-emphasis on the chemical attributes at the expense of the biological attributes and context

The combination of chemical and biological attributes is implicit in the majority of international definitions, although the scope of the term varies widely from country to country, even within an integrated grouping such as the European Union. A useful reference source to compare the registration requirements for biopesticides was provided by OECD (1996).

There is considerable cross-reference within the registration requirements of various countries. Often, the requirements of the US Environment Protection Agency (EPA) are used as guidelines to compare or derive national legislation. Consequently, the EPA definition of biopesticides is of considerable interest and influence.

Definition by the Environment Protection Agency (EPA), USA

The EPA definition is (EPA, 2003): *"Biopesticides are certain types of pesticides derived from natural materials such as animals, plants, bacteria and certain minerals"*. The EPA recognizes three categories of biopesticides:

1. Microbial pesticides - bacteria, fungi, viruses or protozoa
2. Plant-incorporated Protectants (PIP): incorporation of genes for substances with pesticidal properties into plants
3. Biochemical pesticides: naturally occurring substances to control pests by non-toxic means, e.g. pheromones

The emphasis here is on *natural materials* as the basic attribute. However, in contrast to other organizations, the EPA has also included genetically modified plants within the biopesticide definition. Another key component is the acceptance of the fact that pest control can be achieved by non-toxic means. However, this is a rather gray area, which is not universally recognized or defined. EPA has also established a committee to determine whether pesticides should be classified as biological or conventional. In addition, the registration requirements for biopesticides tend to be abbreviated compared with conventional pesticides, thus shortening the time to registration and reducing the cost. However, this model is not universally applied in countries other than the USA.

Definition by the European Union (EU) Core Legislation

Although there is considerable interest in biopesticides within the European Union, there is no single precise definition of biopesticides. Within the harmonized pesticide legislation (Directive EEC 94/414), there are specific references to agents that are defined as biopesticides elsewhere (e.g. EPA), but that are only classified specifically within the EU Directives. The EU legislation provides the following definition of microorganisms: *"A microorganism is a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material. The definition applies to, but is not limited to, bacteria, fungi, protozoa, viruses and viroids"*. Clearly, this definition falls within the universal understanding of biopesticides but does not embrace other naturally derived compounds, which are dealt with generically under pesticides legislation.

Within the EU, there are a number of definitions of agents that can be classified as biopesticides (Table 1). The definitions in most EU countries are restricted to microorganisms and their use is typically regulated under the countries' pesticide legislation. Macro-organisms (e.g. predators and parasitoids) are usually not considered biopesticides and their use is typically regulated by legislation to prevent the release on non-indigenous organisms that might harm the environment.

In the United Kingdom, macro-organisms are dealt with under the Wildlife & Countryside Act in the first instance and, although they would not be regarded as problematic in their own right, any predators or parasitoids have to be screened carefully for non-target effects before permission is given to release them.

Among the interpretations in Table 1, Italy appears to have the most comprehensive definition of biopesticides including all the categories of biopesticides that have been recognized, at least in part, by other countries.

Table 1. Definitions of biopesticides or naturally occurring pest control agents used in selected countries and by international organisations

Austria	Micro and macro-organisms (biological pesticide not defined).
Denmark	Biological pesticides include only living organisms (micro, macro-organisms, transgenic plants). In contrast, semiochemicals and other plant-derived products are regarded as chemical pesticides.
Finland	Not specifically mentioned. Microorganisms including viruses as in EU law, otherwise regard as pesticides.
France	As EU.
Germany	Microorganisms including viruses. Other agents are regulated as chemical pesticides but with slightly lower requirements.
Italy	7 categories: microorganisms, pheromones, insect growth regulators, plant growth regulators, plant extracts, macro-organisms, and transgenic plants.
The Netherlands	Microorganisms including viruses. Most others regarded as pesticides. Macro-organisms and transgenic plants not in Pesticides Act.
Sweden	Living organisms only: microorganisms, viruses, nematodes, insects, spiders.
UK	Microorganisms and semiochemicals.
Australia	Biologically-derived chemicals with direct and indirect toxicity, microbials, other living organisms.
Mercosur (Brazil, Argentina, Uruguay and Paraguay)	Biological pesticide, understood in terms of origin and function, as "an agent of biological control produced artificially, usually a pathogen formulated and applied for the rapid reduction and control of pests".
OECD	Biological entities that are alive or naturally occurring. Microorganisms, pheromones, insect growth regulators, plant growth regulators, plant extracts, macro-organisms, transgenic plants.
FAO	Biological pest control agents that are naturally occurring or genetically modified. They have unique modes of action, are used in low volumes and are specific to target species. There are two major categories: 1. Biochemical pest control agents (no direct toxicity and naturally occurring: semiochemicals, hormones, natural plant regulators and insect growth regulators, enzymes). 2. Microbial pest control agents: bacteria, fungi, viruses and protozoa or genetically modified microorganisms.

Definitions by other nations and international organisations

Also Australia and the Mercosur countries (Argentina, Brazil, Paraguay and Uruguay) recognize the biological origin of the agents as their primary characteristic, while their mode of action (non- or indirect toxicity) tends to be secondary. Thus, unlike EPA, Australia recognizes direct toxicity from biologically-derived chemicals. In this respect, it is interesting to examine the definitions from OECD and FAO (cf. Table 1) based on their wider international perspectives.

While both OECD and FAO follow the theme of *biological* and *natural* origin of the agents, they are more explicit in defining the range of entities that should be included. The FAO definition also identifies the unique modes of action of the agents, and emphasizes the lack of direct toxicity. Both organizations recognize the increasing importance of genetic modification of plants and microorganisms. Commercially available biopesticides fall within the range described by FAO. Thus, The Biopesticide Manual (Copping, 2001) includes micro-organisms (96 products), natural products (51 products), macro-organisms (54 products), semiochemicals (53 products) and genes (19 products) in its second edition. In a practical sense, therefore, biopesticides are recognized by their sources and modes of action, and many are now commercialized, indicating that there is increasing interest in their use.

Why Use Biopesticides?

The development of biopesticides has a long history, as discussed elsewhere in this volume, but recently there has been an increasing interest, driven by worries concerning the use of chemical pesticides. Characteristics of chemical pesticides that make them environmentally less acceptable include the following:

- Relatively low selectivity. Although there is considerable variation in the degree of selectivity among chemical pesticides, they typically have a much broader spectrum of activity than biopesticides. When used correctly, non-target effects can be minimized but never eliminated.
- Potential pollution of environment during use and disposal. Chemical pesticides tend to have modes of action and a chemical structure which increase the risk of pollution both during use and cleaning of equipment and disposal.
- Mainly based on non-renewable resources. Reliance on non-renewable resources, particularly carbon sources, causes concerns about the long-term sustainability of the production of chemical pesticides.
- Risks to personnel during application and harvesting of crops. Great care must be taken to avoid contamination of personnel both during application -when the risks are highest- and during harvesting.
- Development of resistance in pest populations if over-used. The "insecticide treadmill" is a well-documented phenomenon arising when populations of pest organisms receive frequent application of pesticides and develop resistance to the chemicals used.
- Residues in produce may cause health concerns.

Biopesticides offer alternatives to chemical pesticides for a number of reasons:

1. They are naturally occurring with little or no intrinsic toxicity. As indicated above, this is a core characteristic of biopesticides.
2. Selectivity can be very high, often targeted to a single pest species; the applications can be highly targeted.
3. Ideal as a component of Integrated Crop Management (ICM) regimes. ICM regimes are a holistic way of implementing effective pest management, often integrating or extending the well-established Integrated Pest Management (IPM) practices already used in many countries.

4. Sustainable with little or no requirement for non-renewable resources. In many cases, production of biopesticides can be done at various scales, with relatively little use of non-renewable sources of components or energy.
5. Well suited to small scale and traditional crop production systems, especially to organic systems. Their use fits well with the ICM/IPM approach, which can form components of smaller-scale production, with increasing emphasis on organic systems.

Constraints to Usage

While biopesticides offer many attractive characteristics regarding their mode of action and environmental protection, it must be recognized that there are still constraints that must be overcome to extend their usage globally:

- Biopesticides may be more difficult to use compared with chemical pesticides. This will be discussed more fully under the concept of the *Control Window* approach later in this volume.
- Specificity is high. This may restrict usage if several pests are attacking the crop. Ironically, one of the main positive environmental characteristics may be a constraint if several pests need to be being managed simultaneously.
- Scaling-up of the production and quality control may be difficult. This is a well-recognized problem and there are increasing examples of good practices that indicate ways forward in solving this issue. However, it will continue to be a problem for small-scale producers.
- Detailed knowledge on the biology and ecology of the pest is essential to optimize use. As indicated above, production may be difficult and, therefore, it is essential not to waste the biopesticides once they have been produced. A deep understanding of the ecology of the system under management can save amounts of biopesticides and reduce the variability in response.
- Still mainly niche markets: registration costs may be too high for the size of market. This is an important constraint because many biopesticides have to go through similar registration procedures as chemical pesticides; in this case, the costs may be prohibitive and the time-scale too long for a niche product.
- Education and training: initial adoption requires expertise and training. The use of biopesticides requires a very different approach from the use of chemical pesticides and it is important to emphasize that they are not simple substitutions. The chemical paradigm must be avoided!.

Future Prospects

Despite the constraints mentioned above, the prospects for the use of biopesticides remain good. Some of the reasons for this optimism are:

- There is a general shift towards reducing the use of chemical pesticides on a global scale, although this varies enormously from country to country.
- The registration of biopesticides will become more specific to each agent under review and with less dependence on the procedures used for chemical pesticides; consequently, the registration may become cheaper. There is some move in this direction, e.g. EPA in the US, but it is a slow process.

- Transgenic crops are currently receiving much of the development funding, but it is difficult to predict future adoption. This is a controversial area, although the concepts and the delivery of activity precisely at the pest interface are often being well received by farmers who are already using this technology.
- Integrated Pest Management and Integrated Crop Management regimes' are increasing; combinations of biopesticides will be needed, e.g. semiochemicals for monitoring pest populations and microbial or plant-derived agents to reduce critical pest populations.
- Organic farming is increasing. Although still a small component of the total farming system, organic farming carries a disproportionate weight in relation to public awareness and its potential to influence regulatory authorities. This should be exploited for accelerating the adoption of biopesticides, unless they are linked to transgenic organisms which are not allowed in organic farming.
- Biological prospecting will provide new biopesticides. There are many companies globally prospecting for new biologically-derived active compounds and microbial agents that could be developed into biopesticides. Clearly, the modes of action and the Intellectual Property Rights of these new compounds need to be carefully managed if the resulting products are to be made available to all farmers.
- Ecological studies remain essential. This is a recurrent theme for effective use of biopesticides. Biopesticides are not mere substitutes of chemical pesticides.
- We must decrease waste of biopesticides by avoiding poorly targeted use and inadequate dosage and timing.

In conclusion, the prospects for developing and accelerating the usage of biopesticides are good but there are many constraints to overcome before they can be regarded as anything other than niche products. Increased availability of products for the farmers and effective technology transfer and extension services are essential for raising the awareness of the benefits of biopesticides.

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Biopesticides: Historical Roots, Current Situation and Global Markets

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Abstract
There are several barriers affecting the large-scale adoption and further development of biopesticides. The persistence of the chemical paradigm for pest control products leads to an undervaluation of biopesticides and hampers their development. Furthermore, the spread of knowledge and use of biopesticides is confined to extension and regulatory systems that have been molded over time for the development and use of chemical products.

Introduction

Biopesticides are certain types of pesticides derived from such natural materials as animals, plants, microorganisms and certain minerals. They are pest management tools based on beneficial microorganisms (bacteria, viruses, fungi and protozoa), beneficial nematodes or other safe, biologically-based active ingredients. Moreover, biopesticides are slow acting and have a narrow target range and a very specific mode of action, limited field persistence and a short shelf life. They also suppress rather than eliminate the whole pest population and typically present no residue problems. Compared to chemical pesticides, they are overall safer to humans and the environment, and they are amenable to small-scale local production in developing countries.

Many developing countries have research expertise in biopesticides and an adequate level of technology. However, as in many developed countries, there is a gulf between great research ideas and the implementation and adoption of a new technology. Biopesticide research is usually funded piecemeal, largely by the public sector and rarely involves multidisciplinary teams that develop a microbial insecticide from start to finish (Dent, 1997). In spite of this constraint, the research, development, production and commercialization of biopesticides may provide crucial and enormous benefits for generating local employment, reducing health risks and costs, and for improving export earnings through the reduction of chemical residues on high value export commodities.

Historical Use of Biopesticides

Biological control was first applied long before its formal definition, for example when humans kept cats to protect stored grains from rodent infestation as documented in Egyptian records of 4.000 years ago. The first biological control project recorded used predatory ants (*Oecophylla smaragdina*) in citrus orchards to control lepidopteran and coleopteran pests in 324 B.C. On the other hand, insect parasitism was recognized around the turn of the 17th Century. While the knowledge on parasitoids increased rapidly, the first successful importation of a specifically selected organism occurred in 1762 with the introduction of mynah birds from India to Mauritius to control locust infestations.

During the 18th Century an ever-increasing number of references on entomophagous and entomogenous organisms appeared in the literature, largely centered on the biology of parasitoids.

During the 19th century, practical ideas and tests about the application of biological control gradually advanced. Beginning in the 1850s, due to pest infestation of domestic and imported crops and other events associated with the westward expansion of agriculture in the United States, the field of biological control gained increasing attention. Between 1888 and 1944, referred to as the "golden age of biological control", biological control was generally preferred as a pest control strategy. During the following two decades, the then rapidly evolving chemical industry made synthetic pesticides widely available, which impressed the users by their fast action and apparently high effectivity to reduce pests and diseases. This led to widespread adoption and, often, overuse of chemical pesticides, the effects of which became apparent in the 1960s. Rachel Carlson's book "Silent Spring", published in 1962, highlighted the dangers of chemical pesticides like persistent organic pollutants (POPs). Her image of a spring without birds due to the effects of DDT and other chemical pesticides captured public and media attention. This rekindled the interest in biological control and the 1970's, 80's and 90's witnessed many programs on biological control. Some of the highlights include the biological control of the walnut and linden aphids, the cereal leaf beetle, the alfalfa weevil, the cassava mealy bug, and in 1972 the release of *Bacillus thuringiensis*, a microbial insecticide based on isolate HD-1, for the control of lepidopterous pests (www.inhs.uiuc.edu/cee).

Current Situation

There are several barriers affecting the large-scale adoption and further development of biopesticides. Firstly, the political interest in IPM and biological control methods has not translated itself into markets for corresponding biological products. While support for biopesticides has come from researchers and regulators, there has been no powerful economic force driving the deployment of biopesticides except in crisis situations, where synthetic pesticides were either not able to overcome pest problems or caused unacceptably large environmental and healt impacts ("pesticide treadmill").

Secondly, industry has failed to bring products to market. Many companies have invested in research and development of biologicals to manage resistance problems in their chemical product range, to increase the perception of environmental friendliness, to position themselves for the potential profit from these products or associated proprietary technologies, and to develop expertise related to the development of transgenic crops that could enable a shift from crop protection to biotechnology. However, ultimately, biologicals have not proven to be effective competitors with chemical products in the marketplace, due in part to higher costs, limited distribution, problems with handling, and the lack of extension support.

Underlying the failure of biologicals to realize their potential is a more fundamental problem: the persistence of the chemical paradigm for pest control products leads to the undervaluation of biologicals and hampers their development.

The chemical paradigm can easily be seen in statements on what is necessary for products to be competitive, including attributes such as high kill rates, fast action, low costs etc. Further limitations for biologicals arise from the fact that their promotion and distribution is (at least currently) subject to the extension and regulatory systems that have been molded over time for the distribution of synthetic chemical products.

Similarly, the fact that the need for applying biologicals may decline as natural enemy populations recover from years of chemical pesticide use also can be seen as a disadvantage from the perspective of companies that are interested in generating higher rather than lower demands for their products in the future. *Bt*, for example, plays an important role in the recovery of vegetable ecosystems which had been subject to the pesticide treadmills. In this case, it might best be viewed as an environmental remediation product, perhaps transient in nature, but with a continuing small demand in restored systems.

We are today at a unique historical juncture. Demand for biopesticides is increasing, but the systems which produce and distribute new products have so far failed to deliver and distribute such products in adequate formulations and quantities (www.rci.rutgers.edu/~insects/whitepaper.htm).

Conclusions and Recommendations

In spite of various problems besetting the development and utilization of biopesticides, their use will remain as a vital component of IPM and other crop protection strategies. Hence, in the future, there will still be a need for biopesticide development. However, it will likely be largely dependent on the public sector as long as the multinational private sector seeks better investment prospects from biotechnology.

The current restructuring of the agrochemical industry due to pesticide resistance and the re-registration of minor use chemicals all provide an opportunity for the evolution of local and regional niche markets for biopesticides in developing countries. Such markets may be best exploited by small and medium biopesticide enterprises that can remain flexible and respond to markets that are too small for the multinational companies to consider them viable (www.biopesticide.org). Appropriately scaled businesses serving local markets can gain advantages in their roles for local IPM and related systems through increased speed of delivery, improved distribution and extension support, and the reduction of storage problems. The farm sector has considerable advantages as a base for business because of the local abundance and relatively low cost of the key ingredients for the production of biologicals including pests and locally adapted natural enemies, fermentation substrates, labor, etc, (www.rci.rutgers.edu/~insects/whitepaper.htm).

On the other hand, in order to promote the development and widespread utilization of biopesticides, it will be necessary to raise the awareness regarding the opportunities offered by biopesticides with international and national agencies, decision-makers, extension agencies, entrepreneurs, potential commercial investors and farmers. Furthermore, it will be essential to provide basic training in all relevant areas of biopesticide development ranging from the conceptualization, collection, isolation and characterization of the pathogen or biologically active substace, through production and storage, formulation and application, to registration and, finally, the commercialization of the final product.

Furthermore, since toxicological and eco-toxicological tests are required for the registration of the biopesticide with the relevant regulatory authorities, it will be necessary to provide technical assistance on international standards for registration and to provide support to regulatory authorities in line with FAO and OECD harmonization programs. Also, technical and business support should be provided to the R&D teams of fledgling small and medium enterprises in identifying appropriate partner companies, and in establishing the legal and contractual arrangements required to safeguard IPR and the efficient transfer of the technology and subsequent product support.

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Biopesticides and Genetic Engineering: Is There a Need to Draw the Line?

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Abstract
Under authority and mandate of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as modified by the Food Quality Protection Act (FQPA), the U.S. EPA regulates pesticidal substances and their use on plants intended for food or feed. Biopesticides, as defined by FIFRA, include biochemical pesticides (mostly of natural origin, typically used in low dose volumes and non-toxic in their mode of action), microbial pesticides (viruses, fungi, bacteria, algae used for pest and disease control) and plant-incorporated protectants (*i.e.* pesticidal traits expressed in genetically modified plants). This discussion will focus on Plant-Incorporated Protectants with regards to gene flow and potential environmental impact while covering some aspects of genetically modified microbial pesticides as well. This latter group is currently small in number with respect to biopesticides approved for experimental use or as registered products. Plant-Incorporated Protectants (PIPs) are pesticidal substances expressed in plants and the genetic material necessary for their production. These pesticidal substances include the currently registered endotoxins of *Bacillus thuringiensis* (*B.t.*) in maize, cotton and potato, as well as the viral coat proteins expressed in crops like papaya and squash.

Following review of product characterization, toxicity and environmental effects, the agency may issue an Experimental Use Permit (EUP) for field evaluation and then a Section 3 registration for commercial use later. The FFDCA authorizes EPA to establish a tolerance (maximum residue level) or an exemption from the requirement of a tolerance for a pesticide if the 'residue in or on food is safe'. Gene flow between crop varieties wherein a food tolerance is in place does not represent a violation of FIFRA or FFDCA. If a food tolerance is not established, however, any commodity used as food or feed containing the PIP may be considered adulterated. Adulterated food or feed results from the presence of a pesticidal substance in an agricultural commodity, such as a PIP protein for which no tolerance exists, and cannot legally enter the food or feed supply. Such food or feed may be confiscated and destroyed.

Movement of transgenes from PIPs into wild or feral relatives is of concern to the agency and currently, measures are in place to mitigate this possibility with cotton, the only approved PIP with a significant probability of genetic exchange with its wild relatives in the U.S., its territories and possessions. Registrants of PIPs may provide an environmental analysis of gene flow and its potential impacts for specific situations to satisfy the EPA that no adverse effects will be promulgated on man or the environment.

Introduction

The movement of transgenes from the host plant into weeds has been a significant concern for EPA due to the possibility of novel exposures to the pesticidal substance. This concern has been considered for each of the *B.t.* plant-incorporated protectants (formerly plant-pesticides) currently registered, and EPA believes that these concerns have been satisfactorily addressed. The Agency has determined that as currently registered, there is no significant risk of gene capture and expression of any *B.t.* endotoxin by wild or weedy relatives of corn or potato in the U.S., its possessions or territories. In addition, the USDA/APHIS has made this same determination under its statutory authority under the Plant Pest Act and Plant Protection Act. There is a possibility, however, of gene transfer from *B.t.* cotton to wild or feral cotton relatives in Hawaii, Florida and the Caribbean.

There are several concerns with respect to gene flow to wild relatives of PIP crop species. While it is not possible at this time to accurately predict the outcome of transgene movement into wild or feral plants, which are sexually receptive to crop plants containing pesticidal substances, it seems biologically plausible that non-target effects on insects and other invertebrates feeding on such plants could occur. In cases where naturally occurring herbivorous insects control a plant population through feeding or other mechanisms, the gain of a strong resistance mechanism, such as a delta-endotoxin gene from *B.t.*, could allow for expansion of the wild relative or weed. Additionally, the potential for impact on biodiversity of the recipient plant species is not clear. Some mathematical modeling has been performed on the issue of gene flow to wild populations, but as with all modeling there are many assumptions about the nature of the transgene involved, the recipient species, and the niche such a species may fill. What is becoming clearer, however, is that even low rates of gene flow can eventually impact a population - the key question is, then, what is the measurable unit of such an impact and how does it differ from the gene flow already occurring from domesticated crops grown in centers of biodiversity? That is, do we measure the change in genetic diversity as indicated by a genetic analysis of allele frequency of a population of a particular species, or by the number of species present, or through effects on non-target arthropods, or .... ? Impacts in all of these areas have already occurred through crop to weed / feral relative gene flow.

Summary of Gene Flow Risk Assessment

Plant-incorporated Protectants

Under FIFRA, EPA has reviewed the potential for gene capture and expression of the *B.t.* endotoxins by wild or weedy relatives of corn, cotton and potatoes in the U.S., its possessions or territories. *B.t.* plant-incorporated protectants that have been registered to date have been expressed in agronomic plant species that, for the most part, do not have a reasonable possibility of passing their traits to wild native plants. Feral species related to these crops, as found within the United States, cannot be pollinated by these crops (corn, potato and cotton) due to differences in chromosome number, phenology (*i.e.*, periodicity or timing of events within an organism's life cycle as related to climate, *e.g.*, flowering time) and habitat. The only exception, however, is the possibility of gene transfer from *B.t.* cotton to feral or indigenous cotton relatives in Hawaii, Florida and the Caribbean.

The FIFRA EPA Scientific Advisory Panel meeting held on October 18-20, 2000 further discussed the matter of gene flow and offered some issues for consideration in this matter. The panel agreed that the potential for gene transfer between corn (maize) and any receptive plants within the U.S., its possessions and territories was of limited probability and nearly risk free. Similarly, potatoes were seen as nearly risk free with regards to gene flow because the proximity of compatible wild relatives to this crop is insufficient to allow for cross-pollination. Some concern was expressed, however, with respect to *B.t.* cotton grown in areas where wild relatives or feral populations of the crop are known to exist. Since feral populations of sexually compatible cotton species exist in south Florida, Puerto Rico, the U.S. Virgin Islands and Hawaii, EPA has since prohibited the sale or distribution of *B.t.* cotton in these areas. Containment measures prevent the movement of the registered *B.t.* endotoxin gene from *B.t.* cotton to wild or feral cotton relatives in Hawaii and Florida. In Florida, sales and planting of *B.t.* cotton are restricted south of State route 60 (near Tampa), which leaves a large distance between native cotton and any commercial plantings. Experimental Use Permits (EUPs) issued for testing and evaluation of prospective lines in pursuit of a FIFRA Section 3 registration have required isolation distances (3 miles) and border rows (24) of non-*B.t.* cotton or a similar malvaceous species to reduce the potential for insect-vectored pollen flow to the native *G. tomentosum* in Hawaii.

Similarly in Puerto Rico, experimental use of *B.t.* cotton for breeding purposes and seed production has also been closely regulated by the U.S. EPA to preclude the transfer of transgenes from *B.t.* cotton to wild and feral relatives extant on the island. Field studies to examine the risk in one area of Puerto Rico have demonstrated the extremely low rate of pollen transfer to surrounding border row cotton (*i.e.*, no transfer of an herbicide tolerance gene was detected within the 40 foot (13 m) non-transgenic cotton border rows). Continued monitoring of cotton near breeding nurseries will allow for small-scale breeding and seed production on this research station assuming future observations indicate very low or no gene flow to adjacent border row cotton. In this specific instance, geographic mapping of indigenous populations of sexually compatible *Gossypium* spp. and data on gene flow to surrounding plants have provided the Agency with sufficient information to allow for a variance from the stated isolation conditions for Puerto Rico. Field tests in other areas would also require supplemental information to approve an experimental use permit for *B.t.* cotton in Puerto Rico, Florida or Hawaii. The spectrum of chemical insecticides typically applied to cotton to control a variety of insect pests (not within the spectrum of the *B.t.* endotoxin expressed *in planta*) likely influences the pollinator population, thereby reducing gene flow rates to nearby recipients. This is particularly true in high value breeding nurseries and not necessarily the case in commercial production fields.

The Agency has funded research on gene flow from *G. hirsutum* to *G. tomentosum*. Once the findings of this study are known, it is possible that changes in the current restrictions on use of *B.t.* cotton in Hawaii may occur. Such studies are critical to our understanding of the basic pollination biology of crop plants and will be particularly important as other species are considered for registration as PIPs.

The issue of adventitious presence through gene flow will become more critical as the Agency considers regulation and approval of crops with known sexually compatible relatives extant within the U.S. Assessing the potential environmental effects on populations of native plants or established introduced species is complex and requires significant further study. This is especially true in cases where a crop and a noxious weed are known to hybridize and introgress traits freely (*e.g.*, sorghum and Johnson grass/shatter cane). Mechanisms for mitigating gene flow, such as the transformation of chloroplast plastomes, use of natural incompatibility alleles (*e.g.*, teosinte and maize), barnase / barstar and the more recent *cre-loxP* systems, may hold answers to some of these issues and are worthy of further scrutiny.

Microbial Biopesticides

With the GM *Pseudomonas*-based biopesticides, the possibility of gene flow is extremely low as the cells are heat-killed prior to final formulation and the DNA present is unlikely to persist in the environment due to the presence of naturally occurring microbial nucleases and physical (*e.g.*, oxidation) action of the environment. The *Agrobacterium radiobacter* strains K1026 and K84 modified for the control of crown gall disease are similar to naturally occurring isolates and are not expected to present any risk to the environment. The GM strain is a deletion mutant in which the mobility function of the resident plasmid has been removed or inactivated to prevent the plasmid and its associated agrocin-encoding gene from moving to recipient strains in the rhizosphere. These bacteria act to exclude gall-forming strains from colonizing root surfaces through niche pre-emption and do not affect mycorrhizae formation.

The only GM fungus approved for field trials, *Metarrhizium anisopliae*, has been modified to contain a more active form of a protease that is naturally occurring in this species by implementing gene expression under the control of a constitutive promoter. This strain has been demonstrated to reduce the time to kill 50% of the target lepidopteran species, but the LD_{50} and host range have not been altered. Microcosm studies indicate that the GM strain is reduced in its ability to persist in the soil and is diminished in sporulation upon insect cadavers as well. Since this species has no known sexual stage and has a heterokaryon stage that precludes parasexual recombination, the transfer of this modified gene to other members of this clonal species is highly unlikely (Hu and St. Leger, 2002). A small-scale field trial has been approved to further the investigation of this organism and its potential for enhanced biological control of lepidopteran insect pests. A green fluorescent protein from jellyfish was also incorporated to allow for tracking of this strain in the environment.

There have also been small-scale field trials of GM baculoviruses intended to control lepidopteran insect pests in cotton and for some forestry pests. In these instances the baculoviruses were engineered to express scorpion, spider or spider mite toxin genes, which are not known to harbor any mammalian toxicity. Importantly, these strains of the modified viruses were less competitive than the wild type viruses naturally present at the application sites in their reproductive capacities in the insect cadavers. The viruses are also all known to be reasonably specific in their host range and are out competed by wild type strains when co-infection occurs in a susceptible insect.

None of these biological agents have been registered to date and there is apparently little research activity in this area presently. This has occurred for business reasons primarily as some of the larger agricultural companies reduced or eliminated biopesticide-based programs. Concern has also been raised regarding the public response to a genetically modified organism expressing a scorpion toxin, despite the fact that this toxin possesses no mammalian toxicity.

Perspective on Implications of Gene Flow

While the topic of gene flow to wild or feral relatives of crop plants has been a controversial issue since the deployment of GM crops, gene flow has been occurring between plants since pollen evolved (Ellstrand, 2003). It is known that most of the world's crop plants routinely exchange genetic material with their related species in one location or more. Beets, carrots, mustards, maize, cotton and sorghum are just a few of the plants known to cross pollinate and in most of these examples, weedy relatives which present serious problems to growers, exist for these crops. From a regulatory point of view, the EPA cannot expect to regulate all crops nor should they want to as it would represent a logistical nightmare and impede the progress of traditional plant breeding. Traditional crops bred through what are considered traditional breeding practices are specifically exempted from FIFRA oversight. The difference between standard crop to crop gene flow and that originating in registered PIP plants is that the latter are subject to the scrutiny authorized by FIFRA and often contain DNA with pesticidal intent from outside the realm of the species (*i.e.*, inter-species genetic exchange). Gene flow in itself does not *a priori* represent a hazard to the environment. However, the mechanisms of insect or disease resistance engineered into plants as PIPs are such that they are generally more powerful in their action than comparable mechanisms resulting from evolutionary selection within the crop species. If they were not stronger and more durable, the inventors would not waste their money developing them.

With a measure of uncertainty at this juncture with regard to environmental effects from PIP gene flow to wild relatives, EPA has chosen a cautious approach. To date the only PIP with real potential for genetic exchange with a wild relative is upland cotton, *G. hirsutum*. The Agency is attempting to mitigate or preclude the culture of *B.t.*-cotton from areas wherein gene flow may take place. Until data are submitted to the Agency detailing the potential impacts of gene flow on a case-by-case basis, it is likely this stance will remain.

An important consideration in the assessment of gene flow and its impacts on the environment through introgression into compatible species is that genetic exchange that has had and will continue to have environmental implications occurs all the time regardless of the approval or presence of GM crops. In many cases, the genes transferred impart novel phenotypic values to the recipients and have the same biological principles governing the probability of untoward environmental consequences as transgenes derived through recombinant DNA techniques.

Movement of genes from microbes which have been genetically modified present somewhat different scenarios than PIPs. Since most of the microbes approved so far are self-limiting in their ability to persist, the issue of gene flow has not been as focused as that with plants. This in part also due to the more complex and in many cases unknown genetics of most microbial species as compared to plants.

Additionally, the monitoring and assessment of microbes in the environment is more arduous and problematic due to their large numbers, difficulty in direct sampling and significant population fluctuations. In cases where transgenes arise from soil or other ambient organisms, the movement of such genes is not expected to result in an adverse environmental effect since these genes and their associated activities are already present and often readily exchanged between microbes. Containment of microbes for the purposes of field testing is, however, much more difficult and requires significant monitoring to ensure confinement. In cases where total confinement is indicated, it is unlikely the Agency will approve such field testing.

Do we need to draw a line?

At the present time, only three crop species are registered for commercial use and sale as PIPs: maize, cotton and potato. The latter crop is not presently grown in the U.S. for commercial sale, although the registration is maintained with the EPA. These crops and the insecticidal *B.t.* toxin producing genes incorporated into them represent a method of insect control with documented reductions in synthetic (often highly toxic) pesticide use, especially in cotton. The culture of these early generation products of biotechnology has impacted and will continue to impact agricultural practices. Many of the registered PIPs also contain herbicide tolerance genes that allow for the management of weed issues using low toxicity, short persistence herbicides with greater efficacy. This has further allowed for an increase in minimum tillage or 'no-till' acreage, a potentially great benefit for a reduction in soil erosion, and has provided time for farmers to pursue other responsibilities around the farm that would have otherwise been spent on weed control.

When comparing the environmental impact of conventional insecticides (*e.g.*, organophosphates, carbamates) to use of PIP-produced delta-endotoxins from *B.t.*, it is obvious that the narrow spectrum, microbially derived insecticidal proteins have a far lower probability of affecting organisms beyond the intended scope of the target pests. Additionally, the persistence and groundwater contamination issues of many conventional pesticides are not present with the current PIP-based technology.

With respect to gene flow, it is up to individual countries to assess the possibility of genetic exchange between native and feral species which are sexually compatible with introduced genetically modified crops. More importantly, however, is the assessment of the potential impacts such gene flow might have if and when it occurred. This latter point is the more difficult question to answer, as the number of variables is high and the regional variations in species diversity and community structure will influence the outcome of any genetic exchange. Those performing a risk assessment of the introduction of PIP or other GM plants will need to contrast the impacts of gene flow with indigenous species against those impacts already occurring from gene flow between conventionally bred crops or other introduced species and indigenous plants to truly understand if any mitigation measures are indeed prudent or necessary.

There are a host of non-biological issues, such as trade considerations and organic farming paradigms, which are certainly important to the economics of the situation, however, these will not be discussed here as they are secondary to the biology of the situations and are in essence man-made.

The need to draw a line (*i.e.*, set limits) on genetically modified plants for use as food or feed crops should be based on the best available science and is the primary responsibility of the regulatory authorities responsible for oversight (Mendelsohn *et al.*, 2003). As mentioned above, certain aspects of this technology will have to be assessed on a country-by-country basis as parameters may change geographically. With a sound system in place to assess the types of genetic alterations put forth for consideration as food and feed crops, including adequate assessments of human and animal health toxicity, as well as environmental risk assessments, the 'line' should be based upon the need to protect man and the environment. As is the case with almost any technology, there is the potential for adverse effects if careful scrutiny is not applied before widespread use. It is critical to the assessment of the merits of GM technology to understand that each new 'variety' or type of crop proposed must be evaluated as an individual entity and not as a GMO vs. non-engineered crop comparison.

Until more easily adaptable genetic use restriction technologies are in place to prevent gene flow in cases where it is clearly detrimental, there are certain crop-trait combinations that are problematic and will likely not be considered approvable. For example, any crop which has wild relatives which are considered as serious weeds and is known to readily outcross to these, should be used, if at all, very judiciously (*e.g.*, sorghum with herbicide tolerance traits). Similarly, in cases where an endangered or threatened insect species relies on a sexually compatible relative of the introduced crop as a primary food source, it would be unwise to introduce insecticidal properties to the crop if the endangered species is known to be susceptible to that trait.

Genetically modified microbes intended to control or manage pests and diseases of crop plants also need to be considered similarly in the regulatory sense to ensure that the probability for adverse environmental impacts is low and that they offer advantages to the currently used control measures (*e.g.*, conventional chemical pesticides). Since microbes have the ability to propagate largely unseen, the measures needed to contain them in field tests are usually greater than is true with plant species, and in some instances not feasible. One aspect of the environmental assessment of any proposed GM microbial pesticide is the presence of traits or factors which preclude the aggressive spread of the organism. Demonstration of the inability to compete effectively with native strains of the species is important and has been performed in instances where GM biopesticides have been approved. Microbial species known to infect or parasitize man, animals or plants will not be considered for use whether genetically modified or not.

One key to the considerations of this technology is the comparison with the status quo and a true contrasting of the risks and benefits of all alternatives. New technologies often bring with them fears of the unknown, concerns over possible misuse and the need to alter regulatory paradigms to handle risk assessments. Society needs to consider the potential to help mankind through the genetic modification of organisms and to weed through the deluge of misinformation presently flooding the internet and general press prior to making any blanket decisions on the fate of a promising technology. These potential benefits will be viewed and assessed differently in many countries with adoption and restriction following suit, often influenced by political realities.

Conclusions

Genetically modified plants and microbes have been and will continue to be used for pest management in a variety of forms. We are currently in the infancy of this technology in the sense that novel traits being developed currently and in the future will be of an ever expanding number of forms as compared to those approved to date (*e.g.*, viral coat proteins for viral resistance, *B.t.* endotoxins for insect resistance). Undoubtedly some of these will require adjustments in risk assessment methods and may test the frontiers of our knowledge, especially in the area of environmental impacts, biodiversity and community structure.

Genetic exchange between GM plants and their wild relatives or feral escapes may present reason for concern among those concerned with secondary environmental impacts. EPA has taken a cautious approach to gene flow of Plant-incorporated Protectants. Of the three registered PIP crops (potato, corn, cotton), cotton has feral populations (*e.g.*, *G. hirsutum*, *G. barbadense* in Puerto Rico) of sexually compatible species, as well as wild relatives (*G. tomentosum* in Hawaii) capable of genetic exchange, within the boundaries of U.S. regulatory oversight. Production and sale of *B.t.* cotton has been precluded in Hawaii, Puerto Rico, south Florida and the U.S. Virgin Islands as a result of this assessment. In cases where a registrant submits data relevant to gene flow in a specific area, field tests may be allowed with requisite field monitoring for genetic exchange. In the absence of environmental data detailing the possible impacts, a 3 mile isolation distance for *B.t.* cotton is in effect for HI and PR.

As the genetics and monitoring of GM microbes presents new issues to regulators, GM microbes intended for field testing prior to commercial use must have a demonstrated inability to out-compete their naturally occurring counterparts. That is, the lack of aggressive competitiveness of a modified strain is used as a means of curtailing its movement in the environment.

Drawing the line, or setting limits for any technology, evolves over time as the risks and benefits of the methods employed become more apparent and understood. A strong and unbiased regulatory system is critical to the proper risk assessment of any newly release food or feed crop (or microbial) intended to control pests and plant diseases. Following an individual, case-by-case evaluation of the novel trait, the decision to approve or disapprove of a particular crop-trait combination must be based upon the best available science, and not political considerations. Contrasting conventional technologies with the risks and benefits of the new technology is critical to decision making with respect to environmental release of genetically modified plants. Gene flow from conventionally bred crops impacts feral and indigenous plant populations, although it is rarely measured or assessed. The need for comparison of this same phenomenon with PIP plants and other GM crops is great. This comparison may need to be performed on a regional basis as geographical influence is potentially large with respect to gene flow issues.

Prior to drawing any lines around the technology as a whole, this author hopes that the individual aspects of plant and microbial transformation, including the benefits inherent in certain traits, are fairly assessed on a scientific basis, free of political and philosophical interference.

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Supplemental links for further information:

- http://www.epa.gov/oppbppd1/biopesticides/reds/brad_bt_pip2.htm Documents relating to product characterization, human health, environmental assessment of gene flow, insect resistance management
- http://www.epa.gov/scipoly/sap/2000/october/octoberfinal.pdf Includes a copy of the final report from the Scientific Advisory Panel examining the issue of gene flow for *B.t.* crops. For downloading as a pdf file.
- http://www.ostp.gov/html/012201.html Presents a case study analyzing the regulation of a *B.t.* maize registration and review by other federal agencies. Download as pdf files.
- http://ostp.gov/html/012201.html - Case Study Two: *Bt*-Maize plus sidebar (pdf) - Includes overview of U.S. regulatory structure and assessment approach for *Bt*-Maize (MON 810) and a baculovirus modified with a scorpion toxin gene (AcMNPV/LqhIT2).
- http://www.epa.gov/oppbppd1/biopesticides/ Includes the listing of all registered biopesticides along with fact sheets that detail the biology of the active ingredients registered.

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The *Control Window* approach for optimizing the use of biopesticides

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Abstract
The use of Biopesticides must be viewed in the context of the biological characteristics of this group of pest management tools. An understanding of the biology of the pest, its interaction with the crop and the nature of interactions with biopesticides is fundamental and can be incorporated into a single conceptual framework - the *Control Window*. This paper describes the elements of the *Control Window* approach, concentrating on microbial biopesticides and the key elements of target pest species, host feeding sites, characteristics of biopesticides, spray technology and environmental factors.

Introduction

Biopesticides (BPs) cover a wide range of organisms and natural products, as outlined in other papers in this volume. Overall, however, the use of BPs is dominated by microbial agents, especially *Bacillus thuringiensis (Bt)* and, to a lesser extent, fungal and viral agents. While there are well-established procedures for the use of these BPs, it is not always clear how they should be utilized to deliver optimum performance. This was highlighted by Evans (1994) who identified some of the factors that make BPs attractive alternatives to chemical pesticides and the constraints that make them more demanding to apply efficiently. This was further emphasized by the volume on Microbial Insecticides: Novelty or Necessity (Evans, 1997) in which several of the authors described the essential need for understanding the nature of microbial agents and how they can be used more effectively.

This paper considers the key factors that must be included in developing optimal strategies for the use of BPs, with emphasis on microbial agents, although the general principles can be adapted and applied to other BPs. Central to this approach is the concept of a *Control Window*, which is a conceptual framework to consider the variables that must be accounted for in optimizing the use of BPs. The control window was originally introduced in 1994 (Evans, 1994) and later expanded to a more practical version (Evans, 1999).

The *Control Window*

An example of a *Control Window* for Biopesticides is shown in Figure 1. This is based on an original designed to optimize the use of baculoviruses against lepidopteran defoliators in temperate and tropical forests. However, it can easily be adapted to different pest situations and crop systems because it concentrates on the key components that determine the encounter between a target pest and the applied BP.

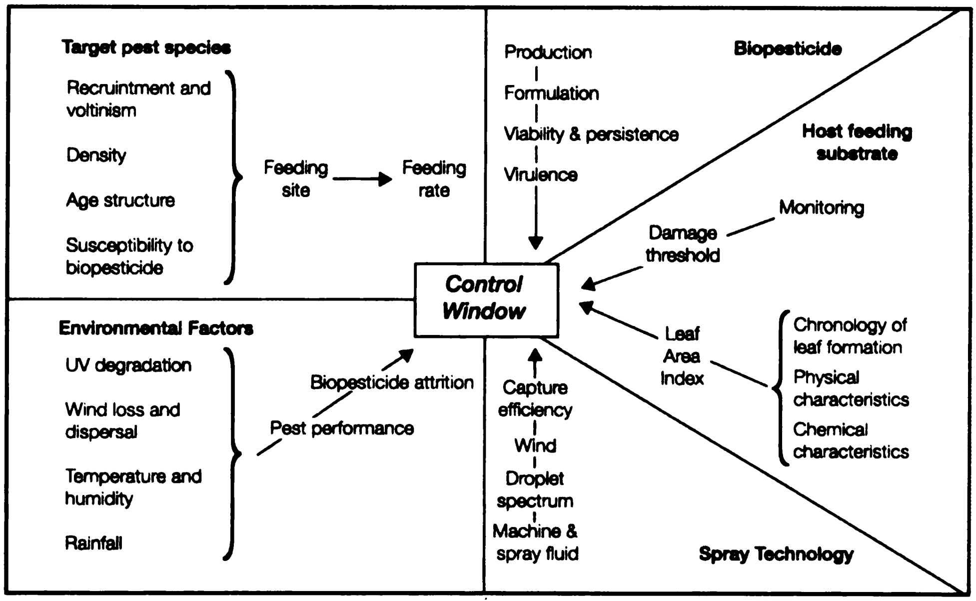

Figure 1. Control Window for biopesticides showing some of the key components for optimizing their use in pest management.

In this version of the control window concept, the five key parameters are the *Target Pest Species, the Biopesticide,* the *Host Feeding Substrate* (or the crop being protected), *Spray Technology* (if the BP is being used in a spray regime) and *Environmental Factors.* However, it would be relatively simple to adapt the concepts to consider, for example, the factors that need to be accounted for in rearing and release of a parasitoid or predator. The key can be summed up in the phrase **know your pest.** The biology and ecology of the pest organism, especially the timing of its life stages, the relationship to crop damage thresholds and, especially, why it is a pest in the first place can provide enormous benefits in designing a sustainable method of pest management. In the following, the *Control Window* concept will be described with microbial biopesticides in mind, but the concepts can be developed and applied also to other systems at a local level.

Target Pest Species

The biology and ecology of the target species determines, in time and space, where it feeds and where it could be most likely to encounter a BP applied to control it. In the case of microbial agents, consideration must also be given to fundamental data on the bionomics of the pest and its susceptibility to the chosen BP. The key parameters here are:

- **Susceptibility to the Biopesticide:** target mortality rate is usually set at 90% with recommended doses therefore corresponding to the LD_{90}. The susceptibility of a pest is usually age-related and therefore it is necessary to know
    - the **age structure** of the target population of the pest,
    - the **feeding site** to determine the target area on the tree or crop to deliver the BP,
    - the **feeding rate** of the target larvae to determine the surface area of foliage consumed in a given time. This applies mainly when a BP has to be ingested for action.

For microbial BPs, the range of susceptibility is age-dependent, with the greatest impact for a given dose being recorded in the early larval instars. Detailed bioassays to determine the precise dose, not the concentration, of BP required to kill a given proportion of the target stages is required. A hypothetical example, but one that is typical for baculovirus responses in Lepidoptera is given in Figure 2. Here the increasing dosage required to kill larvae is illustrated for five larval instars. It is quite typical for the slopes of the probit regressions to be parallel. The target mortality zone is usually >90% and it can be seen from Figure 2 that the required doses differ by more than 10,000-fold between the most and the least susceptible life stage. Determining the optimal dose in relation to the ease of delivering the BP is, therefore, vitally important.

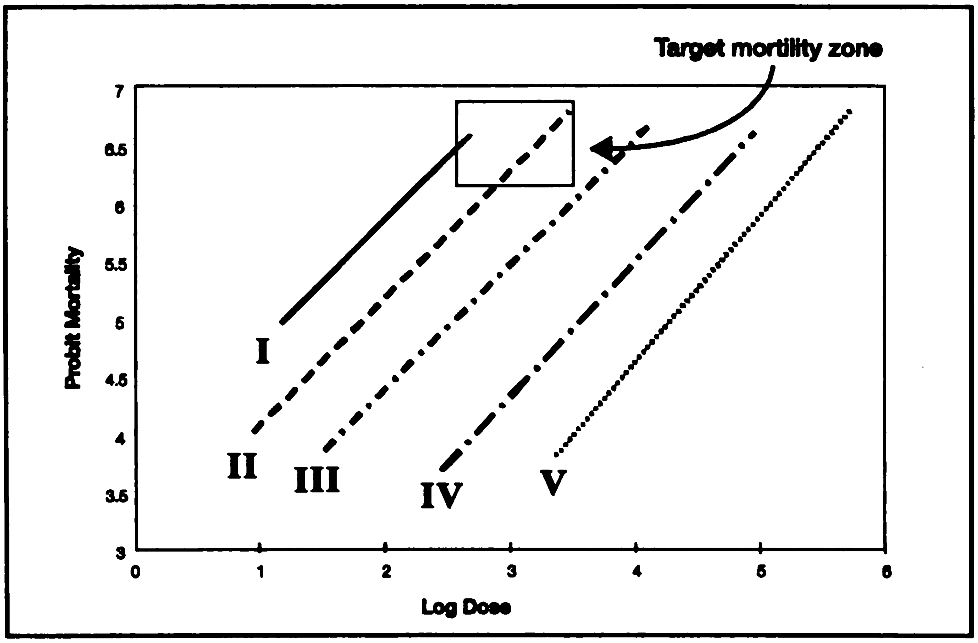

Figure 2. Dosage (log dose scale) and mortality (probit scale) relationships showing the decrease in response with increasing larval age (as instars I to V) and the usual target mortality zone for a hypothetical lepidopteran response to baculovirus.

Host Feeding Site

The host plant has a considerable influence on the likelihood of encounter between the pest and the BP. This parameter brings together knowledge of the biologies of both the pests and the crop/host plant on which they feed. Some of the key variables to consider are:

- **Synchrony:** The host may require synchrony with a particular plant growth stage such as bud expansion, presence of young leaves, etc.
- **Leaf Area Index (LAI):** This determines the target area of the plant (relative to the occupied ground area) for applying BPs as sprays.
- **Physical-chemical characteristics:** These may influence the survival of the BP once it is delivered to the plant. For example, some varieties of cotton have alkaline leaf exudates which may actually kill bacterial and viral BPs, which are unstable in such conditions (McLeod *et al.*, 1977).

- **Damage Threshold:** This determines the need for application of the BP and the target damage reduction once the BP has been applied. The costs of the operation need to be considered at this stage.

Characteristics of the Biopesticide

Production and field performance of a BP will help to determine both the efficacy and the costs of application relative to other pest management practices. It is particularly important to consider these variables for comparing the true performance of BPs. Of particular importance are the following aspects:

- **Mass production:** Can the BP be produced at a reasonable cost and to an acceptable standard? Quality Assurance for all stages of the production process is important.
- **Formulation:** Does the BP require formulation?

These aspects are linked to the BPs **viability and persistence** which determine whether the BP remains viable in the right place at the right time to encounter the pest, its **speed of kill** which is linked to the damage threshold, and its **capacity of reproduction/replication** which may contribute to longer-term impacts against the pest.

Spray Technology for Microbial Biopesticides

The use of microbial BPs requires that the technology of spray application receives careful consideration in designing an effective pest management strategy. Indeed, this is one of the areas where most wastage of BPs takes place, both increasing costs and reducing the efficacy of the applied agent. Particular attention should be paid to understanding the characteristics of the spray system, including the volume delivered and, especially, the droplet spectrum in relation to the delivery of droplets (Figure 3).

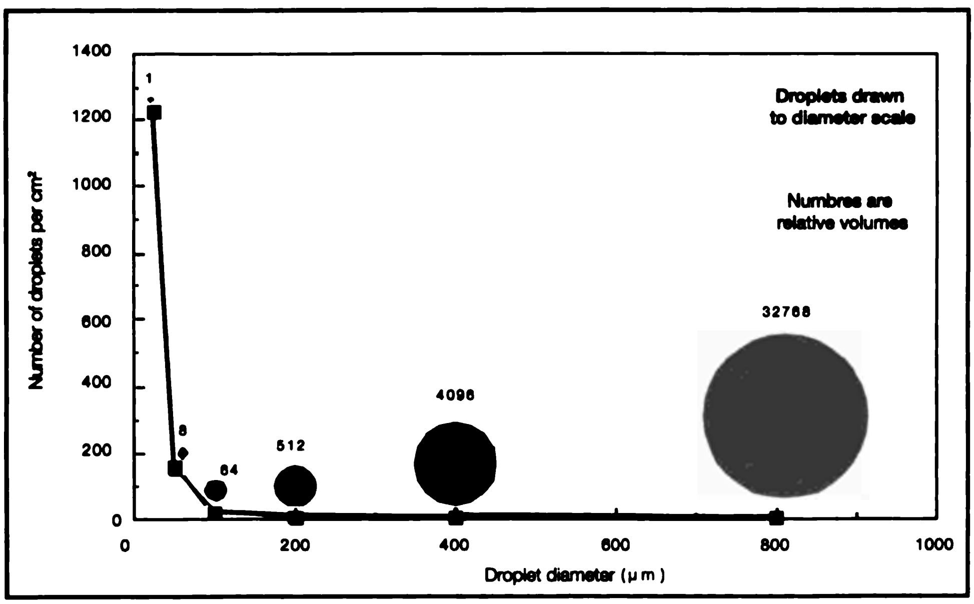

Figure 3. The relationships between droplet diameter, droplet volume and the number of droplets per cm² illustrate the importance of the right droplet size for the spray application of biopesticides. The parameters correspond to the application of 1 litre of spray fluid per ha.

Since the relationship between droplet diameter (the usual characteristic quoted for spray machinery) and droplet volume is cubic, a doubling in diameter actually results in an 8-fold increase in volume. If there is a wide droplet spectrum and many of the droplets are in the larger diameter categories, much of the spray cloud could be delivered to the ground rather than to the foliage. Such variation must be accounted for in determining the best machinery and volume application rates for microbial BPs.

Environmental Factors

All types of biopesticides are subject to environmental factors in relation to their modes of actions, speed of kill, viability, etc. Macrobial BPs will respond to temperature, rainfall and UV light in relation to their activity and rate of reproduction, etc. Microbial BPs are even more sensitive to environmental influences, which can result in very heavy losses of activity in a short time. One of the most important factors is UV light because of its potential effects on proteins and the DNA of microbial BPs. Decreases in viability of >50% in a few hours are quite typical for microbial agents exposed to sunlight in the field. Therefore, formulations to reduce such losses can be important for the effective use of microbial BPs. This is discussed in detail by Burges (1998).

Bringing together the *Control Window* parameters

Evans (1999) provides a detailed discussion of the *Control Window* concept and an example of applying the concept for designing a control program using baculoviruses. This approach has been used for the management of the teak defoliator moth *Hyblaea puera* (Lepidoptera: Hyblaeidae) in India during a joint project between Forest Research, UK, and the Kerala Forest Research Institute of India (Sudheendrakumar *et al.*, 2001). Some of the parameters that were developed within the *Control Window* are shown in Table 1, based on a simple spreadsheet model that allowed the research team to test other variables, such as changes in volume, droplet size and target larval stage.

Table 1. Example data and calculation of required dosage and volume application rates for a baculovirus product based on the principles of the *Control Window* approach.

Parameters	Parameter description	Set or calculated value
CE	Capture efficiency = (area)*(LAI*(1/(s*fr))	2.47E+09
N	Number of droplets per litre:	1.53E+10
Di	Initial dose (PIB[a]/mm^2) = LD_{90}/a	333
V	Theoretical Volume = CE/N litres per ha	0.16
Dl	Dose per litre	5.09E+12
Dha	Dose per ha	8.23E+11
area	Area of ha in mm^2	1.00E+10
Calculate CE	Calculation of CE	
fr	Feeding rate of larvae (mm^2)	18
LAI	Leaf Area Index (ratio to ground area)	4
s	Loss of spray fluid to ground area (1/propn.)	0.9
a	Virus attrition rate (propn. of original)	0.9
LD_{90}	LD_{90} for target larval stage	300
	Spray application rate	
	At normal walking rate of 0.5 m per sec.	
	Volume delivery per ha (litres)	8.67
	Dose per litre for above delivery	9.50E+10

[a] PIB = Polyhedral Inclusion Body

As a general principle, the target mortality is usually set to as high a level as possible within the constraints of time and money. However, because the *Control Window* approach is a knowledge-based system, it is possible to carry out a what-if analysis to test a range of assumptions and their consequences. For example, detailed knowledge of the slopes of the dosage-mortality relationships for microbial BPs can help to determine the realistic mortality level that can be expected in the field. Figure 4 provides an example for BPs with different mortalities as a function of dosage but which are all constrained to pass through the 90% mortality level.

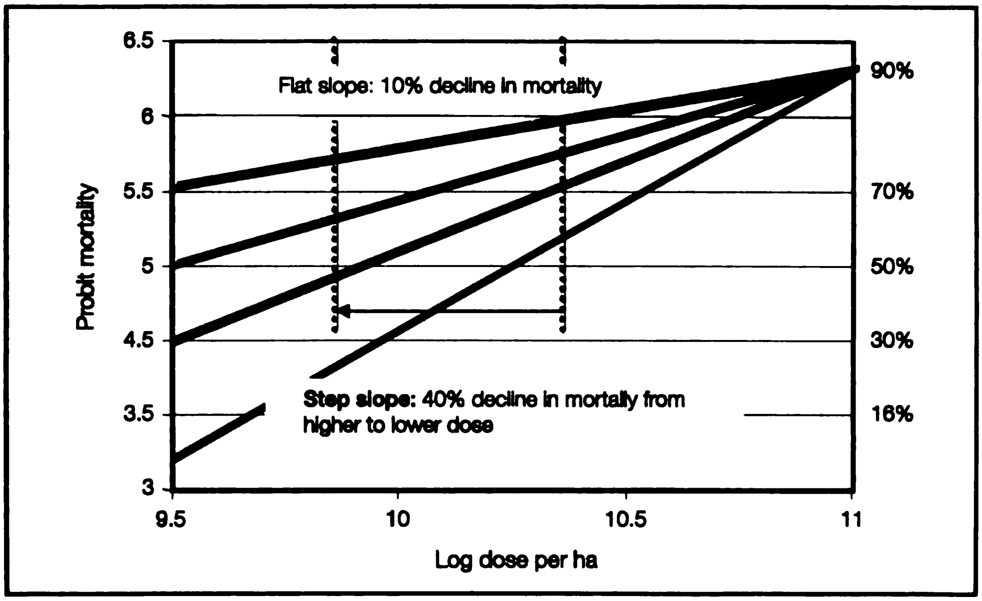

Figure 4. The effects of different slopes of the dosage-mortality relationship on expected mortality in the pest population.

If the costs of reaching 90% mortality are regarded as too high, the relationships in Figure 4 can be usded to examine the consequences of reducing the dosage. While a reduced dose of a BP characterized by a steep slope will result in a sharp drop in mortality, a BP characterized by a shallow slope will suffer a relatively smaller reduction of mortality. For the latter case it would be easier to reduce the dosage of the BP without an excessive reduction of effectivity. An additional factor that can be included is the contribution of secondary inoculum, which may be produced in or on the bodies of infected pests by the applied microbial BP. This would be the case for baculoviruses, fungi and protozoa and, to a lesser extent, some of the *Bt* preparations.

Conclusions

Much can be done to optimize the production and use of BPs. The *Control Window* concept is one approach to achieving increases in efficacy, whilst reducing costs and wastage of BPs. Investment in knowledge on pest biology and its interaction with the crop and with biopesticides will be more than compensated for by improvements in efficiency, thus demonstrating the costs and benefits of a quantitative ecological approach to pest management. This is fundamental to Integrated Pest Management and Integrated Crop Management where BPs are increasingly playing a fundamental role. Provided that care is taken to maintain disease-free insect stocks, the costs of carrying out bioassays to determine dosage-mortality relationships are the main ones required to gather the data. Usually this requires technician time for a three-week period, which includes daily examination of the test insects and analysis of the observed mortality data for trends. Field tests of attrition rates and deposits of droplets can be achieved by replicated assays, each requiring 10-20 days total duration but only relatively small daily staff inputs. The precise costs will, therefore, depend mainly on staff costs.

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Biopesticides: Perspective from the Pesticide Action Network-Germany

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The Pesticide Action Network (PAN) is an international coalition of around 600 non-governmental organisations, citizens' groups and individuals in about 60 countries. PAN advocates the adoption of ecologically sound practices in place of pesticide use.

In developing countries, more than 50% of the working population is working in the agricultural sector. Agriculture is one of the world's most hazardous industries, where pesticides account for 14% of occupational injuries and 10% of all known fatalities. Although only about 20% of the pesticides used globally are applied in developing countries, these countries suffer around 70% of all pesticide poisonings (Forastieri, 1999). It is estimated that 99% of all fatal poisonings take place in developing countries (EJF, 2003). Up to now, the long-term side effects of pesticides on human health, including cancer, damage to the immune system, birth defects and hormonal disruption, cannot be predicted with high accuracy. Beyond the human dimension, pesticides also have adverse effects on local food sources such as fish and cattle, on wildlife, beneficial insects and biodiversity.

In order to reduce or even prevent these effects, PAN is strongly interested in all approaches that allow to reduce the use of toxic pesticides. Among the options, the use of biopesticides holds a potential that should be considered.

This paper has two parts. The first part consists of seven statements regarding biopesticides and non-chemical pest management in general. The second part summarizes the current PAN activities that contribute to the wider use of biopesticides and biological control options.

Seven statements on biopesticides and non-chemical pest management

1) Biopesticides are still caught in a 'comparison trap'

Chemical pesticides cause poisonings of agricultural workers and lead to environmental damage. Some of them are very persistent and therefore exist even in regions where they have never been applied. As a result, it is likely that one can find pesticide residues or metabolites practically in every human body. By contrast, biopesticides show a less negative profile regarding their toxicology and persistence.

Often mentioned "advantages" of synthetic pesticides are that they are apparently more affordable, that they are stable over a relatively long period of time, that they are immediately effective and that they can be applied in different agroecosystems with the same application technologies. In contrast, biopesticides often break down very easily, act slowly and often are highly specific.

However, the advantages of biopesticides should not be expressed only by mentioning the disadvantages of chemical pesticides. It must be emphasized that the advantages of biopesticides can only be fully realized if they are applied as part of a different agricultural production system. Otherwise they will not be allowed to perform to their full potential. This fact should be further elaborated and publicly communicated.

2) The advantages of biopesticides must be made more visible

The demand for biopesticides is strongly fuelled by problems emerging from the use of toxic chemical pesticides (poisonings, residues in food and water, negative effects on biodiversity, etc.). However, from a non-farmer perspective, for example by most consumers, it is not distinguishable whether a farmer is using a biopesticide or a toxic chemical pesticide. Also, the outside observer cannot easily see whether a farmer, by using biopesticides, is contributing to reducing the negative effects of conventional plant protection with synthetic agrochemicals. Furthermore, it is often not easy or even possible to recognise whether toxic chemical pesticides are being substituted by less toxic ones. This means that, although biopesticides are regarded to be safer alternatives to synthetic chemical pesticides, it is typically not visible, WHERE and to what extent they contribute to a less dangerous form of plant protection. In the future, their contribution to reducing the risks of chemical plant protection must be made far more visible.

This is especially important because consumers have been one of the most important driving forces to request new strategies of crop protection and the phasing out of dangerous pesticides. If the benefits from integrated farming systems, biological control and the use of biopesticides are more visible, consumers could be even more effective in pushing for less toxic pest management strategies.

3) Those using biopesticides need to change their communication strategies

If the use of biopesticides as an alternative to dangerous chemicals shall grow, there is an urgent need for new plant protection strategies on the farm and also for new distribution and consumption patterns of agricultural goods produced with biopesticides. Efforts undertaken to change production systems towards sustainability will only be recognised by consumers and other beneficiaries of a change from toxic to less toxic systems of plant protection, if the changes are made visible and are communicated to the outside world of the agricultural production system. Therefore agricultural producers who are willing to change their production system should, at the same time, change their communication system.

4) The sale and promotion of biopesticides should be accompanied by information and training programs

Since the 1960s, plant protection increasingly became dependant of synthetic chemical products with immediate effect. The labels of these products provide key information regarding the crops to be treated, target pests, product preparation and application and safety recommendations.

Compared to synthetic chemicals, biopesticides should be accompanied by additional information, particularly regarding required changes of the production systems and objectives. The promotion and distribution of biopesticides should support farmers also with methodological and technical information to help them analyze and improve their production systems and to strengthen the exchange of information among farmers. Ideally, the distribution of biopesticides should also be accompanied by training programs on essential topics, including the ecology of pests, diseases and their antagonists, and the design of pest-suppressive agroecosystems. Improved farmers' knowledge, sovereignty, and self-confidence are the indispensable basis for the effective use of biopesticides for sustainable pest management systems.

5) Biopesticides should be disseminated using different strategies

Biopesticides can be used in different agricultural production systems including traditional low-input, organic production, integrated pest management systems, and systems which depend on high inputs of agrochemicals. The promotion of biopesticides for these different production systems requires different strategies for the distribution and application. The least toxic products, together with information on how to avoid the use of dangerous pesticides, should be provided cheap or free of charge to farmers who are suffering from hunger and do not even have the basic means to meet international standards for the use of dangerous pesticides. Since the costs of unwanted side effects from the use of dangerous pesticides by untrained users have to be assumed by society at large, it would be reasonable for society to invest in avoiding these side effects and the resulting follow-up-costs. The target group for the information and the beneficiaries for receiving cheap or free biopesticides could be identified via existing training and extension services.

6) The use of pesticides under conditions of poverty needs to be addressed - poor people can't buy - neither products nor consultants!

To underline the previous statement I would like to stress, that those living under conditions of poverty suffer the most of poisonings caused by chemical pesticides. This can be derived from the already stated fact, that although only about 20% of the pesticides used globally are applied in developing countries, these countries suffer around 70% of all pesticide poisonings (Forastieri, 1999). Therefore there is a public obligation to disseminate information on strategies how to avoid the use of toxic pesticides especially by the most affected groups of farmers. One way towards this goal may be the PAN Germany "Online Information Service for non-chemical pest management in the tropics" (http://www.oisat.org) presented below.

7) The term biopesticide should not be used to include genetically modified organisms

Globally there is a growing understanding that products labelled with the prefix "BIO" are not produced by using synthetic chemicals or by using gene technology. Many consumers buy *ecologically, biologically* or *organically* produced food on the assumption, that these products are neither derived from genetically modified organisms nor grown with any use of gene technology. However, the US Environmental Protection Agency (EPA) includes "Plant-Incorporated Protectants (PIPs)", which are genes with pesticidal properties that have been incorporated into plants via genetic engineering, in the category of biopesticides. This inclusion of PIPs under the term "biopesticides" might create a strong confusion among consumers and could, in the long term, harm those farmers and retailers who sell organic food. Therefore it is highly recommended not to use the term biopesticide for practices or inputs that involve genetic engineering.

Contributions of PAN Germany to promote biopesticides

PAN Germany is part of the international Pesticide Action Network which advocates the adoption of ecologically sound practices instead of the use of toxic pesticides. The work of PAN Germany can be divided into five areas:

- strengthening the expertise of non-profit non-governmental organisations,
- awareness raising of all those persons that deal with and/or are potentially affected by the use of dangerous pesticides,
- dissemination of information,
- lobbying for improved pesticide regulations,
- campaigning for sustainable agricultural production systems and consumption patterns of agricultural goods.

In recent years, PAN Germany has been increasingly asked to provide information on non-chemical pest control measures. However, our dilemma has been, that a large part of useful information on natural crop protection is either not shared with others, is written in scientific language or presented in complex databases or is restricted to costly books or limited-access materials. Therefore PAN Germany thought of ways to gather and spread information to all those who are in need but do not have access to this information. One path towards this goal is to develop an easy to read and use "Online Information Service for non-chemical pest control in the tropics and subtropics (OISAT)".

The overall objective of OISAT is to provide practical and relevant information on non-chemical crop protection methods to poor smallholder farmers in developing countries in the tropics. The information is presented in a format and language that is easy to understand and put to practice. It aims to improve smallholder farmers' access to the holistic view of natural pest control practices. Features of OISAT are information on field crops grown by smallholder farmers, general information on pests (information on diseases will be added in the near future), preventive and curative measures (cultural practices, trap & companion crops, plant/pest monitoring, physical control, etc.), a print tool, and links to external sources, as well as a tool for feedback to allow to incorporate the experiences of OISAT users.

The OISAT project was started in January 2003 by PAN Germany in close cooperation with GTZ/gate and with financial support from gate as well as from Misereor and EED, two development agencies of the Catholic and Lutheran Church in Germany. The first phase of this project ended in June 2004 and since 1 July 2004 OISAT is online under www.oisat.org. The second phase of the project started in July 2004 and will end in December 2005 aiming at developing a network of key partners who support the distribution of the information in the online service as well as further developing and verifying the online information. Within this second phase pilot projects are carried out to field test the integration of information from the OISAT homepage (OISAT Info) into existing training and extension services (OISAT PartnerNetwork).

The goal of the first phase of the project was to provide information on production and protection measures for 20 crops and their most frequent 50 pests in the internet. The printing tool of the website allows to print the desired information in the form of a booklet. For more information on OISAT please refer to the paper by Stoll in this volume and to www.oisat.org.

The principle challenge of this project is not only to get accurate and applicable information into the web, but rather to get the information from the web into the field. Consequently, we would like to invite collaborators to improve and complement the information and recommendations on the web and to help establish OISAT as an effective network to disseminate information on non-chemical pest control to farmers in the tropics.

Conclusions

Biopesticides need to be developed and used with care, and within a holistic, preventive approach which is farmer-centred, transparent and publicly communicated. A farmer-driven "extension service" is strongly needed and companies selling biopesticides should contribute to an improved extension service for least toxic pest management systems. For poor farmers unable to pay for the information services and biopesticides, training should be provided free of charge via chemical safety programs like e.g. the Stockholm Convention and the Rotterdam Convention as well as national governments.

Consumers have been one of the most important driving forces for phasing out dangerous chemical pesticides. They should be supported to become allies for phasing in natural crop protection techniques. In order to allow this, consumers have to be well informed not only about the dangers of synthetic pesticides, but also about the advantages of biopesticides. In other words, the potential of biopesticides must be made much more visible. Towards this goal, PAN Germany is currently developing an interactive Online Information Service for non-chemical pest management in the tropics (OISAT) in close co-operation with GTZ/gate and with support of Misereor and EED and partner organizations in Africa and Asia.

In order to enrich this information system, we invite contributions about experiences regarding more sustainable plant production and protection systems.

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Microbial and Botanical Biopesticides: Perspective from the Public Sector, Opportunities and Limitations

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Abstract
The Biopesticides and Pollution Prevention Division (BPPD) was created in 1994 as a separate division within the Environmental Protection Agency (EPA) of the USA to bring safer pesticide products into agriculture and to enhance the use of these reduced risk products. BPPD regulates and registers biological pesticides, which include biochemicals, microbials, and plant-incorporated protectants (PIPs). Biopesticides are typically distinguishable from conventional chemical pesticides by their unique modes of action, low use volumes, target specificity, and reduced toxicity. Many of these biologicals are naturally occurring and others are genetically or chemically modified prior to application. Many of the data requirements and the scientific review process are similar for microbial and biochemical agents. PIPs are a separate issue with some unique requirements in addition to some overlap with the microbial guideline tests; these will be covered only as they influence market share for other biological pesticides. With the strong growth of the organic sector for agricultural production, a steady increase in the sales of biological pesticides has been seen over the last several years. While biologicals still represent only 1 % of the total money spent on pesticides in the U.S., overall the market is large and growing. Expectations are that continued expansion of the organic sector will correlate with enhanced and new markets for biologicals targeting pest control and growth enhancement.

Public Sector Perspective on Biopesticides in the U.S.

In 1996, the Food Quality Protection Act (FQPA) was passed in the United States and this served to modify the application of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as well as the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA is the law or statute, which governs the regulation and registration of all pesticides in the United States, its territories and possessions. FFDCA, in part, provides authority for the U.S. Environmental Protection Agency (EPA) to set tolerances or limits on the amounts of pesticidal residues allowed on food and feed products entering the marketplace.

The U.S. Food and Drug Administration (FDA) oversees the enforcement of this provision of the statute. FQPA has had many effects, but primarily it served to require the EPA to re-examine all previously registered pesticide products (> 9000) for any possible adverse effects on humans with special emphasis on infants, children and the elderly. Clear timelines were established within FQPA to require the EPA to complete these re-registrations and food tolerance reviews, or make moves to restrict or cancel products that were seen as potentially harmful with respect to the criteria established by the Act. One net result of this enactment was that some of the more toxic chemical pesticides were banned from the market, were further restricted in their use or will be banned or restricted in the near future.

A necessary, but unfortunate result of this Act was the need for significant resources for re-registration review of all pesticides, which will to some degree remove resources from registration of newer, less toxic pesticides, delaying their appearance on the market in some cases.

At about the same time as the implementation of FQPA, the biopesticide registration process was undergoing some revision to hasten the entry of biochemical and microbial pesticides into the marketplace. As this process continues to evolve, great strides have been made to move these biologicals through the regulatory process in less time and at lower costs than required for their conventional counterparts.

Biopesticides are generally much less expensive (US-$ 0.5 to US-$ 3 million) to develop and register as compared to conventional chemical pesticides (often US-$ 100 to US-$ 185 million). With ongoing review of the toxicity and safety of all pesticides by the EPA, some older conventional pesticides are losing use sites or registration. The cost of developing newer chemicals, which will take their place, is prohibitively expensive in some cases. New chemicals tend to be targeted at the major crops only, such as maize, wheat and soybean, where markets are inherently large.

While the economy of the United States and many other countries is slowly recovering, the biopesticide industry in the U.S. has seen approximately a 20 to 25% increase in sales per year recently. This is largely due to the growth of the organic food market and the need for producers to follow the pesticides approved by the U.S. Department of Agriculture's National Organic Program (NOP) or by other organizations, which influence the standards for the industry (*e.g.*, Organic Material Review Institute, OMRI; Organic Trade Association, OTA). EPA is working to establish an emblem or logo that may be attached to certain biopesticides that meet the criteria for use in organic production; this includes the inert ingredients as well. Currently there is more than one organization determining the criteria for foods labeled as organic, and this may lead to some confusion as not all practices or pesticides meet all the criteria of every governing body. This will likely resolve itself as time elapses and as producers and consumers become more familiar with the NOP.

Another body that promotes the expansion of the biopesticide industry is the Biopesticide Industry Alliance (BPIA), an organization made up of more than 30 companies which help to maintain the quality of products and ensure that all of its member companies abide by the federal and state regulations governing pesticide use. This organization not only promotes the use of biopesticides, but also ensures that accurate information is disseminated. Despite the many successes of biological control, many farmers and managers still maintain that these biopesticides are not workable or cannot achieve the level of control needed for adequate production. In cases where products have bypassed the registration procedures, some products may not meet high standards of quality control to ensure product consistency or efficacy. The distributors of such products, so-called snake-oil salesmen, are doing a disservice to the industry by promoting products without adequate testing, assessment and proper registration.

Programs such as IR-4 (Inter-regional Research Project #4), a cooperative arrangement between the Federal Government (USDA), the land grant university system, the crop protection industry, the EPA, minor crop growers, and their commodity group organizations, has made great strides in promoting biopesticides as part of integrated pest management practices. IR-4, headquartered at Rutgers University in New Jersey, with satellite locations at other universities and government research facilities, has increased the budget for biopesticide research and registration assistance and has allowed for focus also on minor crops, which, otherwise, may not have received financial support.

There are over 600 crops classified as minor crops in the United States. Their delineation as 'minor' is based on their limited production acreage. Minor crops have a major economic impact with a net value of almost US$40 billion, and include various fruits, vegetables, nuts, berries, herbs, nursery plants, and ornamentals. In total they represent 40% of all crop value in the United States. Approximately 20 states obtain more than 50% of their total agricultural income from minor crops. The EPA has worked closely with IR-4 representatives to establish good communication and understanding of the biopesticide registration process, so that IR-4 sponsored registration submissions are complete and contain all the elements needed for the review of the products' risk and benefit potential.

Since the 1970's, IR-4 has supported the registration of many microbial and biochemical pesticides used today by organic growers and other producers. A formal IR-4 Biopesticide program was initiated in 1982 and continues to this date. The program was expanded in 1994 to provide competitive grant funding to land grant university and government researchers to support studies on early development stage biopesticides for minor crop uses. In many cases, a company may apply for financial assistance with registration fees and other regulatory costs. Funding has also been provided to develop efficacy and performance data on biopesticides currently being commercialized to speed up the availability of these newer technologies to minor crop agriculture.

As mentioned above, FQPA has imposed additional health based standards for all pesticides applied to food or feed crops. The net impact of the FQPA on the availability of pest management options for minor crop growers is unclear, but it is anticipated that they will be affected to a greater extent than those who predominantly grow major crops.

Pesticide producers are more likely to invest research funding into chemical or biological pesticides, which are intended for use on large acreage crops for purely business reasons. Hence, many of the newer products may not be labeled for use on minor crops nor will their efficacy be evaluated in these types of situations. Voluntary cancellations and restrictions on use sites (*i.e.*, crops, greenhouses and other places where pesticides may be applied) for some conventional pesticides by the EPA will undoubtedly impact minor crops as chemical pesticides often reap greater profits on large acreage row crops. Some of these restrictions on sales of pesticides will negatively impact the minor crop producers, as they will have fewer alternatives to turn to for pest management. One possible outcome though, may be the need for growers to investigate more biological pesticides that may have previously been seen as unattractive or economically unfeasible.

Should production difficulties be exacerbated by the loss of available pesticides, then it is likely that the prices for these crops would rise as a consequence. This, in turn, may provide an opening for farm managers to evaluate biopesticides in their integrated pest management programs.

One unfortunate note in the history of biopesticides reflects the difficulty in persuading people to change practices. During field visits to farm managers and producers I have heard the same litany many times: "I tried biological control once and it did not work." The fallacy in this statement is obvious to anyone in agriculture; however, this way of thinking still pervades many who make decisions for pest control options. Choosing the wrong pesticide, biological or conventional, for the job will always result in disappointment. Additionally, in cases where quality control of a product was not up to industry standards, this initial evaluation of all biopesticides based upon the action or lack of it in one product is truly unfortunate. This tends to be a greater problem with biologicals sold illegally (*i.e.*, without evaluation, review and registration by the EPA). Hence, education of potential purchasers of biopesticides is critical to remove or alter the chemical paradigm that is so entrenched in the minds of growers and farm managers or consultants.

In addition to the federally funded IR-4 program, all states have extension service programs usually administered through their land grant institutions (*i.e.*, agricultural colleges and universities). Extension personnel from the state university and county level often provide information to growers individually or as group forums. These lines of communication are critical in reversing some of the perceived notions about biopesticides and introducing novel technologies for pest control and quality enhancement. Many extension agents maintain research evaluation plots of pesticides and use these as showcases on 'field days' to introduce farmers to different approaches to insect or disease control.

The EPA organized a group of regulatory scientists several years ago to promote the adoption of integrated pest management at home, in schools and in agriculture. This 'Partners in Environmental Stewardship Program' (PESP), now incorporated into the Environmental Services Branch of the Biopesticides and Pollution Prevention Division, serves as an outreach service for the Agency to educate people of all ages in the use and benefits of reduced-risk pesticides, including biopesticides. Grants are available to foster research and field evaluation of promising pesticides including biochemicals and microbials. Approximately US-$ 800,000 per year is granted through PESP with an average grant size of US-$ 40,000, although there is some variance year to year. The new "Biopesticide Demonstration Grant" program is useful in highlighting effective biopesticides used in combination with each other and/or conventional pesticides to reduce the use of more toxic alternatives. Other granting programs and opportunities exist within this program as well. Many enterprises, including school systems, corporations, manufacturers, railroads, pesticide producers and users have joined the PESP team as members by agreeing to follow a set of guidelines when making pesticide decisions that may affect the environment.

Limitations of the Registration Process: Regulatory Burden

It is legally mandated that all pesticides sold in commerce in the United States either be registered by the U.S. EPA, be exempted from FIFRA oversight, or otherwise listed for state-only use by a state licensing institution (*i.e.*, FIFRA 24C products). Some products with pesticidal properties and intent are exempted from FIFRA oversight at the discretion of the Agency Administrator. For example, those products which are being adequately regulated by another federal agency may be exempted. Others which are considered as having no potential adverse environmental effects, such as some biological control plants, are specifically exempted. A defined registration process for all types of pesticides is available through the EPA websites and will not be discussed here in detail.

While it is considerably less expensive to register a biological pesticide compared to a conventional chemical pesticide, the product characterization and toxicity studies required may prove to be onerous to small companies trying to gain approval for an agent targeting a niche market. This presents a dilemma to the industry and agriculture as a whole: when a naturally occurring biochemical or microbial pesticide is registered and allowed for sale, it may provide a means of reducing the use of more toxic, persistent pesticides. However, without the proper testing to provide for a full risk assessment (and the associated costs), these pesticides, no matter how 'natural', cannot be approved. Unfortunately, many small enterprises cannot cover the startup costs required to see the product through to submission and final registration.

In the long-term view of biopesticide use and industry growth, it is in the best interest of all, including users of products, to mandate that all active ingredients and formulations undergo a similar scrutiny prior to receiving approval. Quality control during manufacturing is one of the key parameters reviewed by the EPA for experimental use permits or full registration. A screening protocol for chemical and microbial contaminants is critical to this process. In instances where a microbe is known to produce a toxin, levels may need to be monitored during fermentation and at packaging to ensure it is within acceptable levels. This testing analysis is usually presented to the EPA as a five-batch analysis, which details the constituents and their amounts in all five lots. This information may be provided conditionally after initial registration to allow the company enough time to formulate that quantity of product.

While the argument has been made that many of these compounds or microbial species are already present in the environment (therefore we should not be concerned about them), application of concentrated amounts of any substance to a food or feed crop is not the same as natural distribution of the same agent. Fortunately, the majority of microbial species we deal with as potential biopesticides have known biological histories from the literature and can be partially evaluated on that basis. Familiarity with the species in question may allow for data bridging from a previous registration review and reduce the total data set required for any one company. It is important to note, however, that EPA registers strains of microbes, not species as such. As part of the manufacturing process, an analytical method to differentiate the strain to be registered from other strains typical of the species is required. As the database of microbial species with full risk assessments grows, it is hoped that the regulatory process may be streamlined to decrease the overall regulatory burden on registrants.

One aspect of FIFRA, which separates it from many other regulatory statutes, is that it provides a means for the EPA to re-evaluate and require further testing after registration if the current science indicates that this is prudent. For example, the bacterium *Burkholderia* (*Pseudomonas*) *cepacia* (now *cenocepacia*) was registered for use as a seed treatment to control fungal diseases of several crops. Researchers also indicated that some strains had great potential as nematicides, a group of chemicals which are typically quite toxic to mammals. Others had even touted the organism as a useful drain cleaner and included it in other, mostly unregulated, products as well. Over the past decade it became apparent that this species (actually a conglomeration of several species or genospecies) was implicated in the decline of patients suffering from Cystic Fibrosis (CF) or Chronic Granulomatous disease. While it is not possible to determine with absolute certainty the probability that agricultural use of this agent will affect the population of CF patients, a science review panel determined that the potential hazard was too high to warrant continuing use of these products in any form. This past year, the manufacturers halted all uses voluntarily after EPA requested significantly more data to examine field dissemination of this bacterium. This move toward cancellation of the product was ultimately a positive one for users of the product and consumers as a whole; however, the companies involved lost significant research and development input into this line of work. While this is not something easily predicted *a priori*, it is a possible outcome with any new agent, including synthetic chemicals and active microbial or biochemical ingredients, and can influence the survival of a company and even the trust in biopesticides.

Influence of Plant-incorporated Protectants on the Biopesticide Market

The rapid rise and adoption of pesticidal traits expressed in plants, such as *B.t.*-cotton or *B.t.*-maize has been incredible. The majority of cotton in the United States now contains one or more genes from *B.t.* and approximately 35% of the maize acreage similarly contains a delta-endotoxin gene from *B.t.* While only a small percent of the acreage of these crops were ever treated with microbial formulations of *B.t.*, they did represent a sizeable portion of the microbial pest control market, which is estimated at US-$ 160 million per year. There are currently four registered PIPs expressing *B.t.* delta-endotoxins in maize, with stacked products (*e.g.*, two or more pesticidal genes targeting different pest groups) forthcoming. The story in cotton is similar with two different delta-endotoxin genes currently expressed in separate varieties with stacked products awaiting regulatory approval. Some industry estimates suggest that over US-$ 40 million of the former microbial market has been lost to PIP sales.

Given the popularity of these PIP products and their efficacy in controlling their respective target pest groups, it seems unlikely that microbial *B.t.* formulations will ever compete in that market effectively with the exception of organically cultured cotton or maize. A potato variety expressing the Cry3Bb protein for control of the Colorado Potato Beetle and other coleopteran insects is registered, although not currently grown in the U.S. It is not certain what other types of PIPs will be submitted to the EPA for approval in the next five years, but it is clear that they will continue to flourish at the expense of some biopesticides.

Conclusions

Biopesticides cost much less to develop and register when compared to conventional chemical pesticides due in part to the larger number and complexity of tests required to ensure efficacy and safety of chemicals under a variety of field conditions. Smaller or minor crop markets still offer the best potential for biopesticide market growth as larger chemical companies rarely invest the required large financial outlay to target a pesticide product to a smaller acreage crop. In addition, many of these so-called minor crops represent sizeable acreage and represent a valuable market to the organic sector. The Partners in Environmental Stewardship Program at EPA was founded to aid in dissemination of relevant information on biological control and integrated pest management. As part of the Biopesticides Division at EPA, these scientists, and those of the Microbial Pesticides Branch and Biochemicals Pesticide Branch, are charged with reviewing biopesticide applications for human and environmental effects, registering biopesticides for appropriate uses, and disseminating information on the benefits of biologically derived pest control products. Expectations are that continued expansion of the organic sector will lead to enhanced and new markets for biologicals targeting pest control and growth enhancement. The expanding acreage with crops containing plant-incorporated protectants, such as *B.t.*-maize and B.t.-cotton, has significantly reduced the market for some biopesticides. However, despite this, growth for microbial and biochemical pesticides is positive overall.

Relevant websites

- http://www.epa.gov/oppbppd1/biopesticides/ Contains the listing of all registered biopesticides along with fact sheets that detail the biology of the active ingredients registered.
- http://ir4.rutgers.edu/docs/BioRev2000.htm List historical perspective of this project, list of biopesticides and those being evaluated in testing, as well as related information on programs under the IR-4 umbrella.
- http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=474f779beade290997e4611971d078f4&c=ecfr&tpl=/ecfrbrowse/Title40/40cfrv21_02.tpl A reproduction of the contents of 40 CFR, the Code of Federal Regulations, which governs environmental protection and specifically pesticide use.

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Biopesticides: Private Sector Considerations on Industry Standards and Product Quality

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Abstract
The current demand for biological control products has risen in large part because of problems that developed from the use of chemical pesticides. These problems include pest resistance, pest resurgence, environmental pollution, and risks to human health. In order to supply the market with high-quality alternatives such as biopesticides, it is necessary that manufacturers implement a quality management system based on ISO standards and good manufacturing practices (GMP). This paper summarizes essential salient aspects for the development of biopesticides and for quality management by the private sector. Given effective collaboration between the public and private sector and increasing environmental awareness of producers and consumers, the spectrum of biopesticides and the options of using them effectively will likely continue to increase in the future.

Industry Standards for Production: ISO 9000 and Good Manufacturing Practices

The **ISO 9000** family of international quality management standards and guidelines has earned a global reputation as the basis for establishing quality management systems. ISO 9001:2000 specifies requirements for a quality management system for organizations that want to demonstrate their ability to consistently provide products that meet customer and applicable regulatory requirements. For example, the Colombian biopesticide manufacturer Laverlam is ISO-certified based on compliance with the following principles:

1. **Customer focus:** organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements, and strive to exceed customer expectations.
2. **Leadership:** leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
3. **Involvement of people:** people at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
4. **Process approach:** desired results are achieved more efficiently when activities and related resources are managed as a process.
5. **System approach to management:** identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
6. **Continual improvement:** continual improvement of the organization's overall performance should be a permanent objective of the organization.

7. **Factual approach to decision making:** effective decisions are based on the analysis of data and information.
8. **Mutually beneficial supplier relationships:** an organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

The **ISO 9000** standards are of global applicability because they:

1. apply to all product categories and to all sizes of organizations,
2. are simple to use, use clear language, and are readily translatable and understandable,
3. are able to connect Quality Management Systems to organizational processes,
4. provide greater orientation towards continual improvement and customer satisfaction,
5. are compatible with other management systems, such as ISO 14000 Environmental Management System,
6. address the need to provide a consistent basis to address the concerns and interests of organizations in specific sectors.

The **"Good Manufacturing Practices"** (GMP) are technical procedures according to recognized standards to ensure that the products are consistently produced and meet specific requirements for identity, strength, quality, and purity, and that these products are appropriate to their intended use and product specification. Besides these international norms there are also national guidelines which need to be observed for specific national markets. For example, Laverlam applies the guidelines for producing biopesticides contained in the **Food and Drug Administration** (FDA) regulations 21 CFR Part 600 – Biological products and also follows the guidelines for the production of biopesticides in Colombia established by **the Colombian Institute for Technical Norms and Certifications (ICONTEC)**. Under these guidelines, the main requirements for product registration are field efficacy testing and toxicological analysis of the strains. Field efficacy tests are performed and supervised by the Colombian Agricultural Institute (ICA) after approving the test design and statistical analysis of data. For Laverlam's products, toxicological tests were carried out at the Center of Experimental Toxicology (CETEX) in Cuba following the EPA Protocol 152A-10, 11, 12, 13 Tier I studies to test the toxicity/pathogenicity of microbial control agents. After meeting all requirements of the tests on acute oral toxicity/pathogenicity, acute pulmonary toxicity/ pathogenicity, acute injection toxicity/ pathogenicity, acute dermal toxicity/pathogenicity, and on eye irritation, ICA issues the certificates for sale to the public.

Opportunities for Biopesticides

The current demand for biological control products has risen in large part because of problems that have developed from the use of chemical pesticides. These problems include pest resistance, pest resurgence, environmental pollution, and risks to human health. As a result, many countries around the world are moving towards limiting the amount of pesticide residues in foods. The Codex Alimentarius is a joint program by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to protect the health of consumers and to foment fair trade practices. It provides international food safety standards, including recommendations on maximum residue limits (MRL) for pesticides in food. Many national governments have adopted the Codex MRL recommendations as national standards. This is complemented by a growing interest of the food industry, including retail supermarkets, grower cooperatives and large food companies, to commercialize green products among environmentally and health-conscious consumers. Through certification systems for growers and "green" product schemes of retailers, these products are gaining market shares and demanding a premium. The growth of the fruit and vegetable export markets opens new opportunities for many Latin American countries to provide these types of products.

Examples of these new trends are the following: in February 1999, the authorities of Taiwan notified the U.S. Government that new pesticide residue tolerance regulations would be implemented for fruit and vegetable imports beginning June 1999. All fruit and vegetable imports would be subject to mandatory inspection for pesticide residues. Imports that did not comply with Taiwan's tolerance levels would be rejected. By June 1999, zero-residue tolerance was enforced for all pesticides that had no standards. Also European countries like Sweden, The Netherlands and Denmark legislated to reduce pesticide use by 50% by the year 2000. The UK also passed new regulations limiting the pesticide content of foods for infants and young children in 2002. EurepGAP, which will be in force in 2004, is a recent initiative of the private sector to force the reduction of pesticide residues in food and, as a result, to foster the development of new pest control options including biopesticides. Many companies in Latin America that produce fruits and vegetables for the European Community markets are making efforts to comply with EurepGap standards. These developments towards environmentally friendly crop protection are expected to improve markets for crops protected by biocontrol agents and, therefore, to widen demand for biopesticides.

Agrochemical manufacturers are only prepared to invest time and money in registering agrochemicals that have the potential for high-volume sales. Demands by national pesticide registration regulations for periodic reviews of active ingredients, combined with increasing development costs of pesticides, often make it unprofitable for agrochemical companies to register products for minor crop use or to maintain the larger number of formulations specific to different countries. The consequence is that minor crops frequently have no chemical options available for pest control that are tailored to their needs and low environmental impact. Therefore, alternatives such as biopesticides need to be found.

Constraints and Limitations for Biopesticides

The constraints for biopesticides include current technological limitations, inadequate information, and misconceptions. The principal constraints include:

- **Origen of strains:** One of the most harmful perceptions claims that native strains are more pathogenic and that fungi should be best isolated from the target pest itself. This is not always the case. For example, Laverlam has strains that have been isolated from *Coleoptera* that are highly pathogenic to *Lepidoptera* and vice versa. Another example is the strain used to control the Coffee Bean Borer in Colombia recommended by Cenicafe which was originally isolated from *Diatrea saccharalis*, a *Lepidoptera.*

- **Germination requirements and protection of conidia:** it is widely thought that the effectivity of fungi is strongly restricted by the conidia's requirements of high relative humidity and special environmental conditions to germinate. However, with new formulation technologies and the use of new stickers and spreaders, conidia can be protected and their pathogenic effect increased.

- **Assessment of effectivity:** Often, it is expected that insects controlled by entomopathogenic fungi should be covered with mycelia. Consequently, in the absence of obvious mycelia, the action of the product is often questioned even though the target pest may have been effectively controlled by these fungi. Undoubtedly, unbiased protocols to evaluate the effectivity of biopesticides will help improve this situation.

- **Incompatibility with fungicides.** There is a general perception that fungal biopesticides are incompatible with many chemical pesticides. However, compatibility studies have shown that they can be used with some pesticides in the market. According to work at Laverlam, selected biologicals can be effective even in crops that use high amounts of fungicides.

- **Inadequate quality:** An instructive experience for the development of biologicals in Colombia was CENICAFE's action during the eradication programs of the coffee bean borer in Colombia. A pathogenic strain was selected by CENICAFE and given to several companies interested in producing them (Laverlam, Agrevo and Biocontrol). But, due to the apparent "high cost" of the product, these companies decided to train farmers on how to grow the fungus using basic equipment on the farms. Unfortunately, this program failed and most farmers reverted to using the synthetic insecticide Thiodan as a control method. Also in other cases, successful programs have ended, either because the farmers decided to produce their own biopesticides, or because a non-certified producer with doubtful quality offers a cheaper alternative. In the end, the cause of the failure is often attributed to the fungi rather than to the product itself. Clearly, there is a need for a strict monitoring of the product quality during production and of the application procedures.

- **Availability of products.** Many producers are concerned about insufficient quantities available to have a continuous application program. In larger production systems, often only a portion of the land can be treated which limits the potential of the effectivity of the biopesticides.

- **Restricted shelf life and storage requirements.** Currently, the distribution of biopesticides is based on a chemical pesticide model that emphasizes on major crops and focuses on cheap, stable products. Biopesticides rarely fit this model despite their important advantages for human safety and environmental friendliness. Most current formulations have a shelf life of about a year when refrigerated. This requires a distribution network that uses a cold chain.

- **Registration of biopesticides.** An enormous limitation to biopesticides use in many countries is having to move biopesticides through regulatory systems that have been molded over time for chemical products. Efficacy tests are usually designed to measure the direct killing power of a product. Regarding this factor, biopesticides usually have a lower efficacy. Nevertheless, conserving natural enemies proves, in the end, that biologicals often give better results. An extreme example of this was the application of Metarrhizium against grubs. Even though the crop showed no damage and an additional 600 kg per hectare produce was obtained from the fields treated with Metarrhizium, the biopesticide failed the typical tests on kill efficacy.

- **Inadequate labelling and characterization.** Many biopesticide products are branded as generics without brand names and only the active ingredient is mentioned (eg. *Bt*, *Beauveria*, *Metarrhizium*, etc.). Due to the lack of quality of many fungal products, many farmers who had bad experiences in the past with low-quality products are reluctant to use biopesticides.

- **Generic chemicals.** In Colombia like in other Latin American countries, new laws on the use and production of generics have been approved in order to provide a low cost alternative to high-priced pesticides from the company which originally patented the product. This means that agrochemical companies can formulate products using any active ingredient presently used in the country and these products will be given government approval without having to present any studies. Therefore, the cost of developing a product is very low, and consequently, these products are very cheap. However, many of the compatibility studies between these generics and biopesticides will have to be performed again, because most generics are formulated with solvents that are harmful to biopesticides. Therefore, farmers must be careful with the practice of mixing active ingredients or products that may not be compatible with biopesticides.

- **Lack of information and training.** Another important limitation for the application of biopesticides in Colombia is the position of decision-makers. Compared to chemical pesticides, biologicals generally fail in areas such as speed of kill and range of targets. Clearly, biologicals are not effective chemicals or miraculous products. However, the claim that farmers will only accept quick-acting products like chemical insecticides and will not wait for an insect pathogen to kill over a few days does not agree with the widespread acceptance of slow-acting herbicides.

Furthermore, for biological pesticides to be effective more knowledge is needed to understand the pest's life cycle, in order to apply the product at the right moment and directed to the right place. For example, part of the life cycle of thrips occurs in the soil beneath the plant. Therefore, an effective application to control the larvae must be directed to the bottom of the plant. The cultural preference of curative over preventative measures is reinforced when products that are applied at the last moment fail to control a pest. If a slow-acting biopesticide is involved, the failure is commonly attributed to the product rather than to the real reason, namely to applying the product at a wrong moment. Application programs should cover all stages from the nursery stage up to the final product and should include preventive treatments of plants to prevent fungi and/or nematode infestation. The crops should be frequently monitored for diseases and pests, and applications should only be done according to economic threshold levels. According to experiences by the Colombian company Laverlam, BP application programs that have been monitored and managed professionally have been overall successful.

- **Limited investment in R&D.** To date, many governments, international organizations, and farmers have looked to multinational agrochemical companies to lead the development and implementation of biologicals. While some companies have invested in research and development of biopesticides to manage resistance problems in their chemical product range, to increase their reputation of environmental friendliness, and because of the potential profits from these products or associated proprietary technologies, the overall investment is still rather limited. The large inventory of synthetic chemicals and the past investments in their development forces the companies to keep pushing these into countries that still have little or no pesticide regulations. Also, multinationals demand products with global applicability. Since biopesticides are still widely restricted to specific markets, the large companies are reluctant to invest in this business.

- **Biopesticides reduce future application needs.** The fact that the demand for biologicals may decline as natural enemy populations recover also can be seen as a commercial disadvantage for companies interested in increasing their sales. A change in the corporate vision of multinational directors is required if such companies are to get involved in this market.

In summary, there is a growing potential for biopesticides, but there are also many obstacles to be overcome in order to realize this potential. To date, biologicals have not yet proven to be effective competitors with chemical products due in part to higher comparative costs, lower income prospects, restrictions on the ease of handling, and lack of extension. However, given effective collaboration between the public and private sector and increasing environmental awareness of producers and consumers, the spectrum of biopesticides and the options of using them effectively will likely continue to increase in the future.

Opportunities and Limitations for Biopesticides: a Private Sector Perspective

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Abstract
Agraquest is a company based in the US that formulates and distributes biopesticides. This paper summarizes the company's assessment of the status, potential, and limitations for biopesticides.

Registration of Biopesticides in the US and other Countries

The status of biopesticides in the United States has been influenced greatly by the registration process as administered by the Environmental Protection Agency (EPA). Under the Biopesticides and Pollution Prevention Division (BPPD) it is possible to obtain registrations in an expedited review process with fewer toxicology requirements than for the registration of synthetic chemical pesticides. This reduces the registration time from 3-5 years for synthetic pesticides to 1.5-2.5 years for biopesticides. The cost and time for the development of biopesticides in our experience is around 3 years and US-$ 6 million. In comparison, the development of traditional synthetic pesticides requires typically from 8-10 years and around US-$ 185 million. The registration process for biopesticides in developing countries is highly variable, however reciprocity among countries exists in some cases. The registration time of AgraQuest's biofungicide Serenade varied from more than 2 years (Argentina, still pending) to one year (Chile, Mexico, Costa Rica, Philippines) to as little as six months in Honduras and Guatemala. In many cases where no specific procedure existed for the registration of biopesticides, countries frequently used the EPA's biopesticide registration process as a starting point. With regard to formulation, the registration procedures also varied. In the US, changes in formulation frequently trigger a time consuming review process at EPA, while in many other countries formulation changes only require a notification, as long as the active ingredient has not changed. This has expedited AgraQuest's introduction of improved formulations in developing countries.

Uses and Advantages of Biopesticides

Many opportunites exist for biopesticides in the current agricultural sector. Their principal benefits include:

- reduced use of synthetic chemicals and replacement of deregulated pesticides,
- improved resistance management,
- improved worker safety,
- benefits to the environment,
- export advantages.

According to our experience, several synthetic chemical sprays can be replaced in programs by biopesticides with no loss of disease control. For example, the use of the biological fungicide Serenade, based on the action of *Bacillus subtilis*, against the black sigatoka disease of bananas allowed to reduce the use of the synthetic thiocarbamate fungicide EBDC by half. The unique and multiple modes of action of many biopesticides often allow them to be effective even against pests which have become resistant to synthetic pesticides. Biopesticides are typically target-specific making them less toxic to workers and non-target organisms. In addition, production processes based on fermentation are inherently safer to the workers and the environment as there is no need for toxic solvents, and the waste streams are not contaminated with toxic components. For example, in the case of the bacterial product Serenade, the foliar presence of *Bacillus subtilis* is short-lived in the environment and the metabolites present are quickly degraded into non-toxic breakdown products. The lack of residues and the positive environmental and toxicological profile of biopesticides make it much easier to export crops to countries using ISO and CODEX standards. The quick re-entry time after application and the lack of a mandatory pre-harvest interval can also result in cost savings to the grower.

Limitations of Biopesticides

The limitations of biopesticides include:

- a negative perception by the chemical industry,
- the lack of experience of extension specialists in testing biopesticides,
- high fermentation costs,
- the lack of systemic activity, and
- a lack of motivation by distributors due to lower profit margins.

With some effort, these limitations can be overcome. Through careful quality control to manufacture reliable and effective products, biopesticides will eventually gain credibility as the growers have more successful experiences. With expanding production, the cost of production will drop, making many biopesticides more cost competitive with synthetic pesticides. The interest of distributors in promoting biopesticides can be increased in part by higher demand for theses products by growers. However, this is a resource-intensive procedure for small companies. An increased colaboration with larger growers and companies should help improve the services provided by distributors.

Outlook

According to our experiences, the outlook for biopesticides is overall positive. The growing consumers' demand for safer foods is illustrated by annual growth rates above 20% both in the organic food market and in biopesticide use in California. While biopesticides still represent only 1% of the pesticide market, the synthetic pesticide market is declining while the biopesticide market continues to increase. Many opportunities exist for replacing older, synthetic products with new biopesticides that allow to reduce resistance development of pests and that can provide high efficacy without damaging the environment or endangering agricultural workers.

Biopesticides and international conventions on management of chemicals

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Abstract
Biological methods and less toxic biological pesticides are an alternative to the use of dangerous synthetic substances. The phasing out of toxic substances helps reduce the pollution of the environment and health risks for pesticide users and consumers. The elaboration of international agreements on the production, handling, trade, replacement and final disposal of certain toxic chemicals and the support for developing new and less dangerous technologies are important steps towards improved management of agrochemicals on global level.

Background

Some 500 million tonnes of chemicals are produced, used and processed worldwide each year. The International Labour Organization estimates that 50% of all workplace accidents occur in agriculture, making agriculture one of the most hazardous occupational sectors. The major risk is the exposure to pesticides and other agrochemicals. Fourteen percent of all accidents are due to agrochemicals, and 10% of them are fatal. In many developing countries, substances that are already prohibited in industrialized countries are still available. However, due to infrastructure, climatic and socio-economic conditions in developing countries, safe use of agrochemicals in those countries cannot be guaranteed. Therefore, the promotion of information on less dangerous agrochemicals and the increase of their availability in the local markets are seen as priorities.

Damage to human health by agrochemicals and pollution of water and soil resources and the atmosphere must be reduced or, if possible, prevented as it jeopardizes the livelihoods of entire populations. Moreover it is crucial for the sustainable development of a country that:

- The health of the working population is not impaired by workplace accidents and poisonings.
- Situations are avoided that require costly clean-up and disposal measures.
- Residue levels in exported products do not exceed the acceptable limits which would lead to rejection of the products.

Chemicals know no boundaries. Toxic substances can be transported over great distances by air (global distillation), water and contaminated foodstuffs. A single source of chemical pollution can thus affect locations all around the globe. Handling chemicals in an appropriate way is a precautionary approach to global health and environment protection.

Major International Agreements Related to Chemical Management

The **Basel, Rotterdam** and **Stockholm conventions** are major international agreements with relevance to agriculture and pesticides trade, production, use, phasing-out and final disposal. The **Vienna Convention** along with the **Montreal Protocol** regulates ozone depleting substances, including methyl bromide, a pesticide widely used in agricultural production and storage management.

The **Vienna Convention** for the Protection of the Ozone Layer was adopted in 1985 and the **Montreal Protocol** in 1997. Both regulations work towards the systematic elimination of anthropogenic ozone-depleting substances. Besides methyl bromide, these agreements support the substitution of chlorofluorocarbons and hydrochlorofluorocarbons used as foaming agents or refrigerants and the substitution of halons used in fire extinguishers.

The **Basel Convention**, adopted in 1998, regulates the control of transboundary movements of hazardous wastes and their disposal. The export, import and transit of wastes are permissible only after all countries concerned have been notified in advance and their approval has been obtained. The consignment of wastes to non-signatory states is forbidden as a matter of principle and only permissible in exceptional cases. The export of wastes to regions south of the 60th parallel - to the Antarctic - is fundamentally prohibited. The exporter and the country of origin of the waste are responsible for compliance with the Convention. There is an obligation to take back the waste in the event of abortive or illegal waste exports (Table 1).

The **Rotterdam Convention (PIC - Prior Informed Consent)** was signed 1998 and has been adopted in February 2004. It governs the transboundary trade of certain hazardous toxic substances. The convention deals with the regulated exchange of information about the characteristics of the chemicals (physical-chemical, toxicological and eco-toxicological properties), with state-imposed regulations and finally with the enforcement of decisions taken by importing countries, for example with respect to import bans. The convention includes a mechanism which permits to notify additional chemicals and add them to annex III of the Convention. Chemicals have to be notified by two countries from different PIC-Regions. The Intergovernmental Chemical Review Committee evaluates and approves the notifications.

The **Stockholm Convention** was signed in 2001 and has been adopted in May 2004. It is a global treaty to protect human health and the environment from persistent organic pollutants (POPs). In implementing the convention, governments will take measures to eliminate or reduce the release of POPs into the environment. POPs are chemicals that remain intact in the environment for long periods of time; they become widely distributed geographically, accumulate in the fatty tissue of living organisms and are toxic to humans and wildlife. POPs circulate globally and can cause damage wherever they travel. At the moment there are 12 chemicals under this convention, nine of them are pesticides (Table 1). All chemicals under the Stockholm Convention are banned due to their immediate or chronic toxicity and due to their potential danger to the environment, human health, flora and fauna.

Table 1. Rotterdam (PIC) and Stockholm Convention (POPs) in comparison.

	PIC	POPs
No. of chemicals general	32	12
No. of pesticides	24	9
Candidate pesticides scheduled for review	5	--.
Signatories:	73	151

Importance of Preventing Accidents with Agrochemicals

Nowhere in industrialized or developing countries can "chemical-free areas", be found, especially not in agriculture. Despite this, the techniques for coping with the side effects of this development are still in their infancy. To date, policy measures have not been able to keep up with the rapid expansion of the use of chemicals. Evidence of this is given by a host of contaminated sites -old toxic waste dumps, decaying industrial plants, ship graveyards, etc., particularly in industrialized countries. Legislation, institution building and the establishment of licensing and inspection bodies have much catching up to do - in the industrialized world and even more so in developing and threshold countries. It is not by chance that the environmental harm resulting from improper handling of chemicals is most serious in the poorest countries.

In the debates on international development, chemical safety is a relatively recent topic, which has only begun to take shape in the past few years, despite decades of industrial accidents, environmental disasters and criminal practices. Accidents and disasters can only be prevented by precautionary measures such as strict laws and inspections, by better information and education about risks, by making changes in chemical production, by prohibiting hazardous substances and dangerous practices and by the promotion of more environmentally friendly technologies based on the use of less toxic and dangerous agrochemicals.

Cleaning up is much more expensive and costly and, in most cases, damages and harm done by chemicals cannot be repaired at all. A single source of chemical pollution can affect locations all around the globe. Handling chemicals safely is a precautionary approach to global health and environment protection. Dangers to human life and environment can occur during the whole lifespan of a chemical: production, trade, transportation, application and final disposal. Generally spoken: *prevention is preferred to end of pipe technology!*

Activities of the Convention Project on Chemical Safety

Project activities build on Agenda 21, specifically on Chapter 19, which is concerned with the management of toxic chemicals. The project works on a supra regional basis and is designed to act on the request of our partner countries in Latin America, Asia and Africa.

Our worldwide general activities to improve chemical and agrochemical management include:

- Awareness raising on the importance of the conventions and their implementation.

- Creation and support of poison control centres and the development of international networks.
- Promotion of chemical safety for enterprises through workshops and training for companies and trainers in Latin America and Asia.
- Support for the development of alternative technologies in industrial processes.
- Support for the promotion of less dangerous methodologies in agriculture, use of less toxic pesticides, and the promotion of the information exchange on alternative methodologies.

Our specific activities regarding the **Rotterdam Convention** are:

- Support of partner countries in the development of national plans for the implementation of the convention.
- Technical and methodological support for designated national authorities.
- Assistance for the compilation of baseline information on toxic substances for decision makers.
- Collection and evaluation of data on risks and dangers to health due to toxic substances and pesticides - harmonization of data collection in poison control centres in Latin America in cooperation with PAHO/WHO.

Our specific activities regarding the **Stockholm Convention** are:

- Technical and methodological support for the "national focal points" of the convention.
- Technical and methodological support during the development of national plans for the phasing out of toxic substances.
- Support programmes for the reduction of Dioxin/Furan emissions and the phasing out of PCBs.
- Assist partner countries with the development of inventories of POPs chemicals.

Our specific activities regarding the **Basel Convention** include:

- Technical and methodological advice for final disposal of obsolete substances.
- Support to develop strategies for the prevention of accumulation of new stock.
- Support for awareness-raising strategies regarding the danger due to obsolete stock/pesticides.

Conclusions and Outlook

Biological methods and less toxic biological pesticides are alternatives to the use of dangerous substances. The phasing out of toxic substances helps prevent the pollution of the environment and reduces the risk of health dangers for users and consumers. Some steps towards the improvement of the management of chemicals including agrochemicals on a global level are the elaboration and implementation of international agreements regarding production, handling, trade, replacement and final disposal of certain toxic chemicals, and the support for the development of new and less dangerous technologies.

The reasons for pesticide poisoning in developing countries are various: The lack of a legal framework, poverty, illiteracy of users, lack of health and safety rules, missing information and low awareness of dangers, deficiency of water and hygiene, and often the environmental or climatic conditions.

Many countries have institutions that are responsible for monitoring chemical risks. However, typically these have not yet reached the stage where they operate efficiently. They are unable to assess problematical chemicals and often they are not capable of controlling the routes by which the chemicals are transported and the forms in which they are processed. The institutions suffer from a shortage of scientific and technical facilities for assessing the risks from toxic chemicals and likewise a lack of means to control the misuse of toxic substances.

The international conventions provide the framework for the sound management of toxic substances. Actual implementation of these objectives is a responsibility of the countries themselves. This is where bilateral assistance is called for, and where the future tasks of development cooperation in the field of chemical safety will be focused.

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The Montreal Protocol and Methyl Bromide

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Abstract
The concept of fumigating soil with methyl bromide (MeBr) was introduced in the early 1960's, and it has since experienced a steady increase in production and sales. Globally, about 72,000 tons are used each year. In 1991, MeBr was identified as a potential ozone-depleting compound. Under the Montreal Protocol, governments have agreed to phase out MeBr in developed countries by 2005 and in developing countries by 2015.

What is the Montreal Protocol?

The Montreal Protocol is an international agreement that aims to protect the Earth's fragile ozone layer from damage caused by chemicals such as CFC's, halons and methyl bromide (MeBr). The ozone layer is important to life on earth because it screens us from harmful ultraviolet radiation emitted by the sun. In 1991, methyl bromide was identified as a potential ozone-depleting compound. In 1992, it was officially added to the list of ozone-depleting chemicals. The ozone depleting potential of MeBr was determined to be 0.4 higher than the admissible threshold of 0.2. This higher ozone depleting potential of MeBr is primarily due to the elevated capacity of bromine released from applied MeBr to break down ozone. On a per atom basis, bromine is about 40 times more efficient than chlorine in breaking down ozone (Yates *et al.*, 2003, and FAO, 2001).

What is Methyl Bromide?

Methyl bromide is a toxic chemical used to control a broad spectrum of pests in soil, commodities and buildings. It has been used widely since the 1960's as an effective preplant soil fumigant for controlling nematodes, plant pathogens, weeds and insects. The use of a soil fumigant is claimed to be vital for the economic viability of many crops such as strawberries, tomatoes, peppers, tobacco, ornamentals and melons (UNEP, 2000). Its success as a fumigant is largely due to its activity against a wide spectrum of pests, its ability to penetrate the fumigated zones, and its ease of application. When used as a soil fumigant, methyl bromide gas is usually injected into the soil at a depth of 12 to 24 inches before a crop is planted. This will effectively sterilize the soil, killing the vast majority of soil organisms. Immediately after the methyl bromide is injected, the soil is covered with plastic tarps, which slow the movement of methyl bromide from the soil to the atmosphere. Residual methyl bromide is emitted to the atmosphere at the end of the fumigation, when the tarps are removed. About 50% to 95% of the methyl bromide injected in to the soil can eventually enter the atmosphere (USDA, 2001). It is estimated that soil fumigation contributes about 20% of the total MeBr emissions, and the agricultural use of MeBr, including soil fumigation, may be responsible for about 3% to 10% of stratospheric ozone depletion (USDA, 2001). Globally, about 72,000 tons are used each year. North American holds the highest use rate (38%), followed by Europe (28%), Asia (22%, including Israel and the Middle-East), and South America and Africa combined using the least (12%).

The vast majority of this chemical is manufactured by three companies: two located in the U.S. state of Arkansas (Great Lakes Chemical and Ethyl/Albemarle), and one in Israel (Dead Sea Bromine). These companies utilize naturally occurring bromide salts which are either contained in underground brine deposits (as is the case with Arkansas), or in highly concentrated above-ground sources like the Dead Sea (USDA, 2001).

When will Methyl Bromide be Banned?

Under the Montreal Protocol, governments have agreed to phase out MeBr in developed countries by 2005 and in developing countries by 2015. For developed countries the goals for the reductions are, relative to the 1991 consumption levels: 25% by 1999, 50% by 2001, 70% by 2003, and 100% by 2005. For developing countries, the goals are 20% by 2005 and 100% by 2015, based on the average consumption between 1995 and 1998. Presently, 184 countries have ratified the Montreal Protocol and many of them have accepted their amendments (London amendment, 1990; Copenhagen amendment, 1992; Montreal amendment, 1997; and Beijing amendment, 1999).

The phasing out of MeBr requires a shift towards more environmentally friendly agricultural practices. Such behavioral changes require sustained awareness-raising of consumers and producers, as well as training and capacity-building to provide farmers with the knowledge and tools needed to adopt alternatives successfully. This will occur only if farmers and policymakers have practical examples of successful alternatives to MeBr (UNEP, 2000).

The Montreal Protocol's Multilateral Fund provides technical and economic assistance for developing countries to phase out ozone depleting substances. The Protocol has allocated special funds for methyl bromide projects, including, in 1998 and 1999, a focus on evaluating and demonstrating alternative techniques. Guidelines outline the main types of projects eligible for funding, which include demonstrations and projects to disseminate information, develop policies and training activities, and to establish alternative systems. Projects are implemented in partnerships between the governments of developing countries and UNDP, UNIDO, UNEP, the World Bank and development agencies of industrialized countries such as Australia, Canada, Germany and the USA.

What are the Alternatives to Methyl Bromide?

To date, there is no alternative to substitute all the uses of methyl bromide, but there are several pest control tools, including biopesticides, which can be used to effectively and economically manage the pests currently controlled with methyl bromide. In choosing alternatives to MeBr, it is important to increase awareness about the successful use of biological and non-chemical alternative techniques and IPM in order to minimize the risk that MeBr be replaced by other chemicals, which may cause environmental problems, even though they do not deplete ozone.

The Methyl Bromide Technical Options Committee (MBTOC 1994) has noted that the alternatives to MeBr in developing countries are the same as those for industrialized countries, but their application may be constrained by factors such as social conditions and the level of infrastructure. Chemical alternatives include dazomet, metam sodium, 1,3D, chloropicrin and methyl isothiocyanate.

Non-chemical alternatives that are being used with success for many crops around the world include the use of steam, soil solarization, crop rotation, biological control, resistant varieties, cover crops, organic amendments, compost, biofumigation, floating seed-trays, and IPM.

Selected examples of non-chemical alternatives

In the year 2001, in Naivasha, Kenya, the use of MeBr amounted to 77 tons. After a FAO/UNEP project, the options that are becoming popular are non-chemical ones, which consist of bio-fumigation, solarization and the application of beneficial soil fungi of the genus *Trichoderma*. As a result, the use of MeBr in 2002 was reduced to 6 tons. A formulation of *Trichoderma harzianum* (called Trichoflow) is applied via irrigation systems in tomatos in New Zealand, and the use of MeBr in Cuban tobacco production has been replaced by formulations of *Trichoderma* (Jorge Ovies, 2003. Instituto de Investigaciones de Sanidad Vegetal, Ministerio de Agricultura, Cuba. Pers. com.). In Costa Rica, soil solarization is used on more than 1500 hectares for the production of melons, and the planting substrates for the production of fresh flowers are successfully heat sterilized with water steam. In conclusion, there are many documents and experiences presenting promising alternatives to the use of methyl bromide around the world. Adopting these practices and production methods should allow to meet the goals of the Montreal protocol.

Conclusions and priorities for the next years

Developing countries will have to continue to implement projects geared towards the reduction and utlimately elimination of the use of MeBr. Even though the final deadline for the phasing out of MeBr is not until 2015, the international markets increasingly demand agricultural products that have been produced without MeBr. To date, the efforts in developing countries include the successful examples of Cuba, Kenya and Costa Rica, where substantial advances have been made. In Costa Rica, a joint program between UNDP and several universities is currently being implemented to help the producers of melon and flowers as the principal users of MeBr as well as small vegetable farmers who use smaller quantities to adopt alternatives to MeBr. Small farmers are probably one of the most promising groups to implement activities which include new technologies such as the use of biopesticides with the objective to create production systems that are environmentally more benign and that protect the ozone layer of the earth.

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Technical Cooperation and Biopesticides: the German Perspective

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Promotion of non-chemical crop protection
methods through the private sector
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Abstract
For more than 25 years, the German Technical Cooperation, through GTZ (*Deutsche Gesellschaft fuer Technische Zusammenarbeit*), has strongly supported Integrated Pest Management (IPM) systems in developing countries. Biopesticides were always considered an integral part of IPM. The guidelines for the concept of IPM were provided by a number of UN Conventions and, from 1992 onward, by Agenda 21.

Funded by the Ministry of Economic Cooperation and Development (BMZ), GTZ was involved from 1970 to 2000 in more than 50 countries in improving crop protection services. Within these bilateral projects, components on biocontrol of insects and weeds were included. Special projects were launched to use Neem (*Azadirachta indica*) as a botanical insecticide in Asia, Africa and America and to utilize *Metharrizium anisopliae* as a natural pesticide for the control of locusts and *Sarcocystis singaporensis* as a biological rodenticide.

The focus of GTZ has changed over the past 10 years. The UN Millennium Goals (Johannesburg, 2001) are now the guidelines for BMZ/GTZ's work, leading to a more social and economic oriented approach in technical cooperation. Projects in the "green sector" are disappearing fast from the GTZ agenda. Only a few projects oriented towards crop protection have remained, focusing on biopesticides and the private sector: one in Asia and one in Central America. These projects have to be seen as the ending point of three decades of German cooperation in Integrated Pest Management worldwide.

GTZ Working with IPM and Biopesticides (1975 – 2000)

German technical cooperation has to be seen in the context of international development cooperation. The first projects of GTZ in crop protection started around 1960, based on the International Crop Protection Convention. Since then, further UN conventions on plant protection and chemical safety have guided the priority setting in this field (Table 1).

Table 1. UN Conventions on Plant Protection and Chemical Safety

- International Plant Protection Convention, FAO (1952, revised in 1997).
- International Code of Conduct on the Distribution and Use of Pesticides, FAO (1972, revised in 2002).
- Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, UNEP-FAO (1998).
- Stockholm Convention on Persistent Organic Pollutants (POPs), UNEP-FAO (2001).

In the early years, the main objective was to establish national crop protection services to prevent losses due to local or imported pests and, thereby, to support the work towards food security. From the beginning, GTZ participated in the development and implementation of Integrated Pest Management (IPM) systems for different crops, which where offered to more than 30 countries worldwide. In Asia, the countries included The Philippines, Thailand, Burma, Indonesia and China; in the Pacific: Tonga, Samoa and Fiji; in the Near East: Turkey, Jordania, Syria and Yemen; in Africa: Egypt, Sudan, Somalia, Kenya, Tanzania, Morocco, Tunisia, Chad, Niger, Benin and Ghana; in the Caribbean: The Dominican Republic and Jamaica, and in Latin America: El Salvador, Honduras, Nicaragua, Costa Rica, Panama, Ecuador, Brazil, and Argentina.

Special projects have been conducted on topics like the control of locusts and parasitic weeds, quality management of pesticides, and on the use of Neem. A number of GTZ projects were, and still are, directly oriented towards the implementation of UN Conventions on chemical safety in developing countries.

Starting with the ratification in 1992 of the Agenda 21 in Rio de Janeiro, Brazil, this agreement formed the basis and orientation for Technical Cooperation through GTZ. For crop protection and especially Integrated Pest management, the chapters 14 and 19 are of particular relevance (Table 2):

Table 2. Extract from Agenda 21 (Rio de Janeiro, 1992)

Chapter 14: Promoting Sustainable Agriculture and Rural Development.	
14.4.	The following programme areas are included in this chapter: i) Integrated pest management and control in agriculture;
14.77	ii) Consolidate, document and disseminate information on biological control agents and organic pesticides, as well as on traditional and other relevant knowledge and skills regarding alternative non-chemical ways of controlling pests.
Chapter 19: Environmentally Sound Management of Toxic Chemicals.	
19.4	In the agricultural area, integrated pest management, including the use of biological control agents as alternatives to toxic pesticides, is one approach to risk reduction.

Following the discovery of the Antarctic ozone hole in late 1985, governments increasingly recognized the need for stronger measures to reduce the production and consumption of a number of halogenated carbohydrates, especially chlorfluorocarbons (CFCs). In 1989, the United Nations ratified the Montreal Protocol on substances depleting the ozone layer, encouraging member nations to start actions for their substitution. This was reflected later in the Agenda 21, chapter 9. This section has also relevance for crop protection because of the wide-spread use of Methyl Bromide, an ozone-depleting chemical, as a soil fumigant (Table 3).

Table 3. Extract of Agenda 21, Chapter 9: Protection of the Atmosphere

9.22.	Analysis of recent scientific data has confirmed the growing concern about the continuing depletion of the Earth's stratospheric ozone layer by reactive chlorine and bromine from man-made CFCs.

This chapter of the Rio Declaration was later reformulated for a specific UN Convention.

In order to contribute to the implementation of the Montreal Protocol, a special GTZ project called Proclima was launched in 1996. The original orientation was on CFCs used as coolants in refrigerating appliances. In 1998, Methyl Bromide was included into the protocol, setting the year 2005 as deadline for phasing out the use of Methyl Bromide in industrialized countries and 2015 for developing countries. The alternatives promoted by GTZ for this process always included non-chemical pesticides.

During the past 25 years, GTZ's main topics in its development cooperation agenda were sustainable agriculture, natural resource management, education and health. The orientation of the Crop Protection Section as part of the Agricultural Division within GTZ focused on IPM programs, biological pest control, and the development of biopesticides. Most of the work has been implemented in cooperation with government institutions, through bilateral projects, and by supporting international agricultural research of the CG system. This work started in the 60s, and reached a peak with more than 50 projects from China to Chile in the 80s. Since the beginning of the new millennium, these topics have increasingly been phased out. However, the German technical cooperation currently continues to support two areas of strategic importance for sustainable development: bio-control and the development of biopesticides (Table 4).

Table 4. A selection of GTZ-supported projects oriented towards bio-control and/or biopesticides, 1975 – 2003

- Control of Water Lilies (*Eichhornia crassipes*) in **Niger** (1960 - 1970) in cooperation with IITA.
- Control of the Asian Corn Borer (*Ostrinia furnacalis*) with *Trichogramma* in the **Philippines** (1980 – 1990) in cooperation with IRRI.
- Control of the Larger Grain Borer (*Prostephanus truncatus*) in *Benin, Tanzania, and Ghana* (1980 – 1990) in cooperation with CAB International and NRI.
- Coffee berry borer (*Hypotenemus hampei*) in **Ecuador** (1982 - 1990) in cooperation with CAB International.
- Parasitic weeds (*Orobanche spp.*) in **West Africa** (1975 –1985) in cooperation with IITA.
- Biological control of insect pests in vegetable crops in **East Africa** (1985 – 1995) in cooperation with ICIPE.
- Biological control of forest pests in **China** (1980 – 1995) in cooperation with the Forestry Department of Shenyang.
- Biological control of the apple maggot (*Rhagoletis pomonella*) in **Argentina** (1990 – 1996) in cooperation with INTA
- Promotion of non-chemical crop protection products through the private sector in **Central America** (2000 – 2006) in cooperation with CATIE.
- Commercialization of biopesticides in **SE-Asia** (2003 – 2010) in cooperation with the Kasetsart University

Biocontrol projects were always conducted in cooperation with national institutions and supported by a number of regional or United Nations' institutions. GTZ activities on biopesticides were developed on requests from IPM projects in different countries. Three activities were conducted over extended periods of time:

1. The Neem Program (1975 – 2000)
In the seventies, information on the insecticidal properties of Neem (*Azadirachta indica*) emerged and was adopted by different institutions worldwide. In Germany, the University of Giessen dedicated a full working group to this issue and was able to convince BMZ/GTZ in 1975 of its suitability for developing countries. As a result, a long cooperation was established between the University of Giessen, GTZ and national or regional institutions in a considerable number of countries, particularly the Philippines, Indonesia, Thailand, Mayan Mar, Kenya, Ghana, Niger, Nicaragua, and the Dominican Republic.

The efforts to develop Neem as an effective option for pest control concentrated on investigating the efficacy of different varieties under a range of climatic conditions and on different target organisms, and on studying the effects on beneficials, as well as technologies for production, formulation, storage and use. GTZ did not include registration and trade in its efforts, which, from the present perspective, was a mistake.

Thanks to the working group of the University of Giessen, Neem has become one of the most widely known alternatives for chemical pesticides worldwide. However, despite the early expectations of Neem as the major breakthrough of biopesticides in crop protection, not all expectations were met because of socio-economic constraints. Nowadays, there are a few companies producing biopesticides from Neem in Nicaragua and the Dominican Republic which supply a relatively modest demand (see paper by Brechelt, this volume). However, the Central American producer cannot compete with India, the country of origin of Neem which has positioned itself as the biggest and most competitive producer of Neem products by far.

2. The African Locust Control Program (1985 – 1998)
This program was basically a FAO initiative as a consequence of growing concerns over severe locust outbreaks (mainly *Schistocerca gregarina*, but also other species of locusts and grasshoppers) in Africa and the Near East during 1985. Germany was among the donor countries with GTZ acting as coordinator of national programs with FAO. The program included countries in Africa like Kenya, Sudan, Ethiopia, Somalia, Libya, Morocco, Mauritania, Niger and Yemen on the Arabian Peninsula.

Due to growing concerns about the widespread use of chemicals in the control campaigns, the consortium LUBILOSA was founded from a variety of research and development organizations to find less harmful control alternatives. After a long and intensive screening process of alternatives, *Metarrhizium anisopliae* was selected as the most promising option. GTZ was especially involved in the screening process, and later in field-testing. Due to efforts of many countries, and to the cycles in the population dynamic of the locust, the crisis was finally overcome after 10 years. This coincided with the commercial registration of the new product "Green Muscle" based on *Metarrhizium anisopliae* var. *acridium*. It is an effective biopesticide that has been successfully used ever since for the control of different locust types in Africa. However, the efforts to develop production facilities in Africa, the area of its mayor use, have failed, because of lack of funding and low demand for the product in the times between outbreaks. As a result of the project, however, an alternative product with proven efficacy is available when the next outbreak starts. Fortunately, FAO has not abandoned its locust unit and continues to monitor the locust situation in potential outbreak areas.

3. Biological Rodent Control (1990 – 2000)
During the 1980s, within a GTZ crop protection program carried out in Egypt, the protozoa *Sarcocystis singaporensis*, originating from South East Asia, proved to be an effective pathogen to control rodent populations, a mayor problem worldwide. Due to safety reasons, field experiments to identify its potential were conducted in Thailand in cooperation between the University of Stuttgart, the Ministry of Agriculture of Singapore and Kasetsart University. As a result, a new and innovative product is coming into the Asian market at a time when rodents are showing signs of resistance to the traditional products based on chronic poisoning and anti-coagulant activity. Today, through a project based on "Private Public Partnership", GTZ is working with the private sector in Thailand on how to improve formulation and production. It is expected that the product will be registered soon and find its way into the SE-Asian market by 2005.

4. GTZ and IPM / Biopesticides in the New Millennium
The focus of German Technical Cooperation has dramatically changed since 2000. The UN Millennium Goals (Johannesburg 2001) are now the orientation for German Technical Cooperation, leading to programs with a strong orientation towards social and economic benefits (Table 5).

Table 5. UN Millennium Development Goals, Johannesburg 2000

Goal 1:	Eradicate extreme poverty and hunger.
Goal 2:	Achieve universal primary education.
Goal 3:	Promote gender equality and empower women.
Goal 4:	Reduce child mortality.
Goal 5:	Improve maternal health.
Goal 6:	Combat HIV/AIDS, malaria, and other diseases.
Goal 7:	Ensure environmental sustainability.

The new development goals adopted by the United Nations are more oriented towards poverty, education, gender, health (HIV), decentralization, communal development, good governance, public private partnership (PPP) and give less weight to environmental sustainability in agriculture and forestry than before.

In 2003, GTZ was conducting only two regional projects on the promotion of biopesticides, as follow-up activities of programs and projects mentioned before. These projects where created based on the observation of IPM projects that there is a real demand for biopesticides. On the other side, it was obvious that the private sector, especially the transnational pesticide companies, were not interested in bringing biopesticides into the market. The reason is simple in that biopesticides, due to their biological properties, tend to be less needed the more they are used. For the implementation of these projects South East Asia and Central America were selected because of good relations with government institutions and also because these region are promising markets for biopesticides. Furthermore, GTZ had developed a multitude of joint efforts in both regions over the past 25 years.

The Central American project on the promotion of non-chemical crop protection products through the private sector started in 2000 in cooperation with CATIE (Center of Tropical Agriculture for Research and Investigation), a regional research and training center headquartered in Costa Rica.The project objective is to elevate the market share of biopesticides in Central America significantly. The project is working in three Central American countries: Costa Rica, Nicaragua and Honduras. Presently, this venture is training staff from production companies, sales personnel and extension workers. As well, it is laying the foundations to organize the sector in each country and develops registration guidelines for biopesticides. The project also created the first information service on biopesticides in Spanish language (www.bioplaguicidas.org).

The new regional project on the commercialization of biopesticides in SE-Asia started in 2003 with its base in Thailand and activities also in Viet Nam and the Philippines. It follows a similar approach as the GTZ project in Central America through promoting biopesticides through the private sector. It combines the experience on IPM and of the rodent control project to contact partners from the public and private sector.

From the early projects on the control of water lilies in Sudan in the 1960s to the current promotion of biopesticides in Central America and South East Asia, German technical support has been highly effective in strengthening plant protection efforts around the world. In the attempts to improve the environmental and health aspects of crop protection, GTZ had very good partners and alliances in other Technical Cooperation Institutions like USAID, NORAD, DANIDA and FAO. During this period, Integrated Pest Management (IPM) has become the standard approach to crop protection in most countries of the world. There are still many areas to improve, especially in Africa, but most countries are, today, in a much better position to solve their own fitosanitary problems than in 1960, when GTZ started its first IPM project in Sudan. Since the beginning of the new century, topics like "management of natural resources" and "rural development" are disappearing fast from the agendas of Technical Cooperation Institutions, including GTZ, and are increasingly replaced by topics like "decentralization" and "good governance". Considering this tendency, the two GTZ projects on biopesticides may well be seen as a final point of 44 years of German Technical Cooperation in the sector of crop protection.

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Section 2
Innovations, Production and Applications

Industrial and Small-Scale Production of Biopesticides Derived from Antagonistic and Entomopathogenic fungi

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Abstract
Relatively high costs of pesticides in Costa Rica, affecting particularly small and medium farmers, have promoted the development of small-scale production units of biopesticides. These units, equipped with the basic infrastructure, and technically supported by the Costa Rican National Institute for Training (Instituto Nacional de Aprendizaje), are producing fungal-based biopesticides through methods such as fermentation on solid substrates. So far, the installed laboratories supply much of the needs of phytosanitary programs for specific crops like rice, coffee, cocoa, vegetables, roots and tubers, strawberries, ferns and flowers.

Introduction

The need for alternative agricultural production methods to control diseases and insect pests of crops, and the advantages provided by biological control have lead to a renewed interest in the use of microorganisms for this purpose. Consequently, increasing attention is given to the improvement of effective and economical technologies for the production of quality biopesticides from antagonistic and entomopathogenic fungi.

Worldwide, fungal biopesticides have been produced using either industrial techniques or small-scale techniques, depending on the required production scale and on the specific characteristics of the fungal strains to be multiplied.

Current Situation of Biopesticides in Costa Rica

One of the major problems for agricultural producers is finding non-synthetic products to control diseases and insect pests in crops. During the past decade, research at the INA has focused on developing small-scale home production systems for different types of biopesticides. Initially, most efforts were directed to solve phytosanitary issues for principal crops such as sugar cane. In order to meet the demand of producers devoted to other agricultural crops, biopesticides of industrial origin (Chart 1) had to be imported. However, in many cases, these are not affordable for small and medium producers.

Thus, research focused on developing technologies, which can be easily and cheaply adopted by the producer, while allowing to maintain a high quality standard.

Table 1. Biopesticides available in Costa Rica

Biopesticides	Brand name	Origin
Beauveria bassiana	Beauvedieca	National
	Brocaril 50 WP	Imported
	Native 2 SC	
Metarhizium anisopliae	Destruxin 50 WP	Imported
	Metadieca	National
Entomophthora virulenta	Vektor 25 SL	Imported
Verticillium lecanii	Vertisol 50 WP	Imported
Myrothecium verrucaria	Ditera 90 WP	Imported
Hyphomycetes fungi	Nemout 0.67 PM	Imported
Trichoderma lignorun	Mycobac 50 WP	Imported
Trichoderma koningii	Promot	Imported
Trichoderma harzianum		
Paecilomyces lilacinus	Biostat 50 WP	Imported

Source. www.bioplaguicidas.org

Industrial Production of Biopesticides Based on Fungi

In Latin America, the most important industrial producers of biopesticides are located in Colombia, Mexico, Venezuela, Argentina and Cuba. The most common production method is fermentation in liquid substrates where the conditions for biofermentation such as temperature, pH, air flow, etc, are regulated automatically. The success of this system depends on the use of contaminant-free batches at all stages. This implies that the fermenter, the equipment and additives (antifoaming) as well as the culture environment must be sterile before the inoculation. Furthermore, the air supplied during the fermentation must be sterile and there must be no mechanic openings in the fermenter that could allow microbial contamination.

Small-Scale Production of Biopesticides from Fungi

Besides developing industrial technologies for the large-scale production of biopesticides, some attention has also been devoted to developing small- or medium-sized technologies for the production of biopesticides in production units at the farmers' homes. Towards this end, the fermentation in solid substrates is very promising. In Costa Rica, INA's Center for Organic Agriculture has been running applied research programs with the objective to generate new technologies in this field and to transfer them directly to the producers. The experiences at the INA have shown that microorganisms can be successfully and reliably cultivated with homemade methods based on the fermentation in solid substrates. Throughout the country, small home laboratories have been created which have the minimum infrastructure and the required equipment such as pressure cookers with pressure gauges, transfer hoods, microscopes, glasswork etc. These facilities supply biopesticides for a wide range of crops including rice, coffee, cocoa, vegetables, roots and tubers, strawberries, ferns, flowers, etc.

Advantages and Disadvantages of the Industrial Production

The industrial production offers the following advantages:

- Large batches of microorganisms can be reproduced quickly.
- Manual manipulation of the cultures and materials is minimal, thus the risk of losses is reduced.

- Allows long-term storage and conservation of the biopesticides (freeze drying etc.).

The disadvantages of industrial production include:

- High energy consumption and costs due to the need for all equipment parts (joints, valves and electrodes of the fermenter itself) to be sterilized at all times. Discontinuous sterilization procedures, most widely used in industrial production, require longer sterilization times resulting in considerably higher energy consumption and costs compared to other sterilization protocols. Also, this heat-sterilization process may cause marked changes in the nutrient media, often resulting in discoloration, pH modifications and vitamin destruction. Although continuous sterilization demands less energy, some nutrient solutions may form insoluble salts (e.g. calcium phosphate or calcium oxalate) with this method.
- Restricted availability in remote areas. Typically, industrial biopesticides cannot be produced locally and therefore often have to be imported. This can often result in higher prices than for chemical pesticides.
- Lack of local adaptation of the microbes: biopesticides such as microbials require an adaptation process to the local environmental conditions.
- For many industrially produced fungal products, the germination time may be longer.

Advantages and Disadvantages of Local Small-Scale Production of Fungal Biopesticides

The advantages of home production units are:

- Benefits from working with local microbial strains: Costa Rica is characterized by a wide range of environmental conditions that create a great diversity of ecosystems where strains of beneficial microorganisms as potential control agents for agricultural diseases and pests can be found. Our work with native strains of microorganisms has demonstrated that these locally adapted strains tend to be more stable in the environment, and often give better results in the control of diseases and insect pests. Additionally, screening and selection among local strains may permit to select strains of higher effectivity and specificity towards controlling a particular pathogen or insect.
- Reduced costs because of reduced requirements for equipment.
- Permits increased frequency of applications because fresh material is continuously available.

The disadvantages of home production units include:

- Higher risks of contamination since these methods involve more manual manipulation of materials. It is estimated that the percentage of loss lies often between 20 and 25%.
- Difficulty of quality control because the special equipment required for quality control, particularly microscopes and hemacitometers ("Nebauer chambers"), is costly and often not affordable for small farmers.

- Since the production method depends on solid media, the final product has moisture contents above 10% which requires the product to be used immediately or stored in refrigeration.
- Limited shelf life of the final product: the final product must be stored at temperatures between 1°C and 10°C; however, under these conditions the products cannot be stored for extended periods of time (often exceeding 6 weeks) without affecting their quality.
- Labor, time and knowledge intensive: the process is labor intensive, time consuming and requires specialized personnel.

Quality Control for Biopesticides Produced In Home Production Units

In both methods, home and industrial production, pre-established norms and techniques contribute to the quality control of the biopesticides. However, for home production units the quality control must be even stricter because of the increased risks of contamination from manual manipulation. Thus it is essential to:

a. Screen to select the most promising strains for improvement.
b. Select culture conditions that maximize the pathogenic potential of the microorganism to be isolated.
c. Develop formulations for maximum product stability during storage and after application in the field.
d. Monitor the quality of the raw materials, production processes, final product, storage, transportation conditions and methods for implementation.

As a result of the training provided at INA's Center in Organic Agriculture, approximately 20 homemade laboratories have been established in different parts of Costa Rica. These are supplied with high-quality biological material (strains) and methodological backstopping for quality control. The quality control procedures provide norms of asepsis in the laboratories, and guidance for adequate use and maintenance of the lab equipment, as well as for the maintenance of microbial strains. Recommendations are given on: appropriate solid cultivation media, adequate concentrations of inoculum, temperature, relative humidity, photoperiods, oxygen availability, length of production cycles, and on procedures for drying, storage and transportation. Furthermore, farmers are advised to screen their native strains through tests of antagonism, pathogenicity and severity.

During production the following aspects are evaluated:

- Purity: samples are taken, processed and observed under the microscope to analyze the particular structures of the microorganism being studied (conidia, conidiophores and mycelium). Also, microbial populations are monitored under specific culture environments to detect contaminants.
- Conidia concentration: the counting is performed using the Neubauer camera using international standards as reference for each microorganism.
- Viability of the conidia: samples are diluted in water until obtaining a minimum of 100 conidia. These samples are transferred to concave slides that provide specific growth environments, and are then placed in growth chambers under controlled temperature and moisture conditions.

- Germination time of the conidia: the germination rates are correlated with the environmental conditions to determine the period of maximum germination.

To assure maintaining the best quality possible for field application, training sessions on product handling are given to the personnel involved in transporting, preparing and applying the biopesticides in the field.

Conclusions

Both the industrial as well as the home production of biopesticides are subject to advantages and disadvantages. The choice will usually depend on the availability of economic resources. The success of the production depends on having the adequate biological material available, adjusting production times, and performing strict quality control during each stage of the process, all the way to field application.

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Development, Production and Use of Biopesticides in Cuba

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Abstract
Within Latin America, Cuba is the country with the highest levels of production and use of bioproducts. The increasing concern of consumers about chemical residues in food has triggered increasing interest in the production and use of biopesticides. Supported by a strong institutional network of research and development, Cuba has implemented an industry of biopesticides that combines small-scale home production units, with large-scale and state of the art technology compounds. This combined production mode has provided enough biological output to replace most conventional chemical inputs for agriculture.

Present status of the Use and Commercialization of Biopesticides in the World

The use of chemical pesticides in agriculture is an important concern to people because of the high level of contamination in soils, food and the environment. The number of ecologists asking for the elimination of chemicals is increasing every year. In fact, the consumption of organic products has been spreading widely in the last years, despite their often higher price than for products treated with chemicals. This trend encourages the development and use of biopesticides, in agreement with the new concepts of organic and sustainable agriculture. However, two of the main obstacles for the expansion of this field are insufficient production of biopesticides and insufficient experiences about the proper use of these products. Overcoming these obstacles represents the principal challenge for the industry (Harris, 1997; Lisanky, 1993).

The global market value of biopesticides ranges between US-$ 100 and US-$ 150 million per year, representing less than 2% of the total pesticide use at present. The relatively high prices of biopesticides, the specificity of some products, and the lack of information and promotion are current limitations to expand the sales.

Among the biopesticides, more than 90% of the products are derived from *Bacillus thuringiensis* (*Bt*). The production of many bioproducts derived from other organisms such as fungi and viruses is limited by technological and economical reasons. In the future, the development of new technologies to obtain more effective, cheaper and more stable products will have to receive increased attention.

For over 30 years, Cuban institutions have developed their own products to guarantee product specificity, efficacy and low price (Fernandez- Larrea, 1997 and 2001). As a result Cuba is the country in Latin America with the highest levels of production and use of biopesticides.

Historical Overview of Cuba's BP Production

In Cuba, the development of low-technology production techniques at industrial scales permitted to provide a stable supply of biopesticides, which allowed to replace high-input chemical agriculture by production systems which require very low levels of chemicals, and in some cases, none at all. Starting in 1960, the country began to import and use some *Bt* products to control lepidopteran pests of economically important crops such as vegetables and tobacco, obtaining excellent results (Rijo, 1997).

Later, Cuba began to produce some *Bt* products using low technology methods in liquid culture media under static conditions. Research at the Plant Protection Research Institute of Cuba focused on the search for new strains of *Bt* and entomopathogenic fungi and on the development of low technology methods to increase the production through simple and inexpensive systems.

Between 1970 and 1980, the Institute developed technologies for the massive reproduction of *Bt*, and of the fungi *Beauveria bassiana* and *Metarrhizium anisopliae*. These fungi have been reproduced on solid media using different kinds of grains such as rice and maize. The recovery procedure consisted of collecting the grains with the conidial mass of the fungi. These simple methods permitted to spread production nation-wide. Although the small bio-laboratories did not have the best conditions, they were useful to introduce farmers to the use of biopesticides. This was the first step in the development and use of biopesticides in Cuba.

The successful research between 1980 and 1988 and the widespread farmer acceptance of biopesticides and other biological control agents motivated the establishment of a National Program of Biological Control supported by the Ministry of Agriculture and the Centers for Reproduction of Entomophages and Entomopathogens (CREE). Over that period, new technologies to reproduce other *Bt* strains against mites, nematodes and coleopterans were introduced. In addition, technologies were implemented for the massive production of antagonistic fungi like *Trichoderma harzianum* for disease control. Furthermore, new strains of *Verticillum lecanii* for White fly control and strains of *M. anisopliae* and *B. bassiana* that are active against ants and thrips were isolated and the technology for their reproduction was developed. The technologies for the reproduction of viruses and nematodes were also refined.

In 1991, three new fermentation plants, each with a capacity of 120.000 liters per year, were built to produce *Bt* products using submerged culture techniques. These facilities allow to obtain different types of *Bt* products that are effective against many pests, including lepidoptera, mites, nematodes and coleoptera. The products are presented as aqueous concentrated fluids with good stability (up to 6 months at room temperature). Presently, Cuban laboratories produce four *Bt* products and four fungal products (Table 1).

Table 1. Biopesticides produced at large scale in Cuba in 2003.

Poducts	Pest	Principal Crops
Thurisav 3 (*Bt*)	Nematodes	coffee, banana and fruits
Thurisav 13 (*Bt*)	Mites	citrus, banana and vegetables
Thurisav 24 (*Bt*)	Spodoptera and other lepidoptera	maize, vegetables
Thurisav 26 (*Bt*)	Heliothis and other lepidoptera	tobacco,vegetables
Basisav (*B. bassiana*)	Coleoptera and lepidoptera	sweet potato, beans and vegetables
Metasav (*M. anisopliae*)	Coleoptera and lepidoptera	coffee, potato, vegetables and rice
Vertisav (*V. lecanii*)	White fly, lepidoptera and ectoparasites	beans, tomato and other vegetable pastures
Tricosav (*Trichoderma* spp.)	Phytopatogens, fungi	various crops, vegetables, tobacco and coffee

Chronology of Biological Control in Cuba

1968 – 1975:
- Assays with commercial foreign products.
- Field application tests to control important pests.
- *Bt* formulations used extensively in crops as tobacco, tomato, cabbage and pasture.

1976 – 1982:
- Isolation and selection of native strains of *B. bassiana*, *M. anisopliae* y *B. thuringiensis*.
- Development of production methods. Small-scale production in plant protection labs.
- Studies of effectiveness under laboratory and field conditions.
- Training of specialists in the different provinces.

1983 – 1987:
- New products and upgrading of the production capacity in Cuba's provinces.
- Medium-scale production for *B. bassiana*, *M. anisopliaea* and *B. thuringiensis*.
- Farmers receive training in biopesticide use.
- Biopesticides applied in state enterprises and private areas.
- Need for larger amounts of biopesticides.

1988 – 1992
- Establishment of the National Program of Biological Control.
- Construction of three fermentation plants: two in Havana and one in Santi Spiritus.
- Establishment of 220 CREE (production centers of entomopathogenic and entomophageous organisms) with improved capacities

From 1992 to the present:

- Continuous operation of the three fermentation plants to obtain *Bt* products from different *Bt* strains.
- Collaboration among over 20 research institutes and many researchers to further the development of biopesticides within the framework of the Agricultural Biotechnology Program of the Ministry of Science and Environment. The most important results were:
    1. New entomopathogenic and antagonistic strains of bacteria, fungi and nematodes were obtained.
    2. Development and implementation of improved protocols for solid state fermentations for mass production of entomopathogenic and antagonistic fungi.
    3. Development of *Trichoderma* products against many important phytopathogens in important crops.
    4. Improved technology for virus production.
    5. Isolation and selection of new strains for weed control.
    6. New products for the biological control of ants, mites, cockroaches, ticks and nematodes.
    7. Introduction of toxicological tests, molecular studies, and metabolite assays to characterize microorganisms used for biological control
    8. Approval of procedures for the registration of biopesticides based on biosafety and environmental impact protocols.
    9. Some patents were presented, and many studies were conducted about the formulation, packaging, storage and economical impact of bioproducts.
    10. Improved technical protocols for *Bt* production. The construction of the INISAV pilot fermentation plant concluded.

Cuban technicians have also worked on the fermentation process for certain entomopathogenic fungi to obtain conidial biomass formulated as a dry powder. However, currently there are no projects in this area because of their high cost and the poor product stability in storage. A new product "Giuticid", derived from *Pseudomonas fluorescens*, was developed and its effectiveness against phytopathogens and weeds has been demonstrated. Currently, bionematicides based on *Corynebacterium* are under development. With the goal of future marketing of Cuban products in other countries, Cuban laboratories continue to search for new microbial strains and better production technologies to lower costs and increase the effectiveness of the products.

During the past decade, biopesticides began to be used for urban agriculture where many synthetic chemicals are not allowed. The evolution of biopesticide technologies has allowed for a marked expansion of organic production in Cuba (Vasquez, 2001).

Achievements, Limitations and Challenges for Cuba's Biopesticide Production

Cuba's extensive work on biopesticides has allowed the following advances (MINAGRI-CNSV, 1998, Varios, 2003):

- Cuba's biopesticide program has highly qualified personnel.
- Farmers are confident about the use and effectiveness of biopesticides.
- Cuba has more positive results than most countries in the region regarding biopesticide production.

However, there are also limitations and challenges:

- Biodiversity as a source of bioproducts is not exploited widely.
- Some production technologies must be improved and optimized.
- Production costs are high.
- Recovery and formulation of the final product have to be improved for consistent quality and longer shelf-life.
- The present work on toxicological testing will have to be expanded despite its high costs.
- Goal for the future: commercialization of products to other countries.

At present, Cuba has more than 150 production centers of entomopathogenic and entomophageous organisms (CREE) throughout the country's 14 provinces (INISAV-CNSV, 1998). In addition, there are three fermentation plants which mass-produce eight types of biopesticides (Table 1 and Figure 4).

Since 1992, the country has reached a stable production level of about 2000 metric tons per year surpassing the total quantity of biopesticides produced between 1989 and 1991 (Figure 1). Since then, Cuban producers applied this output to about one million hectares per year (Figure 2), resulting in an important reduction of agrochemicals' use (Figure 3).

The three fermentation plants mentioned above produce more than 25% of *Bt*'s total production, which allows to cover the annual needs of biopesticides for about one million hectares.

Currently, with the support from NGOs and the Cuban government, new production centers are being constructed to obtain high quality products that meet biosafety standards. These centers include a new fermentation plant with increased capacity and a fermentation tank with a 500 liter capacity that has been installed at the INISAV Pilot Plant in order to increase the production for field tests (Figure 4). For the training of additional personnel, specialized courses, seminars and post-graduate programs on biopesticide technologies are offered in collaboration with various universities and research institutes. In the field, basic courses and demonstrations help increase the farmers' knowledge about biopesticides.

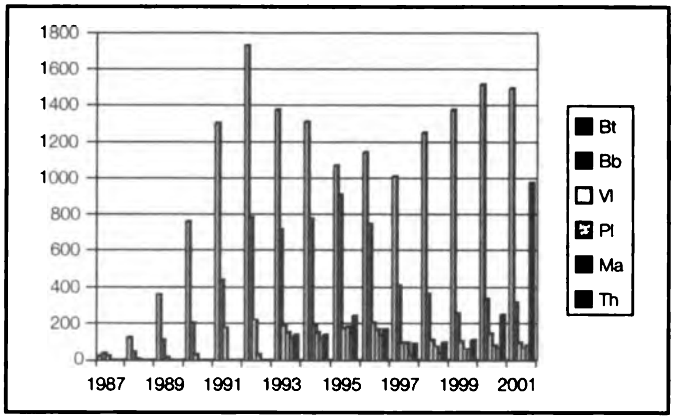

Figure 1. National production of biopesticides (metric tons) (*Bt* = *Bacillus thuringiensis*, Bb = *Beauveria bassiana*, Vl = *Verticillium lecanii*, Pl = *Paecilomyces lilacinus*, Ma = *Metarrhizium anisopliae*, Th = *Trichoderma harzianum*)

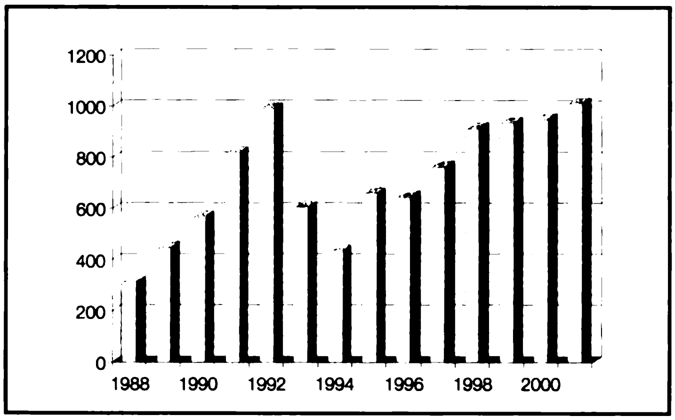

Figure 2. Cultivated area treated with biopesticides (1000s of ha)

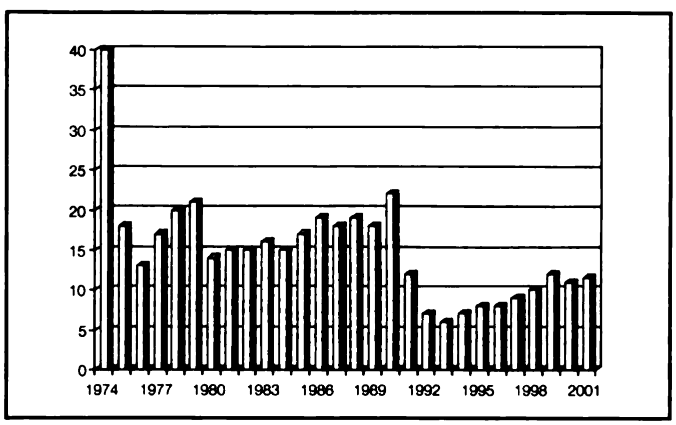

Figure 3. Agricultural area cultivated with synthetic agrochemicals (1000s of ha)

Conclusions

The development and successful use of biopesticides in Cuba comprises more than three decades. The effectivity of biopesticides has allowed to substitute for a large portion of synthetic agrochemicals. In additon, the relatively low toxicities of biopesticides allow them to be used for organic agriculture and, increasingly, for urban agriculture where many synthetic chemicals are not allowed.

For the future, the most important challenges for Cuba's biopesticide industry are:

- The development of technologies to obtain more effective, stable and cheaper biopesticides.
- To convince farmers and other users about the advantages of using biopesticides.

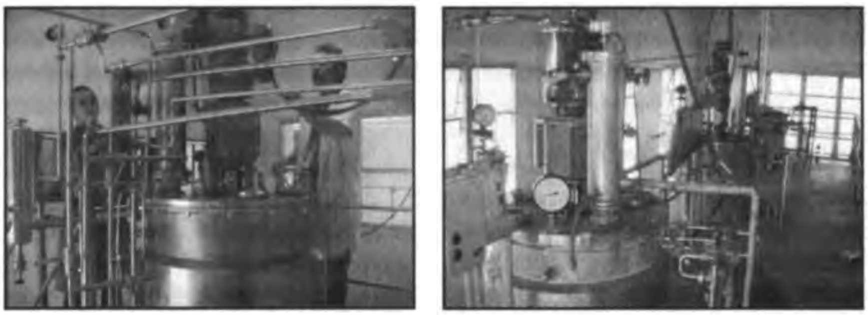

Figure 4. Industrial productions centers in Cuba.

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Biopesticides in Cuban Agriculture

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Abstract
The transformations in Cuba's agricultural production over the past four decades have been driven by a process that has promoted the diversification of cropping systems and the production of crops in smaller fields and in multi-cropping systems. Nationwide, the development of efficient biological control methods and the establishment of production facilities for biological control agents have allowed to reduce the use of synthetic agrochemicals by more than 75%. In recent years, the spread of urban agriculture where many synthetic chemicals are not allowed has contributed to a growing interest in biological control options. Over the past decades, these transformations have had a great economic, social and ecological impact.

Historical Changes in Cuban Agriculture

Cuban agriculture has experienced significant changes over the past 44 years in correspondence with the evolution of modern agriculture: first, through the development of intensive agricultural units, and later through the development of production systems which incorporate components of sustainable production, environmental protection, and, recently, tourism and the production for export markets.

Land property and land use schemes in Cuba suffered profound changes in the 1960s with the promulgation of the Agrarian Reform Law in 1959 and 1963. This legislation contributed to diversify both public and private production. Two important organizations, the Agricultural Production Cooperative (APC) and the Credits and Services Cooperative (CSC), were born amid the emergence of the cooperative movement. These production units facilitated the introduction of new technologies for agricultural production. Since 1983, further transformations took place in the agricultural sector with the creation of the Basic Units of Cooperative Production (BUCP), which were launched to provide farming areas to new growers. The process still continues until today.

Parallel to this development, an extensive network of research centers and experimental stations has been created and strengthened over the past 40 years to provide the scientific and technical foundations for the development of Cuban agriculture.

The Cuban Plant Health System

The Cuban plant health system, organized by the government since 1973, has facilitated the application of a pest management policy based on pest monitoring and on the application of diverse control strategies, where the use of chemical pesticides is just a component and not the dominant tendency. The system consists of 14 laboratories of plant health (LAPROSAV as Spanish acronym) and 67 stations for plant protection (ETPP) distributed throughout all provinces. Furthermore, there are 190 reproduction centers (CREE) of entomophagous and entomopathogenous organisms and three industrial facilities for the production of biopesticides, which play a fundamental role in the National Program of Biological Control. This plant protection network, along with the web of national research centers and universities (INISAV, CENSA, IIFT, IIA, INIFAT, UNAH, UCL, among others) guarantees an appropriate infrastructure suitable for the socio-economic conditions of the country. The outstanding educational level achieved by Cuban technicians and producers, which facilitates the implementation of new technologies and the efficient transfer of know-how offered by training programs, is a clear indicator of this organizational effort. The results obtained through extensive IPM research are disseminated by Territorial Stations of Plant Protection (ETPPs).

The creation of the national plant health system and the implementation of a National Program on Biological Control in 1988 have had an important impact on agricultural production by reducing the consumption of chemical pesticides by more than 75% (Figure 1). Other factors that have contributed towards a stronger agro-ecological focus in pest management are the increasingly independent handling of phytosanitary problems by farmers and a focus on the conservation of natural enemies. Parallel to the reduction of the use of synthetic pesticides, the use of biological control mechanisms became more an more widespread. Presently, more than 900.000 hectares of agricultural land in Cuba are treated each year with biological means. (Figure 2).

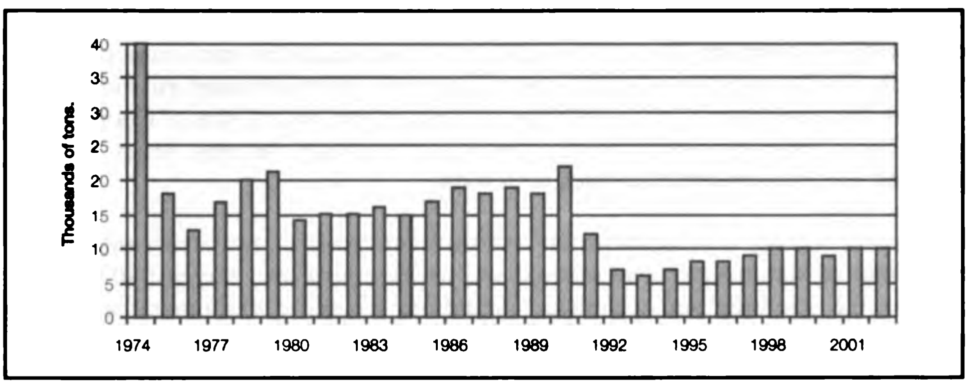

Figure 1. Synthetic pesticide use since 1974 in Cuba. Note the drastic decline after the creation of the plant health service in 1988.

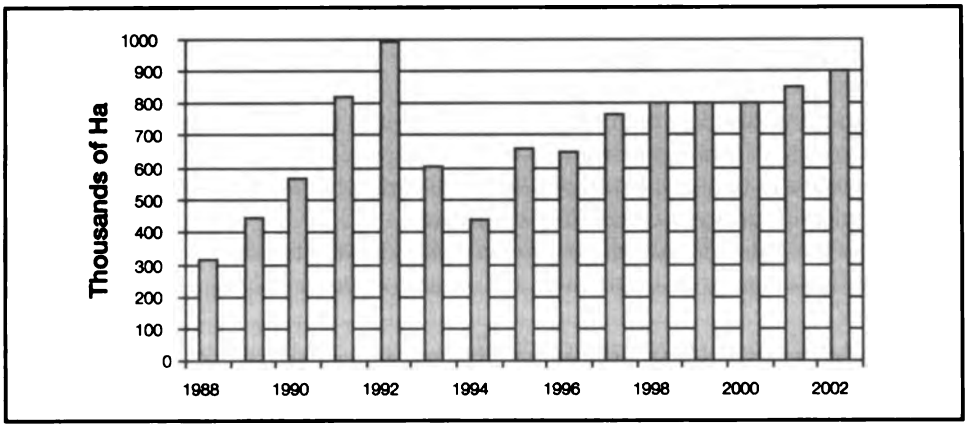

Figure 2. Total area treated with biological pest control means in Cuba.

Strategy and Advances in Plant Health Research

Since the 1960s, the country has dedicated important resources to develop a research branch specialized in plant health. This research effort is reflected in the creation of several scientific centers, the training of personnel and the organization of integrated scientific and technical programs.

Plant health research has continued to grow since the late 70s, when the foundations of current developments were laid. The most important results were:

- Development of new diagnostic techniques for the identification and characterization of noxious organisms.
- Studies on pest ecology and epidemiology.
- Studies on the economic thresholds for pests.
- Development of reliable prediction methods, as well as the study and validation of control methods.
- Promotion and development of effective techniques for the production of biopesticides and for the reproduction of entomophages.
- Expansion of analytic methods to monitor the fate of pesticides in crops, export products, water and soil.

These results have allowed the implementation of an Integrated Pest Management (IPM) approach that improved the integration among biological control, cultural practices, plant breeding and selection and other methods used against pests. The long-standing history and success of the multiple programs of IPM and crop protection put Cuba in a privileged position within the Americas regarding the massive use of these technologies.

The IPM approach in Cuba has generated programs directed at controlling many diseases and pests, including:

- Black and yellow Sigatoka (*Mycosphaerella spp.*) in bananas and fruits.
- Nematodes (*Meloidogyne spp.*) in coffee and vegetables.
- Nematodes in bananas (*Radopholus similis* and *Meloidogyne spp*).
- Red mites (*Tetranychus tumidus*)in banana.
- Yellow tea mite (*Polyphagotarsonemus latus*) in vegetables.
- Whitefly-geminivirus in tomato and bean (*Bemisia tabaci – TYLCV, HTV, BGMV*).
- Coffee leaf miner (*Leucoptera coffeella*).
- Coleopteran (*Cylas formicarius elegantulus*) of sweet potato.
- Mealybugs (*Planococcus spp, Pseudococcus spp*) on coffee.
- Cabbage moth (*Plutella xylostella*).
- Corn moth (*Spodoptera frugiperda*).

Furthermore, programs have been designed to control pests in tobacco, citrus, rice, sugar cane, potatoes, and in organic production systems in urban units. However, despite the decrease of crop losses to pests and the better quality of products as a result of the sustainable agriculture approach, not all plant health objectives have been met. At the forefront of scientific research, there is a move towards a wider use of advanced molecular and biotechnological methods for improved plant health. This includes generating resistant varieties through genetic engineering, modernizing internal and external quarantine systems, and improving participatory farm management programs; further aspects are the use, conservation and reproduction of natural enemies, the optimization of technologies for high-quality biopesticide production, as well as the promotion of information systems on plant health.

Registration, Biosafety and the Environmental Impact of Biopesticides

Cuba has a strict protocol on biopesticide registration that incorporates criteria from FAO and other international regulatory agencies, as well as its own experiences. This document was validated and approved by the National Center of Biosafety and Environment. To meet the biosafety standards and guarantee the safety of the production procedures, it is necessary to meet all of the established regulations relating to products, production centers and their personnel.

The quality of the production processes and their output is controlled in each production center under the supervision of the province's laboratories of the National Institute and National Center of Plant Health. These institutions are in charge of implementing the standardized procedures to control the quality in all of the nation's production centers.

The environmental impact of biopesticides is assessed regularly and programs are implemented to identify new natural enemies and to monitor the persistence of microorganisms in the field. Today, the overall safety of bioproducts is widely accepted by the Cuban public which receives updated information about the advantages of biopesticides through the mass media and, more directly, through the extension service.

Conclusions

The development of biopesticides in Cuba has a history of more than four decades. The positive experiences of implementing agro-ecological methods of pest prevention and control have allowed to reduce the use of synthetic pesticides by more than 75%. Today, an extensive institutional network dedicated to plant health supports the Cuban producers in all provinces of the country.

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The Production of a Neem-Based Insecticide in the Dominican Republic

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Abstract
Despite its various insecticidal properties, medical benefits and veterinarian uses, the marketing of neem seed oil is hindered by three obstacles for small producers: first, the high registration costs; second, the lack of laboratories capable of performing quality control analyses and third, the information requirements for biopesticide registration which were developed for synthetic pesticides.

Driven by a promising market, large companies with the economic capacity to do large-scale marketing and to meet the registration regulations dominate the market and outperform small Dominican producers of neem-based insecticide.

Introduction

Neem (*Azadirachta indica* A. Juss.) is a tree with very interesting properties. Almost all of its parts are bitter and contain active substances that act as insecticides. Way before the development of synthetic insecticides, farmers in India used these substances for vegetable protection. But neem was also known for its antiseptic and healing effects in human and veterinary medicine.

The introduction of synthetic wide-spectrum insecticides of quick efficiency and apparently easy application, as well as the development of modern medicine in tropical countries, displaced neem as a source of natural products, and for many years this tree was forgotten. However, the negative secondary effects of many synthetic insecticides rekindled the search for alternatives that do not harm the beneficial fauna and the environment in general. As a result, research about neem properties was renewed in the 1980s.

During the past 20 years, 25 different active ingredients have been isolated, among them at least nine affecting the growth and the behavior of insects. The typical ingredients of *Azadirachta* are triterpenoides, also called 'limonoides', among which the derivatives of *azadirachtin*, nimbin and salanin are the most important substances, each affecting different phases of the growth of the insects.

Small-scale Commercial Neem Manufacturing in the Dominican Republic

FAMA (*Fundación Agricultura y Medio Ambiente*) is a non-profit foundation, which is processing neem extracts in the Dominican Republic. neem products are distributed by an independent company called EXPROECO (Exportadora de Productos Ecológicos C&A).

The original concept was that a farmers' association should provide the processed neem raw material, and in return, FAMA would provide them with the neem pesticides for distribution among the members of the association. However, this concept failed. Due to the tedious process of preparing and applying aqueous extracts of neem kernels (NKWE) to crops and the high labor costs, hardly any of the 200 cooperating farmers applied the method. As an alternative, FAMA developed formulated neem oil, which was well accepted.

Production Process

Seed Collection and Treatment:

Neem seeds are predominantly collected and wet processed by groups of women and children in the south of the island. The neem fruits are depulped and the seeds are washed and dried. This manual process usually requires three to four days. Once or twice a week, the pre-dried seeds are collected and transported to the installations of FAMA where they continue to be dried under shade. However, since no artificial dryer is available, there is a great risk that the seeds will be affected by mildew in the humid tropical climate.

Production of Ground Neem Seeds:

Neem seeds are ground in a hammer mill (max. capacity: 500 kg/h). Afterwards the seeds are packed in polyethylene bags of 50g, 250g, 1 kg or 2 kg size, which are then sealed and packed in cardboard containers.

Production of Neem Oil:

Neem seeds are hulled in an electric thresher and afterwards pressed in an oil expeller (Comet/Monfort, Germany). Two kg of neem seeds gives about 1 kg of neem kernels after the shell is removed. At first pressing, 1 kg of neem kernels produces 260 ml oil and 740 g neem cake. Therefore, the production of one liter of neem oil requires approximately 4 kg of neem kernels or 8 kg of neem seeds. Additionally, FAMA imports neem oil and blends it with the locally produced one. Afterwards the oil is bottled and packed in units of 50 ml, 100 ml and 1 liter or 200 L.

Manufacture of Formulated Neem Oil:

The following ingredients are necessary to manufacture formulated neem oil: raw neem oil, Tween 60,Cosmoflux 411-X, isopropyl alcohol, and distilled water. The combination of these ingredients results in the formulated neem oil called NIMOIL-AZ 0.20 EC with an *azadirachtin* content of 0.05%. This process takes place in a stirrer, which requires about one hour for the formulation of 100 l. The oil is bottled in 100 ml, 1 L, 3.5 L and 200 L units.

Manufacture of Neem Cake:

The cake is the by-product of oil pressing. It is processed in a hammer mill and afterwards packed and sealed in plastic bags of 20 g, 250 g, 1 kg and 2 kg.

Quality Control:

Currently, no laboratory in the Dominican Republic offers a routine analysis of the *azadirachtin* content. Therefore, quality control is limited to checking whether the product is free of impurities and whether the quantities are bottled correctly.

Registration of Neem Products:

In the Dominican Republic, the legal framework for the import and handling of pesticides is laid down in the regulation No. 311 on trading of agricultural inputs and complemented by regulation No. 1390 (6.10.1972). The Ministry of Agriculture is the responsible national authority. For the registration of botanical insecticides, there is a similar set of regulations as for chemical products. The following documents are required to obtain the registration:

- Registration certificate for the processing company.
- Regency certification.
- Chemical composition and toxicity of the product.

Only the formulated neem oil needs a registration, while ground neem seeds or neem cake do not require it.

For export, FAMA must register the products with the importing countries. This is the major constraint for the export of neem products. Although FAMA's neem pesticides are cheaper than those of many competitors, authorities in other countries often obstruct or delay the import especially when other neem pesticides are registered in the country. The high registration costs do not permit FAMA to obtain the required authorization in importing countries. Given increasing enforcement of plant protection regulations, FAMA will be more restricted to the national Dominican market in the future.

Economic Analysis of Production and Processing

In 1998, a study of the economics of neem production and processing revealed that even in a very good year with high production, there would be a loss for FAMA of US$ 20,326. Based on this analysis, the specialist recommended to increase the price of the products, to increase the production, and to invest in a neem processing plant to generate added value. Of course, these recommendations are only relevant if there is a permanent market and if registration was reasonably cheap.

Principal obstacles

Production and Processing

For the elaboration of a natural product, the main difficulty is to obtain a stable supply of uniform-quality seeds since both the market and the registration of the product demand a standardized and stable product. The market also requires a high and stable concentration of *azadirachtin*, the main active ingredient. Meeting these conditions is difficult and small factories often cannot afford it.

On the other hand, the comparatively high wages of US$ 7 to US$ 8 per day for Dominican workers combined with the current rather inefficient extraction technique, leads to relatively high prices for neem products of Dominican origin. Consequently, the manufacture of neem-based pesticides from Dominican raw material is not profitable under the present economic conditions.

Commercialization

In order to sell an insecticide it is necessary to register it. However, for registration of natural products, Latin American or European countries require the same procedure as for the registration of chemical products. Since a natural product such as neem oil has many active ingredients, it is nearly impossible to fulfill all the requirements without transforming the product too much. Furthermore, the required analyses are often prohibitively expensive for small enterprises. Considering these factors, a small production unit would not have access to this formal market and would not have the option of marketing its product in an appropriate way. The phytosanitary controls and the requirements for the registration only allow large companies to register a pesticide.

Many formulated neem products in the Latin American market are alcoholic extracts that are concentrated to an *azadirachtin* concentration of 3%. Many of these products come from the USA with the completed registration and with the necessary funds for large-scale promotion. The initiatives developed in the Dominican Republic, Nicaragua, Cuba and Venezuela have prepared the field successfully, so that these products are well accepted. However, currently US-formulated neem products flood the Dominican market and displace the local products.

Inadequate Vision

The lack of clear orientation regarding the production and commercialization of neem products has limited the impact of the work supported by international technical organizations. In the past, most of the projects concentrated on scientific research, but did not address neither the registration requirements nor the farmers' needs of a stable supply of the processed products.

Conclusions

There is no doubt that neem products are an effective alternative for many chemical products. Global markets show a tendency towards concentration of processing and marketing capacity in the hands of a few multinational companies with enough economic power to manipulate the markets to their convenience. This tendency seems to be the same in the market for organic products and inputs. The most serious limitation for neem products is commercialization. Given the differences in the organizational capacity in formulation, documentation and marketing, it is not likely that small institutions with simpler products will be able to access the market in similar conditions as large chemical companies. In order to allow that the activities and impact of these small companies could grow beyond pure training and extension work, it is necessary to look for possibilities so that they can also participate in the benefits of commercialization. The requirements to make this possible include:

- To inform the offices in charge of the registration of pesticides in the different countries about the characteristics of the natural insecticides with proven efficiency. This information should lead to implement a shorter and cheaper process of registration with reduced requirements for this type of substances.
- To search for alternative markets where simple products such as the neem seeds and neem cake can be sold without an official registration.
- To create an organism or an international network that supports small institutions in the following fields: (1) access to toxicity analyses at affordable prices, (2) improvement and standardization of the formulation of the products, (3) backstopping on the efficient design and organization of the production, and (4) commercialization and development of alternative neem products.

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The use of Neem-Based Insecticides in the Dominican Republic

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Abstract
Contrary to many countries in Asia and Africa there is no long-stading tradition of using the neem tree in Latin America. The plant was recently introduced and disseminated in many countries in Central and South America including the Dominican Republic and Nicaragua. While the planting of neem trees was first promoted by US church groups as shade trees in Haiti, the field station of the supra-regional project "Production of natural insecticides from tropical plants" in the Dominican Republic established about 500,000 neem trees between 1987 to 1995. The trees were planted along roadsides, irrigation canals and small plots of fallow land with the purpose of using the seeds as a botanical insecticide. At the same time, the project imported neem seeds from Haiti to start a training program on processing and use of a neem water extract.
Since 1992, a collection system was started in the Dominican Republic, based on village trades undertaken mostly by women. The raw material was bought according to certain quality parameters. The project improved infrastructure and equipment for processing the neem and for producing aqueous extracts, and made the products available to the farmers.

The Concept of the Dominican Neem Project

In 1987, the Dominican agricultural service with support from GTZ, Germany, created a field station to investigate the use and acceptance of a simple neem insecticide for horticultural production. Since then, the extension service has worked with 200 farmers in the South of the country. The trainers of the project, visiting the farmers once or twice per week, supplied ground neem seeds and a simple equipment for producing the water extract and provided guidance for elaborating and using the extract. The project focused primarily on farmer adoption of home-made neem extracts as a botanical insecticide rather than on production, promotion, and registration of commercial neem products for internal and export markets. However, the initial idea that the farmers would harvest the seeds from their own neem trees and that they would do all the processing by themselves had to be substituted by one in which the ground seeds were provided by the women in charge of harvesting. When the project concluded, most of the farmers had stopped using the neem insecticide because they were not prepared to do the whole process of producing, harvesting, depulping and processing the seeds. Due to the laborious, therefore relatively expensive, process of preparing and applying the aqueous extract, the farmers preferred a liquid processed product similar to chemical insecticides that would have a stable supply in local commercial centers.

The New Concept of FAMA

When the GTZ project concluded, FAMA, a Dominican non-profit foundation, took over the neem processing and tried to improve the production conditions oriented towards commercialization, including in international markets. As a result, the following products were developed:

- Ground neem seeds and neem cake in different presentations for export to Europe; these products are not accepted by Dominican farmers.
- Formulated neem oil: this product substituted the water extract in the Dominican Republic and is registered as an insecticide.
- Other products including a repellent against mosquitoes and products for skin care.

The main idea was to use more of the raw materials of the neem tree to reduce the high production costs of the insecticide and thus make its production more efficient. To increase the distribution, FAMA offered its simple neem products on the international market, mainly in Germany.

Market Potential for Neem Products

In the Dominican Republic, it is a common practice to apply synthetic insecticides. All pesticides are imported, except for locally manufactured neem byproducts. The Ministry of Agriculture is in charge of supervising the import and registration of the insecticides. In order to enhance agricultural production, all imported agricultural inputs (including insecticides) are tax-free,. However, middlemen usually have a mark-up between 80% to 100% of the wholesale price and thus increase the costs considerably. IPM systems have been introduced to reduce the problems caused by indiscriminate use of wide-spectrum pesticides, but are not available for all crops and are not applied by small rural farmers.

FAMA's neem-based pesticides are most effective against the following groups of pests of economic importance: larvae of lepidoptera, aphids and whitefly. They compete with the following chemical pesticides: M.T.D. 600, Decis, Tamaron, Lannate, Monitor, Diazinon, Thiodan, Eviset, Danitol, Pegasus, Thionex, Ekatin, Javelin and Dipel.

In the past, most of the synthetic insecticides were cheaper and easier to apply than the neem oil and the water extract. Nevertheless, these insecticides cannot be compared directly because they are affecting different pest species. While synthetic insecticides can be applied on all sorts of crops, neem products are currently used only in high-priced niche markets such as vegetables, fruits and flowers. Using neem is only economically feasible within some IPM concepts and where no synthetic insecticides are allowed like in organic farming. Many farmers using neem are supported by international projects.

Today, most of the small-scale industrial production of neem products in the Dominican Republic is oriented towards export markets, especially to Europe. While synthetic pesticides are distributed from importers to retailers, neem products usually are not sold via the normal agriculture supply system. One exception is the wholesaler LIGA. The main reasons are the lack of funds for the promotion and the smaller mark-up for the retailers if it is a Dominican product (see Table 1).

Table 1. FAMA's sales of neem products (in kg and L)

Year	Product	National market	International market
1995	formulated neem Oil	2,182 l	
	Ground neem Seeds	500 kg	8,095 kg
	Ground neem Cake		420 kg
1996	formulated neem Oil	1,141 l	2,064 l
	Ground neem Seeds	800 kg	6,091 kg
	Ground neem cake	142 kg	718 kg
1997	formulated neem Oil	1,716 l	7,899
	Ground neem Seeds	91 kg	3,766 kg
	Ground neem Cake	42 kg	3,747 kg
1998	formulated neem Oil	1,500 l	2,776 l
	Ground neem Seeds	50 kg	11,195 kg
	Ground neem Cake		4,941 kg
1999	formulated neem Oil	1,860 l	7,558 l
	Ground neem Seeds	182 kg	7,010 kg
	Ground neem Cake	6 kg	4,413 kg
2000	formulated neem Oil	1,314 l	9,600 l
	Ground neem Seeds	31 kg	10,740 kg
	Ground neem Cake	104	5,200 kg
2001	formulated neem Oil	4,464 l	4,000 l
	Ground neem Seeds	189 kg	13,798 kg
	Ground neem Cake	9 kg	400 kg
2002	formulated neem Oil	1,160 l	
	Ground neem Seeds		6,515 kg
	Ground neem Cake		1,093 kg

Challenges for the Future Expansion of the Dominican Neem Industry

Production:

- The high labor requirements for the collection of the seeds and the old and inefficient technology for grinding the seeds and for extracting the oil makes the Dominican seeds and neem oil relatively expensive as raw materials for the insecticides.
- Oil and neem products from Asia are cheaper and better industrialized.
- It is very difficult to get high quality seeds.

Registration:

- In almost every country, it is necessary to register an insecticide before selling it. This registration process is typically the same for biological or chemical pesticides.
- For small enterprises or organizations, it is nearly impossible to assume the registration costs for an insecticide to be sold in the European or North American markets. This situation limits the international marketing of simple neem products.

Commercialization:

- Presently, biological insecticides like neem and *Bt* still cannot compete with cheap and wide-spectrum synthetic products.
- Normally, the use of a biological product requires training and advice from a professional salesman; While this information can be provided for standardized chemical products, this is not the case for the products of small producers which often vary in quality.
- The limited funds for promotion and an inefficient distribution system makes it very difficult to reach interested farmers.
- FAMA is not in a position to set up an effective distribution chain and pesticide distributors have shown little interest to manage the distribution.
- The best possibilities are in organic production, but in the Dominican Republic, the main organic production is for export bananas, cocoa and coffee. Unfortunately, the pests that neem products could control in these crops are not economically important.
- Organic horticulture, in most cases, depends on international projects and almost every time when the project finishes the use of neem stops immediately because of lack of assistance.
- Presently, a few large producers generate a welcome and secure demand for Dominican neem products. However, when these clients disappear, the cheaper products from Asia are likely to displace the local production.

Conclusions

The current situation does not allow Dominican neem products to compete with chemical insecticides or imported biological insecticides. Although the farmers are interested and would accept these products, the lack of an efficient distribution service severely hampers the availability of the products to many farmers. This situation can only be improved by drastic changes in the production methods and through the help from local governments and international agencies. In particular, the following changes are required:

- Production costs have to be reduced and new markets have to be identified. International agencies could provide contacts for joint ventures with European or American companies interested in technology transfer and promotional aid. Also, this could be fostered through creating an investment fund for improving production and promotion capacities of small enterprises.
- In order to reduce the costs of registration for small farmers, international cooperation agencies could help obtain registration documents and support the creation of a fund to finance toxicological and other required tests.
- Local governments through their Ministries of Agriculture should promote the production and the commercialization of local natural products by providing appropriate incentives and by recommending the use of these products through the national extension service and IPM programs.

Unless these recommendations are implemented, neem production in the Dominican Republic is likely to decrease and possibly could even disappear in the future, resulting in the loss of invaluable experiences gathered by local groups and small enterprises over the past two decades.

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Production of Biopesticides by the Columbian Company Laverlam

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Abstract
The production of biopesticides by Laverlam in Colombia began in the late 80's. Aiming at high yields of contamination-free biopesticides, the company investigated how to control key factors such as water and air quality, steam sterilization processes, and adequate personnel and equipment to ensure a high quality product. In the process, Laverlam allocated substantial resources to lab and field investigation to select appropriate strains. In a first stage, the production focused on *Beauveria bassiana* and *Metarhizium anisopliae*.

Introduction

The main goal of Laverlam as a producer of biopesticides is to provide high quality products that are free of contaminants and that are elaborated ad formulated under strict quality control standards in order to satisfy consistently the expectations of our clients.

The traditional method of reproducing fungi on rice cultures gives good yields, but the large volumes and bulkiness of the materials require large areas and the possibilities of contamination are very high. Laverlam's experience and infrastructure for the production of vaccines utilizing fermentation technology permitted to develop a system that provides high yields and that is free of contaminants. Special media were developed for growing fungi under fermentation conditions, and a two-stage system for producing spores was established. The first efforts were directed at producing *Beauveria bassiana* and *Metarhizium anisopliae* under this system. Several key factors were identified to prevent contamination risks during the production process: water quality, steam generation, sterilization, air quality, cleanliness of the working area, handling of material and equipment and personnel. The control of these factors is essential for a standardized production.

Biological Products and Production Standards of Laverlam

Laverlam produces seven biopesticides based on fungi for national and international markets (Table 1). The company has established successful application programs in several crops such as bananas, coffee, fresh-cut flowers, fruits and vegetables.

Table 1. Laverlam's supply of national and international markets with fungal biopesticides and its current production capacity (Laverlam, 2003).

Product	Supply to national market (2002-2003)	Supply to international market (2002-2003)	Production capacity
BIOSTAT (*Paecilomyces lilacinus*)	6,400 ha	22,500 ha	1'000,000 ha
MYCOBAC (*Trichoderma lignorum*)	9,000 ha	20,000 ha	1'000,000 ha
VERTISOL (*Verticillium lecanii*)	500 ha	15,000 ha	500,000 ha
BROCARIL (*Beauveria bassiana*)	500 ha	15,000 ha	500,000 ha
DESTRUXIN (*Metarrhizium anisopliae*)	6,000 ha	51,500 ha	200,000 ha
VEKTOR (*Entomophthora virulenta*)	1,000 ha	15,000 ha	50,000 ha
TURILAV (*B. thuringiensis*)	10,000 ha	31,500 ha	Not available

Besides following the norms of ISO 9000 and the "Good Manufacturing Practices", Laverlam also follows the guidelines for producing biopesticides given by the Food and Drug Administration (FDA) of the US and by the Colombian Institute for Technical Norms and Certifications (ICONTEC). For details on these production standards the reader may consult the other paper in this volume. At present, Laverlam has registered biopesticides in many countries in Latin America including in Mexico, Guatemala, Honduras, Costa Rica, Dominican Republic, Venezuela, Ecuador, Peru, and Bolivia. Products are also being registered in Argentina, Uruguay and Chile.

Production Methods at Laverlam

The water used to produce the media for the cultivation of fungi is filtered and deionized. The filtered water is also used to generate clean vapor utilized in the sterilization processes. Steam is important to achieve the adequate sterilizing temperature during a defined period of time. Also, all the materials used in the production process have to be sterilized using autoclaves. This process usually requires 120°C over a period of one hour.

One of the most critical aspects to control is the air that enters the production areas. An air-conditioned system filtering air at various stages is used. The air is prefiltered with 80% filters and then passes through 95% filters. For critical areas the air is passed through HEPA filters which are rated at 99.9% efficiency. Selected procedures of culture transfer are carried out under laminar flow hoods equipped with HEPA filters.

Production areas are built to comply with good manufacturing practices (GMP) specifications to prevent the accumulation of possible contaminants through proper sanitizing. To avoid cross contamination, UV traps separate work areas, and double-door autoclaves are used to pass materials from one area to another. Residues and contaminants are eliminated in an environmentally friendly way using a special furnace.

All of the materials used in media formulation are obtained from certified suppliers and are checked for their specifications. Essential equipment such as bioreactors, tubing and valves are built from stainless steel, which allows for proper sterilization with vapor. Qualified and trained technicians are involved in every step of production, including preventive maintenance and quality control.

The company has invested substantially in research and development both in the lab and in the field. Research and development in the lab is critical to select the appropriate strains and to make improvements in different production steps. Great efforts have been made to select promising strains and to identify optimal growth conditions. For example for viral strains, the optimal strain for industrial production should have certain characteristics: first and foremost, it should show a high pathogenicity towards the target pest. In addition, it should provide a high spore yield, which must be viable and stable in time. Moreover, it should have a low toxicity for non-target organisms, yet significant pathogenic activity towards more than one pest. The strain selection process is guided by the determination of the a key factor called Multiplicity of Infection (MOI), a term used in virology to describe how many virus particles are needed to infect a cell. This number can vary widely from less than one to more than 10 and it depends on several factors including the attachment to receptors, the penetration process and viral replication. This concept can also be applied to fungal biopesticides to identify how many spores are needed to cause the infection of an insect. In this case, the concentration needed would depend highly on the pathogenicity and viability of a strain. In other words, a highly pathogenic and viable strain would require a lower concentration to achieve infection.

Once different media have been tested in small growth units, a 30-liter bioreactor is used to optimize growth parameters. For this purpose, the main parameters that are controlled are temperature, agitation, pH and aeration. Once the optimal conditions are determined, the growth of the strain is tested in a larger reactor under these same conditions. If no significant differences are found, the strain will then be considered a good candidate for industrial production.

The production of biopesticides is based on a two-stage system, which has several phases. The liquid culture produced in a fermenter is used as inoculum for the solid substrate, which is then incubated under controlled conditions and finally dried. The dried material is pulverized and spores are isolated. Following quality control tests, the product is then formulated to comply with specifications. This two-stage system has several advantages: first, compared to a one-stage system on solid media, the competitiveness of the fungus is enhanced, reducing the risk of colonization of the substrate by contaminating microorganisms. Also, the colonization and conidiation are more rapid. Furthermore, the liquid culture stage can act as a screen for contaminations. Finally, it ensures an even coverage of the solid substrate resulting in homogenous growth.

The process begins with the inoculum being replicated in a small flask. This is then used to seed a solid or semi-solid substrate in a 30-liter fermenter, which is also used to seed a 300+ liter fermenter. If necessary, the process can be scaled up to a larger fermenter. Conidia production is monitored and incubation is stopped once the ideal growth is reached. The next step is the drying process under filtered-air conditions to prevent any contaminations. Once the material reaches 5% humidity it is ready for further processing. The dried material undergoes pulverization to isolate the spores. This process has to be done with great care to avoid affecting adversely the viability of the conidia. Once the conidia are isolated, they are placed in containers in refrigerated conditions.

This material then undergoes quality testing, as described below. Once the quality tests are performed, the final product is formulated and dispensed in containers. Again, care is taken to avoid any contaminations in these final steps utilizing laminar flow hoods.

Quality Control Protocols at Laverlam

The quality control routines at Laverlam follow the standards of ISO 9000 and good manufacturing practices (outlined in another paper in this volume). They involve contamination checks throughout the production process to assess the quality of the final product regarding contamination, moisture content, number of conidia per gram, viability, and pathogenicity. All of these factors play a significant role in the efficacy of the final product. Contamination checks are carried out at the following stages:

1. Stock strains are visually inspected before being used as inoculum for the liquid medium.
2. A sample of the spore suspension and un-inoculated liquid medium is dispensed onto agar plates that are incubated at 25°C for four days before checking for the appearance of any contaminants.
3. Several samples of the solid substrate are placed on agar plates before and after inoculation with the liquid culture. Plates are incubated and checked as before.
4. Solid substrate containers are visually inspected for verifying the presence of any contamination, in which case the affected containers are discarded.

The spore powder is also subjected to a number of quality control checks to ensure conformity with the product specifications. Both biological and physical-chemical analyses are performed. The biological tests done are:

1. **Typification:** This is a qualitative test that allows the sample to reach a mature state so that the characteristics and structures of the reproductive structures of the desired microorganism can be studied.
2. Direct count of the **number of conidia.** This quantitative test determines the number of typical reproductive structures of the microorganism per gram of product.
3. **Viability.** This test permits to establish the percentage of conidia that are able to germinate during a period of time. This is quantified by preparing a 1 in 10 dilution; 0.2 ml of each dilution in the series is spread onto two replicate agar plates, incubated at 26 °C and evaluations are done at 24, 48 and 72 hours.
4. **Pathogenicity.** The virulence of the spore powder is assessed and quantified using a laboratory bioassay on the target pest. This test determines the mortality rate of the target pest and the expression of the microorganism. Mortality rate should be above 80%.
5. **Purity.** The purity of the final spore mass is determined. The presence of contaminating microorganisms is assessed by preparing a 1 in 10 dilution series ranging from 5×10^7 conidia/ml to 50 conidia/ml; 0.2 ml of each dilution in the series is spread onto two replicate agar plates. The plates are incubated for 4 to 6 days at 25°C. Then, the number of colonies is counted on all plates where single colonies can be distinguished in order to derive the actual concentration of the original conidia suspension. Secondly, contaminants appearing on any of the plates are then counted and the proportion of contaminants is estimated and expressed as a percentage. Contamination levels should be $<0.002\%$ by number.

6. **Stability.** A stability test is run to guarantee that the spores will be viable throughout the shelf life of the final product, usually one year.

Several physico-chemical analyses are also done to check the following parameters:

1. **Humidity:** A thermo gravimetric analysis is performed to determine the loss of weight of a substance subject to temperature variations. With this test, the humidity of the product after the drying is checked to ensure a level of 5% moisture or less.
2. **pH:** This test is performed by preparing a 2% solution of the product in distilled water to measure its final pH.
3. **Dampening:** To determine how long a product that has been formulated as a powder requires to moisten itself, an amount of product is added to 200 ml of water without agitation or movement.
4. **Suspensibility:** An amount of product is suspended in distilled water to measure the amount of product that remains suspended during a period of time.
5. **Nebulization:** Used to determine if the particle size of the product does not clog the application equipment.

Once the product has passed all tests and is cleared by the quarantine department for sale, the final product is sent to the different national and international distributors. By meeting consistently the specifications and requirements of products, Laverlam has been able to provide quality biopesticides to national and international markets.

Production of Biopesticides and Botanicals in Africa

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Abstract
The toxicological and environmental problems created by the injudicious use of synthetic pesticides worldwide have led to an increasing interest in the development of microbial and botanical-based pesticides as alternatives. In Africa, the use of microbial pesticides or biopesticides is still very limited, and mainly at an experimental stage. However, there is a growing interest and a number of commercial products are now available in many African countries. Comparatively, botanicals are more widely used. In particular, there is an increasing interest in the use of neem extracts for pest control, especially in the context of integrated pest management. In spite of these developments, the use of botanicals is still limited. Wide-scale adoption of biopesticides and botanicals in Africa is hindered by a number of constraints, including low acceptance by farmers due to a lack of understanding of their mode of action, high production costs, low stability, relatively high costs of products compared to synthetic pesticides, limited availability, and the lack of adequate regulatory frameworks for biopesticide registration in most African countries. The demand for 'green products' by consumers, high-value niche markets, and stricter requirements for export crops c reate significant opportunities for biopesticides and botanicals in Africa. Therefore, efforts should aim at further research on low-cost production systems and marketing issues. Similarly, farmer education, and adoption of harmonised regulatory and quality control procedures are key ingredients for the future expansion of biopesticide use.

Introduction

The growing awareness of the toxicological and environmental problems created by the use of synthetic pesticides has led to an increasing interest in alternatives. Special attention has been given to biopesticides such as microbial pesticides and botanicals.

Many insect pathogens (fungi, viruses, bacteria, protozoa) cause lethal or debilitating diseases in a wide range of pests that attack crops and transfer diseases. These pathogens sometimes cause spectacular epizootics without any human assistance. Such epizootics do not occur reliably enough to be integrated into pest management programs, but their obvious ability to destroy pests has led to many attempts to increase their incidence artificially. This requires mass production of the pathogen for field trials to confirm laboratory results and improvements of the characteristics and formulation of the pathogen for posterior commercialization of the products.

Farmers have used plant concoctions since long to protect their crops in many parts of the world. These traditional methods were nearly forgotten with the introduction and wide distribution of synthetic pesticides. A few plant derivates such as pyrethrum, nicotine and rotenone are still used in modern agriculture. Interest in botanicals has revived in the last decades, particularly as selective natural pesticides derived from plants.

Intensive research and screening of plants with insecticidal properties have shown that neem (*Azadirachta indica*) extracts are the most promising plant extracts for insect control, especially in integrated pest management (Schmutterer, 1995). The unique properties of neem as a pesticide (toxic to a wide range of pests, but relatively low toxicity to non-target organisms including mammals, and low persistence in the environment) make neem-based products a better option than synthetic chemicals, particularly in the context of environmentally sound plant protection. The potential of the neem tree as a source of natural pesticides has led to the production of neem-based pesticides, often in home or small-scale industries in several developing countries.

Mass Production of Insect Pathogens

Insect pathogens can be produced in living systems and on artificial media.

- **Production in living systems.** All pathogens can be produced in their living host species (*in vivo* production). However, this is usually the least economical method of production and is employed only for obligate pathogens. *In vivo* production can be done in two ways:
  - Production in living hosts: viruses, *Nosema*, *Bacillus popilliae*, *Entomophaga*, *Neozygites*.
  - Production in tissue culture: Baculovirus, *Nosema*. This production mode has the advantage of requiring lower investments and less labor for harvesting and of facilitating a high degree of quality control.

- **Production on artificial media.** This method of production is more economical that *in vivo* production and also provides two options:
  - Liquid fermentation: *Bacillus thuringiensis*, infective juvenile steinernematid and heterorhabitid nematodes, and fungi.
  - Production on solid substrates: hyphomycetes fungi.

Research in developed countries has concentrated on high technology methods involving complex equipment and sterile culture conditions for mass production of microbials. These methods are inappropriate for developing countries, which require production systems using cheap, locally available raw materials and equipment. The success of such programs in Brazil, Cuba, China and West Africa demonstrates the feasibility of this approach. Prior (1989) discussed the issue of high technology for microbial production in the developing world. He concluded that the disadvantages of high technology production of biopesticides can be summed up as "high technology = high cost". In particular the following disadvantages were identified:

- Requires complex equipment such as fermentors, which are difficult and expensive to maintain.
- Depends on the maintenance of sterile culture conditions on a large scale.
- Some aspects of the production/formulation process are patented, making the technology even more expensive.
- Requires the development of stable formulations and long shelf life to permit the products to compete with chemical pesticides.

In contrast, low technology production is more suitable for smallholders and agro-industry in the developing world. The main advantages of this technology are (Prior, 1989):

- Does not require complex equipment and media.
- Allows better control of the production parameters (temperature, pH, air supply, stirring, homogenous conditions).
- Some systems do not use sterile culture, e.g. in China.
- No patents are involved because production uses local strains and simple equipment.
- Screening for contaminants is easier.
- The product is not formulated to compete with chemical pesticides.

However, there are also constraints that need to be pointed out. They include higher risks of contamination, poor stability of the products, lower economic returns, difficulties to assure worker safety, the use of food products such as rice or maize as cultivation media, the lack of process control, low capacities, limited possibilities to scale-up, and finally, often a lack of reliability.

Quality Control

Quality control is important for the production of microbials. Product quality is monitored at several points during the production process, from the initial stock to the final product. The final product is subjected to a number of quality control checks to ensure conformity with the product specifications. Typically, the controls for entomopathogenic fungi include monitoring moisture content, viability, virulence, rate of contamination, particle size, and yield (Cherry *et al.*, 1999).

Production of Neem-based Pesticides

The on-farm production of simple, homemade pesticides (such as water extracts from seeds, fruits or leaves) from the neem tree was initially considered the best option for resource-poor farmers in developing countries. Simple techniques were developed to promote this strategy. The easiest way is to crush seeds and grind or pound them in a mill or mortar. The seed powder can be used as a granulate pesticide, or for production of water extracts. This is done by soaking the crushed neem seeds in water for 5 to 8 hours, the neem extract can be filtered and sprayed into the target crop. The basic technology and expertise needed are simple and can be learned easily by the users. However, this approach has shown several shortcomings, namely:

- High labor requirements,
- Storage problems. Due to the time-limited fruiting season of neem trees the seeds or neem-products needed to be stored to guarantee their availability when pests occur. Fungal growth during seed storage can be a problem causing contamination with aflatoxins. Home-made products are unstable (due to the quick degradation of the main active ingredient azadirachtin) and cannot be stored for long,
- Phytotoxicity of products due to the high oil content, and
- Restriction of its uses to neem-producing regions.

In the late 1990s, emphasis was put on the promotion of formulated neem-based pesticides, and a considerable number of marketable neem–based pesticides were recently developed. These commercial formulations are mainly done by extraction of the principal active ingredient azadirachtin. In industrialized countries, they are formulated into sophisticated, uniform, stable products, similar to conventional synthetic pesticides. These standardized pesticides are easy to use, and have made neem products available also to regions where neem does not grow, for example in highlands with intensive horticultural production. However, their main disadvantages are that other active ingredients are excluded that could be of value in preventing the development of resistance and that these products are expensive due to the high costs of extraction and formulation.

An intermediate technology to produce simple, standardized, ready for use pesticides with improved shelf life may be a better alternative for developing countries. These products are based on homemade pesticides, but involve additional processing steps such as basic standardization, formulation and packing (Föster & Moser, 2000). Quality control of neem-based pesticides focuses primarily on the contents of azadirachtin and on the detection of contaminants such as pathogens (mainly fungi and bacteria). Particular attention is given to the presence of aflatoxin from possible contamination by *Aspergillus* spp. of the seeds and processed products.

Status of Microbial and Botanical Pesticides in Africa

In recent years, research and development institutions in Africa have developed a number of microbial pesticides and some of them are being mass-produced at commercial scale. They include Green Muscle®, *Bb* Plus, *Bb* Weevil, Pl Plus, *Tricho* Plus, Dudustop®, T77 and Betel. Other products such as Metathripol and Muchwa Raid hold promise and are still under development (N.K. Maniania, pers. comm.) (Table 1).

Table 1. Production of microbial pesticides in Africa

Trade name (Company)	Active ingredient	Quantity	Target pest	Status
Green Muscle® (BCP) (LUBILOSA)	*Metarhizium anisopliae*	100kg (2001) 160kg (2003) 350kg/year	Locust, grasshopper	Registered
Bb Plus (BCP)	*Beauveria bassiana*	---	Red mites, aphids	Registered
Bb Weevil (BCP)	*B. bassiana*	---	Banana weevil	Registered
Pl Plus (BCP)	*Paecilomyces lilacinus*	---	Root nematodes	Registered
Tricho Plus (BCP)	*Trichoderma harzianum*	---	Growth and fungal disease	Registered
T77 (Agricula, Zimbabwe)	*T. harzianum*	100 tons per year (fig. 1996)	*Rhizoctonia* spp. on tobacco	Registered and patented
Not available (Agricula)	*Verticillium chlamydosporium*	---	Root knot nematodes	Not registered
Metathripol (ICIPE)	*M. anisopliae*	Field trials	Thrips	Not registered
Muchwa Raid (ICIPE)	*M. anisopliae*	On request	Termites	Not registered
Betel (NPP, Reun.)	*Beauveria brongniartii*	---	Cockchafer	Registered
Dudustop (Univ. Helsinki/ICIPE)	*Bacillus thuringiensis*	---	Filth flies	Registered

BCP: Biological Control Products (South Africa); LUBILOSA: Lutte Biologique contre les Locustes et Sautériaux (West Africa); ---: not available.

Förster and Moser (2000) reviewed the status of neem use at a global level. The neem tree is believed to have made its way to Africa along with Indian immigrants in the early 1900s. Currently, it is found in variable numbers in many countries. The tree is used for shade, as a source of firewood and in traditional medicine, but its use as a source of natural pesticides is still limited.

Simple techniques for production of homemade neem pesticides have been developed and promoted by bodies such as UN, the German Agency for Technical Cooperation (GTZ) and NGOs in several countries in Africa. This is the prevailing mode of production of neem as a source of pesticides in many African countries, including Benin, Burkina Faso, Ghana, Ivory Coast, Kenya, Madagascar, Mauritania, Mauritius, Mozambique, Niger, Tanzania, and Togo. In Togo, the "Group of Action for the Protection of the Environment and Culture" (GAPEC) produces basic simple neem products (neem oil and neem powder) that are sold to farmers.

Other simple but standardized neem-based pesticides are being produced commercially in some countries such as Ghana, Kenya and Senegal. Table 2 presents an overview of the production of formulated neem-based pesticides in Africa.

In Senegal, a commercial agricultural input supplier (SENCHIM) is producing and selling formulated oil and emulsifiable concentrate (EC) formulations of alcoholic extracts since 1998. In Ghana, the first neem products were reportedly manufactured by commercial companies in 1999. In Sudan, the National Center for Research (NRC) and the Environmental and Natural Resources Research Institute (ENRRI) have implemented a research programme to provide farmers with stable commercial and readily available neem-based pesticides (Föster and Moser, 2000)

In Kenya, the GTZ together with the International Centre of Insect Physiology and Ecology (ICIPE) as the executing agency, and a local company SAROC (now SARONEEM) started a project in 1996. The aim was to promote the production of neem-based pesticides by using an intermediate technology. The production steps developed during the project are presented in Figure 1. Currently, two locally produced neem-based pesticides, Neemroc® and Nemmros® have been registered in Kenya and Uganda and are being sold for the control of a wide range of pests of horticultural crops (Förster *et al.*, 2000; Varela and Rocco, 2002). Registration with the local pesticide regulatory body was based on efficacy tests conducted by authorized national institutions and a recompilation of literature on toxicological and environmental fate and residue data.

Table 2. Production of Neem-based Pesticides in Africa (Förster and Moser, 2000)

Country	Product	A.I	Status
Niger	Formulated azadirachtin-enriched extract, Formulated oil	N/A	About to be registered[1]
Togo	Press cake, oil	N/A	No registration required
Benin	Formulated oil	N/A	Unclear
Kenya	Neemroc EC oil Neemros (NCP) Neemcake	0.03% Azad. 0.5% Azad.	Registered Registered
Senegal	Formulated oil	N/A	Provisional registration

[1] (Förster and Moser, 2000)
Note: There is no information available on quantities produced in the different countries.

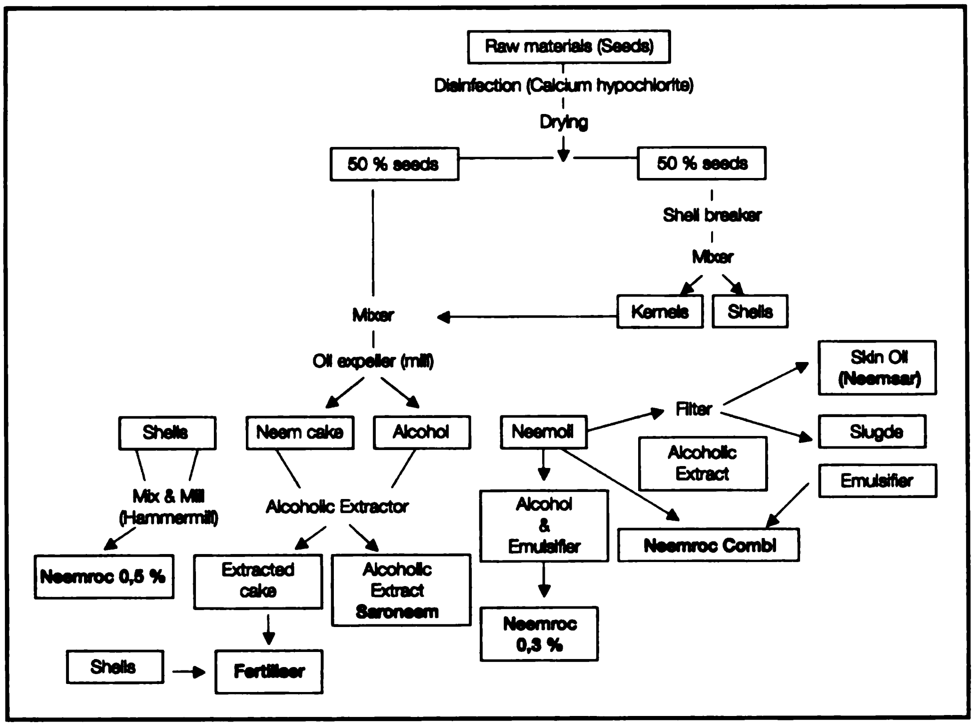

Figure 1. Processing of neem seeds into pesticides (Varela in Föster *et al.*, 2000)

Major Obstacles for Microbial and Botanical Production in Africa:

The following factors have been identified, many of them by the company "Biological Control Products", South Africa, as constraints to mass production and commercialization:

Constraints for Microbials

- Lack of understanding by farmers of the nature of biocontrol agents;
- The absence of sufficient market pull and support from regulatory body;
- The requirement by the majority of these products for cold chain distribution;
- Inability of small limited-resource producers to offer incentives to distribution agents that are similar to those offered by chemical competitors;
- High costs of equipment, labor and cultivation media;
- Variation in the yields of the pathogen depending on biotic and abiotic conditions;
- Specificity of microbial pesticides: although specificity is desirable in IPM programs, it reduces, at the same time, the potential uses, markets, and consequently economic returns;
- Reduced speed of kill: pathogens generally take longer to kill their hosts than synthetic chemical pesticides, with which people are familiar;
- High losses due to contamination, occasionally up to 30%, from other microorganisms.

Constraints for Neem-based Pesticides

- Lack of understanding by farmers of the mode of action of neem-based pesticides.
- Lack of effective and reliable collection system for neem seeds.
- Lack of reliable preparation of neem seeds of good quality.
- Short shelf-life of home-made products.
- High-quality stable products require high and sophisticated investments.
- Difficulty to register neem-products due to the large number of active ingredients.
- Synthetic pesticides are in general cheaper and are easier to obtain and to use.

Conclusions and Prospects

There are many initiatives and projects that have used and are trying to use biopesticides and botanicals as solutions to pest problems in Africa. Therefore, there is a great potential for biopesticides in IPM and other management systems such as organic production. However, one of the constraints has been their limited availability due to the virtual absence of mass production units. Other constraints include relatively high costs, unresolved issues in formulation and insufficient product stability. Future research efforts should aim at addressing these issues. The currently high costs of biopesticides are largely a result of the small size of the market, but it is likely that prices will fall once the market size (and with it, the production units) increases. Although the costs of biopesticides often are not competitive with synthetic chemicals, this is not always true. For example, the price of applying biopesticide products against nematodes is around US-$ 85/ha in South Africa, which is below the typical costs for applying synthetic chemicals (Biological Control Products, pers. comm.). Farmer education about the use of biological agents for pest control will be a key feature for the expansion of biopesticide use. This is well illustrated by the successful adoption of baculovirus for the control of soybean velvet caterpillar in Brazil, which was achieved through a focused education program for the involved farmers (Moscardi, 1999). The increasing demand for 'green products' by consumers provides an additional incentive for the expansion of the use of biopesticides in the near future.

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Use and production of biopesticides in Thailand

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Abstract
Inadequate access to information and insufficient product availability currently limit the market share of biopesticides in Thailand. Although the country is experiencing an increasing awareness on the benefits of BPs, a more active role of the private sector through the production of competitive and accessible products is still needed to boost this industry. In order to increase the interest of farmers in bioproducts it is important to develop formulations that are easier to apply and store, that have an extended shelf life, and that are cost effective.

Use and Registration of Biopesticides in Thailand

Biopesticides from plants such as *Derris elliptica*, tobacco and neem have been used in Thailand for a long time before synthetic chemical pesticides were imported. *Bacillus thuringiensis* (*Bt*) was the first biopesticide product to be introduced and commercialized into the Thai market since 1965. Then, farmers did not know much about *Bt* due to its slow and highly selective action. However, nowadays biopesticides seem to be more accepted and have obtained a larger market share as farmers are increasingly under pressure to reduce toxic residues in agricultural products.

In Thailand, there are six major biopesticides in the market: *Bt*, neem extract, *Trichoderma harzianum*, entomopathogenic nematodes, nuclear polyhedrosis virus (NPV), and entomopathogenic fungi. *Bt* is the most commonly used biopesticide. It is divided into three subspecies: *B. kurstaki*, *B. aizawai* and *B. tenebrionis*. These biopesticides have overall good acceptance depending on application convenience, product availability, and the level of control achieved against various insect pests. Under the current market conditions, *Bt* could replace a substantial portion of synthetic insecticides. More than 90% of the *Bt* used in Thailand is sold in unregulated markets and the rest is subsidized through the Department of Agricultural Extension or provided as samples by the Department of Agriculture's pilot plant.

Under the Food Safety Project of the Thai government, selected farmers receive not only *Bt*, but also neem extract, entomopathogenic nematodes, *Trichoderma harzianum* and virus (NPV) formulations from extension officers. However, limited availability of these biopesticides and low awareness of their potentials limits farmers' demand. Consequently, the dissemination of information and training of farmers are essential to increase the acceptance of biopesticides and, thus, boost their market participation.

Farmers usually obtain information and knowledge related to biopesticides from training courses, leaflets and samples of products provided by government officers of the Department of Agricultural Extension, of the Department of Agriculture and of universities. The private sector also has established demonstration plots and provided biopesticide samples, leaflets, brochures and lectures on specific topics.

The government program on food safety (2000 until 2004) aims at training agricultural officers to adopt the concepts of Integrated Pest Management and of Good Agricultural Practices. Using this framework, the technological components have been transferred to the farmers by means of:

1. Training of officers of the Department of Agriculture and Extension.
2. Training of farmers,through demonstration plots and,
3. distributing samples of biopesticides from the pilot plants to interested farmers.

In Thailand, biopesticides must be registered under FAO's guidelines and under the Toxic Substance Act of the Agricultural Regulatory Institute, the Department of Agriculture, and the Ministry of Agriculture. This Act is more flexible for biopesticides than for chemical compound registration, which requires to indicate toxicological data on each package. In general, chemical compounds are still allowed to be used under adequate safety recommendations, but hazardous compounds in Class IA are banned, and a list of more than ten further compounds is included in a watch list.

Driven by the Sanitary and Phytosanitary Program, Thailand is currently experiencing a peak at encouraging farmers to use more biopesticides and at creating awareness on the harmful impact caused by synthetic chemical pesticides. However, the private sector should contribute to this process by producing more high-quality biopesticides of sufficient quantities to meet the market demand. The opportunities for increasing the use of biopesticides will be expanded if:

1. The quality of the products is competitive.
2. There is a higher efficacy in pest control.
3. Prices are lower.
4. The application and storage is easier.
5. Storage conditions do not require refrigeration or any other special condition.
6. The product's shelf life is prolonged.

Production of Bio-pesticides in Thailand

This section presents examples of the main biopesticides that are currently being produced in Thailand.

Neem. Farmers have been familiar with the neem seeds for a long time, typically soaking crushed seeds in water for 24 hours before application. Commercial neem extract is currently the most important biopesticide produced in larger amounts under the local name "Sa Daw Thai". It contains its active ingredient azadirachtin at about 0.03% EC. It is obtained by extracting neem seeds with alcohol in small and intermediate industries.

Unfortunately, the output is quite low due to limited investment, and lack of a competitive production method and equipment. These constraints limit the economic feasibility greatly. Moreover, the neem seeds often are insufficient and provide variable amounts of AI, resulting in higher prices for high-quality standardized products. Furthermore, the higher phytotoxicity of the alcohol extracts compared to water extracts limits acceptance and sales. Another critical issues is the degradation of the AI after packaging the extract. The concentration of the active ingredient is unstable, as it is degraded during extended storage, especially if exposed to sunlight and microorganisms.

Trichoderma harzianum. "Uni-Green" and "Uni-Safe" are the commercial names of *Trichoderma harzianum* distributed in Thailand by UniSeeds Co. Ltd. The yearly sales correspond to approximately 20 to 25 metric tons, of which more than 90% was bought by government institutions. The limitations of this product are its relatively short shelf life, slow action and efficacy, the requirement of high moisture and low temperatures, the need for cold storage, and a relatively high price. In general, farmers do not trust its efficacy and are reluctant to use it, due to its complicated application requirements and techniques. Consequently, sales are poor. However, if the product formulation can be improved and more farmers are involved in successful field trials the use of *Trichoderma harzianum* may be expanded in the near future..

Entomopathogenic nematodes. "Unema" is the product name given to *Steinernema carpocapsae* distributed by Uniseeds Co., Ltd. The yearly production capacity is up to 100,000 bags (with 4 million nematodes per bag). Numbers on sales of this product are not available. Its main limitations are that it must always be kept in cool storage, has a short shelf life (3 to 6 months in refrigeration), is highly selective to control 2 to 3 insect species, performs best under high moisture and low temperature conditions during application, and is relatively costly. Due to these difficulties, the acceptance of the current product by farmers is very poor. Again, new formulations and the expansions of the target spectrum may improve acceptance in the future.

Virus. Nuclear polyhedrosis virus (NPV) is an effective microbial insecticide developed by the Department of Agriculture, the Ministry of Agriculture and various cooperatives of Thailand. The production is about 1.000 to 1.500 liters per year. However, this amount is not enough to satisfy the farmers' needs. The private sector has tried to produce it but has failed. A wider use of NPV is limited by its relatively slow action, highly selective control, the need for cold storage, and its reduced effectivity at high temperatures. In order to tackle these issues, the government and private sector should allocate more resources to develop a powder formulation with extended shelf life and to increase the production volume to meet the farmers demand.

Bacillus thuringiensis (Bt). "Red Cat" is the commercial name of a domestic *Bt* product that has a potency of 16.000 IU/mg in powder formulation. The Department of Agriculture produces it in a liquid formulation. The main limitations of *Bt* in Thailand are due to the "low-technology" manufacturing process which produces a formulation of low stability, low efficacy and a lack of consistency. As a result, the current formulations of *Bt* products have a low acceptance by farmers.

Conclusions

In summary, the current initiatives by the Thai government and the private sector to support the transition towards more sustainable agricultural production systems and food with reduced pesticide residues still requires a lot of help. The main issues to resolve include the development of new formulations of biopesticides to extend the shelflife of the products and to reduce the need for cold storage. Also, more training programs should be established to strengthen the dissemination of information about biopesticides and their potential. Monitoring of experimental and demonstration plots will generate much needed information on the effectivity of the biopesticides used.

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Section 3

National and regional regulations and information systems on biopesticides

U.S. Regulations Regarding the Importation of Pesticides and Pesticide Treated Foods into the United States

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Abstract
The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA) are the two primary statutes regulating pesticide use in the United States. FIFRA is the law or statute, which governs the regulation and registration of all pesticides in the United States, its territories and possessions. The Federal Food, Drug and Cosmetic Act (FFDCA), in part, provides authority for the U.S. Environmental Protection Agency (EPA) to set tolerances or limits on the amounts of pesticidal residues allowed on food and feed products entering the marketplace.

To date, all the microbial or biochemical pesticides registered are exempt from the requirement of a food tolerance, *i.e.*, no residue levels need to be set. The U.S. Food and Drug Administration (FDA) and individual states oversee the enforcement of this provision of the statute. Foods and feeds which are not in concordance with the tolerance levels established or which lack a tolerance exemption may be confiscated and considered as adulterated as defined in FFDCA *i.e.*, not allowed for sale. Data required for the determination of a tolerance level or exemption from the requirement of a food tolerance are found in a North American Free Trade Agreement Guidance Document on Requirements for Tolerances on Imported Commodities (June 1, 2000; April 16, 2003). For persons wishing to import pesticides or pesticide-treated products into the United States, a pesticide registration notice PR 99-1 (March 1, 2003) details the legalities surrounding importation. In general, pesticides that are not registered in the U.S. or their active ingredients are not permitted for importation without registration data and review.

Importation of Pesticide Treated Agricultural Commodities

A U.S. food tolerance (the equivalent of a tolerance is sometimes called a maximum residue limit, or MRL, in other countries) is the maximum residue level of a pesticide permitted in or on food or feed grown in the U.S. or imported from other countries. Food or feed may not lawfully be sold in, or imported into, the United States, its possessions or territories, if the food contains detectable pesticide residues above the level permitted by a tolerance, or at any level if no food tolerance exists, or an exemption from the requirement of a tolerance has not been established. For pesticides that have undergone a full toxicology study with no adverse effects or for which there is no reason to expect any toxicological ramifications from residues remaining on treated agricultural commodities, an exemption from the requirement of a food tolerance may be granted. To date, this has been the case for all microbial pesticides registered by the U.S. EPA (*i.e.*, they have all been granted an exemption from the requirement of a tolerance).

Section 408 of the FFDCA authorizes EPA to establish, modify, or maintain tolerances or tolerance exemptions for pesticide residues in or on food. Once established, a tolerance limit or exemption applies equally to domestically produced and imported commodities. EPA has an obligation under section 408 of the FFDCA to establish tolerances for pesticide chemicals at levels that are "safe" 1). EPA also has an obligation to ensure that the tolerances continue to be "safe" over time, since new information may alter the Agency's earlier safety finding under the FFDCA.

The Food Quality Protection Act of 1996 (FQPA) made several changes to the U.S. laws affecting pesticides (FIFRA and FFDCA). Following FQPA, a single, health-based standard based upon a "reasonable certainty of no harm" was imposed for all pesticide residues in food. This action served to eliminate previous inconsistencies in the way in which raw foods and processed foods were considered. Emphasis was placed upon potentially sensitive groups such as infants and children by FQPA with respect to toxicity. All tolerances, including import tolerances, must be evaluated according to this new health standard. Now EPA must consider aggregate non-occupational exposure from the pesticide (including exposure from food, drinking water, and pesticides used in and around the home), cumulative effects from pesticides with a common mechanism or mode of toxicity, and the potentially increased susceptibility of infants and children or other sensitive groups. Additionally, the potential for estrogenic or other endocrine effects, which may be present in some chemicals and biochemicals, must be evaluated prior to tolerance assessment.

Three additional provisions of FFDCA as amended by FQPA are particularly important for this import tolerance guidance: Section 408(b)(4) International Standards; section 408(f) Special Data Requirements; and section 408(l)(2) Revocation of Tolerance or Exemption following Cancellation of Associated Registrations. In establishing a tolerance, FFDCA section 408(b)(4) requires EPA to determine if the Codex Alimentarius Commission has established a maximum residue level. If EPA does not adopt the Codex level, then the Agency must publish a notice for public comment explaining the reasons for the deviation.

Tolerances established for raw agricultural commodities apply also to processed food derived from the treated crop, even though levels of the pesticide residue are likely to be lower in the final food product. Processing data are required by EPA to determine the amount of residues likely to remain. If residues in processed food are concentrated to higher levels than in the raw commodity, separate tolerances will need to be established to cover residues in the processed food. Most often, a food tolerance is established at the time of registration. If a product is not registered in the U.S., interested persons may submit a petition requesting that EPA establish a tolerance or a tolerance exemption for a pesticide residue on a commodity that would allow treated food to be legally imported into the United States. As mentioned above, no distinction is made between a tolerance established for importation of a commodity and that established for a commodity and pesticide treatment occurring in the U.S. using a registered product. A tolerance may be established for the commodity without an accompanying FIFRA registration.

The data requirements for obtaining a food tolerance, as part of an importation of treated commodities, is often the same as that required for registration and tolerance issuance if the pesticide was intended for use in the U.S. The total data set is substantial and too lengthy to list herein, but a website link at the end of this paper will allow the reader to peruse the list firsthand. Product chemistry and characterization; toxicity tests for mammals, birds, fish and invertebrates; and commodity-specific data are all required as part of the data set submitted. As with all registration or tolerance actions, it is always in the best interest of the applicant to arrange a pre-registration meeting with the EPA to discuss in detail what data will be needed and what tests or studies may be waived, if sufficient information exists in the literature, or if the test does not have direct bearing on the particular pesticide-commodity combination in question.

Importation of Pesticides into the United States

The import of unregistered pesticides or devices into the United States is prohibited by FIFRA unless the following criteria 2) are met: 1. The foreign producing establishment must be registered with the EPA and is compliant with Section 7 (FIFRA) reporting requirements. 2. Importation of the unregistered pesticide or active ingredient complies with all applicable regulations and section 17 of FIFRA (including presentation of an EPA authorized Notice of Arrival, which specifies the quantities to be presented to Customs upon entry into the U.S. 3. The shipment otherwise complies with all applicable Customs laws and regulations; 4.) Upon lawful release by Customs, the imported unregistered pesticide or active ingredient is transported directly to a registered pesticide establishment. The owner of such establishment shall be responsible for filing an appropriate report under FIFRA section 7 concerning such imported pesticide or active ingredient which indicates the relevant activity, such as reformulation, relabeling or distribution. 5. Section 17(a) allows distribution (and importation) of an unregistered pesticide or active ingredient only if the pesticide or active ingredient is intended solely for export and has been prepared or packaged according to the specifications of the foreign purchaser. EPA interprets this to mean that the importation (and any subsequent movement) may occur only after a foreign purchaser has been identified and has provided the specifications for the exported product. 6. After the final product for export is formulated and packaged, any distribution or shipment of the product must be solely for facilitating export of the product (*i.e.*, all movement of the product must be directly related to exporting the product, such as shipment to a warehouse awaiting export, dock or broker). 7. The unregistered pesticide or active ingredient, and each person with any obligation under FIFRA section 2, 7, or 8 with respect to the unregistered pesticide or active ingredient, are at all times in compliance with all the applicable provisions of FIFRA identified in 17(a)(1). 8. The export of any unregistered pesticide or active ingredient complies with the purchaser acknowledgment requirements of 17(a)(2) of FIFRA; 9.) The importer can demonstrate that, ultimately, all of the product has been exported, or is being held pending export.

As is evident from the criteria listed above, importation of an unregistered pesticide is only permitted when the pesticide is intended for re-export. If the pesticide is intended for use or sale within the United States, its territories or possessions, then the standard requirements of registration hold and must be completed prior to importation or distribution in the U.S. 3)

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http://www.epa.gov/fedrgstr/EPAFR-CONTENTS/2000/June/Day-01/contents.htm - (scroll down to EPA, Notices)

Federal Register Volume 65, Pesticides; guidance on import tolerances and residue data for imported food, 35069-35089 and,

http://www.epa.gov/EPAFR-CONTENTS/2003/April/Day-16/contents.htm - Federal Register, Volume 68, Minimal risk active and inert ingredients; tolerance exemptions,18550-18553 (scroll down to EPA Proposed Rules)

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European Regulations of Biopesticides and Plant Protection Products for Organic Production

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Abstract
In organic agriculture, the substances and products allowed for use in pest control are determined by standard setting bodies of the government and the private sector. In the case of the EU, there are three hierarchical levels of regulation, namely the EEC Regulation 2092/91, the national pesticide legislation of each member country and, finally, the private sector. Developing countries often synchronize their list of permitted substances and products with those of their major export markets to ensure market compatibility. Biopesticides have to comply with the requirements for substances and products for organic agriculture. In order to market their products for use in organic agriculture, the biopesticide industry should participate in the ongoing process of harmonization of standards and regulations.

Introduction

By definition, the design and management of organic agriculture depends largely on the adoption of a systems approach which permits to create an environment of diversity with a high degree of self-regulatory mechanisms. The functioning of these mechanisms is the key strategy in pest management. The beneficial organisms include not only insects, but also microorganisms and other life forms such as birds, lizards etc. Curative plant protection means in the form of employing plant protection products including biopesticides should only be used if preventive measures fail and the yield is expected to suffer beyond an acceptable economic damage threshold.

Requirements for Plant Protection Products for Organic Agriculture

According to the Codex Alimentarius guidelines for organic agriculture, plant protection products for organic agriculture are defined as "any substance intended for preventing, destroying, attracting, repelling, or controlling any pest or disease, including unwanted species of plants or animals, during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds" (Codex Alimentarius, 2001). In most cases, the organic sector distinguishes the following five groups of plant protection products:

- Products of plant or animal origin.
- Products of mineral origin.
- Products based on microorganisms.
- Products used in traps, barriers or as repellents.
- Others.

Increasingly, users of these products use terms such as "biopesticides" or "biocontrol agents" for these products, but the definitions of such terms is neither consistent throughout the organic sector nor are these products necessarily restricted to applications in organic agriculture.

In order to be approved as inputs for organic production, the Codex Alimentarius requires that plant protection substances must meet a set of minimum requirements which must also be in line with all applicable statutory and regulatory provisions of the country concerned. As part of the approval procedure, new substances or products must meet the following general criteria:

- Their origin and use must be consistent with the principles of organic production.
- There should be a clear need for the application of the substance.
- The use of the products does not result in, or contribute to, harmful effects on the environment.
- The product must have the lowest possible negative impact on human or animal health and on the quality of life.
- Approved alternatives are not available in sufficient quantity and/or quality.

Standard Setting Procedures for Plant Protection Substances and Products

The internationally most important bodies for setting the guidelines for organic standards are the International Federation of Organic Agriculture Movements (IFOAM) and the Codex Alimentarius. IFOAM originally initiated the standard setting process which began in the early 80s and continues to evolve (IFOAM, 2002). Generally speaking, private sector bodies refer more to the IFOAM Basic Standards (IBS), whereas governments relate more to the basic standards of the Codex Alimentarius, which were first formulated in 2001. However, many aspects of the IBS are reflected in the Codex' standards as a result of intensive consultations when the latter were formulated. A central part of all basic, national or private standards is the list of permitted products for plant protection. These so-called positive lists of the IBS, the Codex Alimentarius and the countries which constitute the major markets for organic products represent, at the global level, the most important listings of plant protection products.

In the European countries, organic agriculture is subject to the overall legal framework established by the EEC Regulation 2092/91. However, some differences exist among the EU member countries, because the final responsibility for the national regulations rests with the national governments. In recent years, also developing countries have begun to establish their own national regulations and lists of permitted products. Often, these countries shape their lists of permitted products according to the lists of their major markets in order to reach compatibility.

Approval and Registration of Plant Protection Products in the EU

In Europe, the private sector bodies have to meet the requirements of the legal framework set by the EU and by the national legislation for their private standards. Currently, the private sector bodies in Germany are considered to be the most active among the EU countries. They are actively adapting their own standards, which pursue strongly a system-based approach to pest management and the use of natural substances for plant protection.

In order to be allowed for use in organic agriculture in the EU, biopesticides must meet the requirements of three hierarchical levels of regulation. For any European country, the highest body for the determination of permitted products is the EEC Regulation with the Annex II B, in which the permitted products are described. The second hierarchical level is the national legislation. In Germany, for example, the responsible governmental body is the BBA (Federal Biological Research Centre for Agriculture and Forestry). At this level, the general national regulation of pesticides determines which of the products permitted by the EEC Regulation can be authorized for use in Germany. Since each member country still has its own pesticide regulation, the list of permitted products may differ from country to country.

Finally, the third level that regulates the permitted products is the regulation of the private sector. The involved actors can be large organic associations such as Bioland, Demeter or Naturland, or they can be independent certification companies. The private sector regulation in Germany is among the strictest in Europe. The differences among the standards at the three hierarchical levels or among the national standards of different countries can be further illustrated by the following examples:

- A recent example of Germany's private sector influence on the organic standards is the case of **piperonyl butoxid**, a synthetic additive to pyrethrum products. With the development of a natural substitute, piperonyl butoxid must now be replaced by rape oil. Consequently, while piperonyl-butoxid is still accepted according to the EU and the national government regulations, it is no longer permitted by the German private sector.
- Whereas the EU Regulation authorizes **synthetic pyrethrum** since 2002 for use in traps and against snails, the private sector does not permit the use of this product.
- **Methaldehyd** is approved against snails and slugs under the EU Regulation and Codex Alimentarius, but not by the private sector in Germany.
- The EU Regulation allows **copper** applications at a rate of up to 8 kg/ha and year, whereas Demeter restricts copper to 3 kg/year. Some certification bodies are restricting copper increasingly because of its negative long-term effects for ecosystems.
- While **rotenone** is not allowed by the private sector in Germany, ist use is allowed or restricted in all other European countries. For example, in the UK, the use of this product is subject to approval by the British certifying bodies (particularly, the Soil Association and UKROFS).
- **Neem** is now approved in Germany by the national regulation for use against various pests in fruit and in vegetable production. However, it is not yet approved in the UK, but attempts are under way to meet the requirements for the registration of the product.

A problematic issue is the regulation of formulation aids. While the EU regulates active ingredients, it does not regulate the use of formulation aids. However, formulation aids are regulated according to the IBS, the Swiss list of permitted products, and the Organic Materials Review Institute (OMRI) of the USA. There are emerging efforts towards a comprehensive evaluation of formulation additives and an interest in an international harmonization in order to reduce the current inconsistencies of regulations, which inhibit market development. These efforts are still slow but the need to tackle them has at last been recognized.

European Harmonization Efforts

Within the 6th European Research Framework, a 3-year research project is underway to harmonize and standardize the procedures for the evaluation of plant protection products, fertilizers and soil conditioners for use in organic agriculture and the procedures for the approval process. The project's main goals are:

- To provide policy makers with a tool to improve legislation and standards on organic agricultural production products.
- To facilitate the more rapid approval and use of newly developed inputs.
- To improve procedures for input evaluation.
- To give the organic farmers in Europe equal conditions in European and world markets.

Principal Barriers for Plant Protection Products in Europe

The main barriers are:

- Often, the **regulations differ** or are interpreted differently in different member countries. This results in confusion and uncertainties for the producers of plant protection products regarding the approval of the products in different countries.
- **Lack of toxicological information** on many substances and products. When a product has a toxic effect, the product needs to pass the same environmental and health tests that are required for the registration of conventional pesticides. The required costs are often prohibitively high considering the more restricted application range due to the typically higher specificity of biocontrol agents compared to synthetic chemicals.
- **Many products are not included in the positive lists of approved inputs.** It is imperative that the products are explicitly allowed and included in the lists. However, to get into the list is very difficult and follows different criteria and procedures in the different countries of the EU. This is often criticized by farmers as causing unequal competition.
- **Excessively long time for registration of new products.** The current regulations require that once a potential product has been proposed to the responsible EU authorities, this proposition is passed on to the representatives of all the 25 member countries for discussion in their countries. The recommendations of the countries are then taken back to the EU level for final decisions. Unfortunately, such processes take years which makes the development and registration of new products very difficult since companies which propose environmentally friendlier products have to pre-finance their proposed products during this long administrative procedure.

Conclusions and Recommendations

A key strategy of pest management in organic agriculture remains the prevention of pests and diseases based on mechanisms for self-regulation as stipulated in the organic standards and regulations. The complementary curative control means using external substances and products is regulated by listing the substances and products which are allowed for use. These products are not necessarily identical with biopesticides. Up to now, the procedures for assessing external substances and products allowed by the different governmental and private standard setting bodies still vary.

Although biopesticides are not specifically developed for use in organic agriculture, biopesticide producers who want to sell their products for use in organic agriculture, must comply with the organic standards. However, the existing diversity of standards and regulations is creating barriers for the development of new products and for the market development of organic products. The increasing awareness of this problem at all levels of the bodies involved with organic agriculture is supporting current initiatives geared towards the harmonization of these guidelines. If the biopesticide industry wants to position its products systematically for organic agriculture, it is essential that this sector participates actively in the efforts to harmonize the standards and regulations that govern plant protection products nationally and internationally.

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Regulation of Biological Control Agents in Europe

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Abstract
The International Biocontrol Manufacturer's Association promotes the use of the expression "Biocontrol Agent" rather than the term "biopesticide". Biocontrol agents have an enormous market potential with sales estimated to reach US$1 billion in the year 2008, representing approximately 4% of the total plant protection business worldwide. This paper focuses on the regulatory structure of the European Union for biocontrol agents, pinpoints current limitations for BCAs, and provides recommendations to strengthen the sector.

Introduction

The term "Biocontrol Agent" (BCA) should be used to replace the word "Biopesticide", which has an intrinsic negative connotation. The "International Biocontrol Manufacturer's Association (IBMA), an affiliation of more than 85 companies worldwide, and the International Organisation for Biological Control (IOBC) actively lobby and promote the use of BCAs and try to substitute the expression "Biopesticide" by the more appropriate term "Biocontrol agent". IBMA classifies biocontrol agents in four groups, which are also the working groups for the work of the organization:

- Macrobials.
- Microbials.
- Natural products.
- Semiochemicals (insect behaviour modifying agents).

Global and Regional Markets

At the turn of the millennium, the global pesticide sales amounted to about US-$ 27 billion corresponding to a volume of approximately 10 million metric tons of formulated products. In contrast, the global sales of BCA's totalled about US-$ 578 million (Table 1), representing about 2% of the total plant protection market. Among the BCA's, the most important products by value are microbials (41%), followed by macrobials (33%) and, finally, other natural products (26%). The largest market shares correspond to North America with 44%, followed by Europe with 20%, Asia (13%), Oceania (11%), Latin America (9%) and Africa (3%). Recent forecasts predict BCA sales to reach US-$ 1 billion by 2008, *i.e.* about 4% of the plant protection business. However, most BCAs, as for example virus products, have a very high specificity and, consequently, relatively narrow markets. Another important obstacle for the future development and spread of BCAs and the corresponding production systems is the high cost of the registration for the products. This will be discussed in the following sections.

Table 1. World market for biocontrol agents by region and BCA group (million US-$).

	Europe	NAFTA	Latin America	Africa	Asia	Oceania	Total
Macrobials	60	80	10	5	20	15	190
Microbials:							
• bacteria	20	90	10	5	15	30	170
• virus	6	4	5	1	3	2	21
• fungi	5	15	10	1	7	6	44
Subtotal	31	109	25	7	25	38	235
Others (biorationals):							
• natural products	20	42	10	3	12	10	97
• semiochemicals	6	25	4	3	15	3	56
Subtotal	26	67	14	6	27	13	153
Total	117	256	49	18	72	66	578

Registration of Biocontrol Agents in Europe

1. Principles

The Directive EEC 94/414 governs the registration procedures in the European Union. Under this norm, it is necessary to register all plant protection products and systems, with the exception of:

- Macrobials which are regulated by different procedures, especially for the control of introductions of "exotic" species.
- Pollinator attractants which are sprayed during crop flowering to increase pollination activity; these substances are not considered plant protection agents.
- Monitoring pheromones used for prediction and survey of insect populations.

2. Regulatory System

In the EEC Directive 94/414, a special annex details the regulations valid for microbials. Pheromones and natural products are considered as chemicals. However, since the current registration procedures for BCAs were largely derived from the registration system for synthetic chemicals, it is suffering from many limitations.

2.1. Regulation of Microbials

The requirements are similar to the EPA system and include the following aspects:

i. Identification/characterization of the product based on
- RFLP, DNA sequencing of the microbial strains,
- the manufacturing method,
- impurities (metabolites, toxins, or microbial contaminants).

ii. Biological, physical and technical properties
- Stability of the product,
- mode of action,
- shelf life and storage stability,
- criteria for quality assessment.

iii. Toxicological studies

- Studies on acute toxicity (oral, dermal, inhalation, eye irritation, skin reaction),
- mutagenicity,
- risk assessment to operators,
- residual effects.

iv. Ecotoxicological characterization by measuring acute effects on fish, daphnia, algae, birds and beneficial organisms.

In some cases, for example for some pheromones, where the required information can be obtained form reliable sources and is well documented, certain requirements can be waived.

2.2 Regulation of semiochemicals

These products are not biocides aimed at reducing the population size of the target organism, but rather are substances that regulate pest populations by diverting insect away from preferred crops or by attracting insects to physical traps or trap crops. Typically, these substances are very specific to their target insects. Under lobbying pressure, the European Commission has accepted amendments to the requirements, but new guidelines have yet to be published urgently.

3. Registered and Notified BCAs in Europe

All plant protection products registered before 1994 are subject to notification and re-registration procedures to assure complete and up-to-date information on their properties. Once accepted, they are included in a positive list that is valid for all EEC countries. The first positive list of 90 active ingredients (from more than 800 registered) has just been reviewed and some BCAs are to be revised by 2007. Table 2 gives an overview of currently notified BCAs for the use in the EU. With 15 or more countries joining the EU in 2004, all registrations will have to be harmonised under the EEC 94/414 system. The majority of candidate member countries have already adapted their registration systems, but some discrepancies still exist, particulary in the area of BCAs. The registration of products after 1994 follows the 94/414 EEC Directive. Under this guideline, only two microbials have been registered in 8 years, namely the fungi Coniothyrium minitans and a species of Paecilomyces. The estimated costs for the development and registration of these two products exceeded 2 million US-$.

Table 2. Currently notified/registered BCAs for use in the EU.

Organism type	Number of products and organisms
Fungi	10 products derived from *Beauveria* (2), *Metarrhizium* (1), *Trichoderma* (3), *Verticillium* (2), *Phlebiopsis* (1), and *Streptomyces* (1)
Bacteria	One product derived from *Bacillus thuringiensis*
Viruses	2 products from *Cm*GV, *Ns*NPV
Pheromones	35 different components of pheromones and 3 types of attractants
Other natural products	43 products derived from plants, 4 products from animals, and 12 products derived from minerals

4. Principal Constraints to the Registration of BCAs

The principal constraints to the registration of BCAs are due to the following characteristics of the products:

- BCAs are not conventional pesticides; consequently, the registration procedures for synthetic chemicals are only partially adequate.
- The high specificity of most BCAs to pests and crops restricts the range of applications and therefore the demand. It is economically less feasible to register crop protection agents of high specificity than products that have a broad use spectrum (and therefore larger markets).
- The specific mode of action aims at regulating pest populations rather than at eliminating them.
- Many BCAs are useful in production systems for specific markets, including organic and IPM production systems; however, some markets impose additional restrictions on the materials that can be used.

The total cost for the development and registration of microbial products often exceeds US-$ 1 million, while the cost for pheromones ranges from US-$ 0.3 – 0.5 million, and that for other natural products from US-$ 0.2 – 0.4 million. Consequently, the development of BCAs as an alternative method of plant protection is often limited by the relatively high ratio of costs of production and registration to projected revenue. A typical example of this high investment necessary is the case of the codling moth granulovirus (CmGV) which has been registered in various countries (in 1993 in France, in 2003 in the USA). The establishment of the commercial production facilities amounted to about US-$ 3 million and the registration to an additional US-$ 2.2 million. The recuperation of the investment took about 9 years with sales volumes rising slowly from about US-$ 0.5 million in 1995 to about US-$ 3 million in 2003. Unfortunately, such slow return is unacceptable to the main-stream plant protection industry.

Conclusions and Recommendations

There is an urgent need for an amended EU guideline for BCA registration with clear registration requirements for BCAs. For example, it is currently not clear whether microorganisms need to be registered at the level of species or strains, or whether pheromones should be registered as blends or individual components. Furthermore, the waiver policy should be revised and the requirements for exotic strains should be clarified. In spite of the relatively small market and the comparatively long recuperation periods for the large investments in the development and registration of BCAs, the global BCA market will likely continue to expand slowly. In order to support this process, the IBMA recommends:

- To reduce registration costs by reducing the number of required risk assessment studies and by implementing simple and effective guidelines and standards.
- To harmonize registration procedures internationally.
- To adopt a regulatory system that is adapted to the characteristics of BCAs which require a totally different approach than the registration of synthetic chemicals.
- To provide active support to the relevant authorities and companies in order to strengthen research, registration and the promotion of effective alternatives to synthetic chemicals rather than to stifle innovation by static and unflexible conditions.

Legal Basis for Using Biopesticides in Organic Production in Peru

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Abstract
In the Andean region, there is not an exclusive legal norm or regulation related to the use of biopesticides in organic production. Regionally, their use is determined by national and international regulations for ecological agriculture, where biopesticides are mentioned as 'ecological resources' for pest and disease management or as resources to manage soils and organic production.

Introduction

In Peru, the national laws do not specifically regulate the use of alternative resources for ecological production. Thus, there is no specific list of biopesticides that can be used.

In general, the legal body used to regulate the use of biopesticides is based on five regulations for ecological agriculture: EU 2092/91 (European Union), IFOAM, NOP Regulation (USA), JAS (Japan), and OMRI (Organic Materials Review Institute). Local certifiers rely on these national and international regulations and norms and adapt their contents to the specific problems of Latin American agriculture.

It is very common that local retailers offer commercial biopesticides indicating that they are organic, but without any certification to confirm such claim. This situation is due to the lack of specific norms to regulate the commercialisation of biopesticides for organic production.

Deficiencies in the certification of biopesticides for organic production are caused mainly by high costs for the relatively limited quantities demanded by small farmers who often do not consider applying biopesticides within IPM-management schemes.

Biopesticides and the Norms of Organic Production

In general, the norms of organic production establish that biopesticides can be used only when other pest control alternatives are not effective or in cases of severe infestations. This measure is shared by international entities related to the regulation of ecological production such as IFOAM. These policies state that biopesticides are allowed in organic production under the following conditions:

- To prevent, contain and control a pest, weed or disease.
- The application of BP should be documented as a part of a production system management plan.
- Some botanical biopesticides cannot be used repeatedly in the pest management system.

- In case of emergency, some chemical pesticides may be allowed during limited periods to resolve the emergency issue; however, this option, as last resort, is subject to approval by the respective certifying body.

The Peruvian norm known as CONAPO establishes conditions for the use of biopesticides. It indicates that they can only be used when proved absolutely necessary. Additionally, it clarifies that they must have been selected considering their impact on the environment. The norm applies the term "restricted" to biopesticides whose use is subject to the conditions specified in a certification program.

Table 1. Allowed biopesticides according to the norms of IFOAM, Biolatina and the Peruvian national norm CONAPO

IFOAM	Biolatina	CONAPO
Neem (*Azadirachta indica*)	Azadiractina extracted from *Azadirachta indica* (Neem tree)	*Azadirachta indica* (neem) Restricted
Tobbaco tea (pure nicotine is prohibited)	Extract of Nicotine (watery solution) of *Nicotiana tabacum*	*Nicotiana tabacum* (watery solution) Restricted
Vegetable oils	Vegetable oils (for example, mint oil, pine oil, caraway oil)	Vegetable oils (for example, mint oil, pine oil, and caraway oil) Free
Pyrethrum extracted from *Chrysanthemum cinerariaefolium*. The use of synthetic *Butoxid-piperonil* is prohibited. If the agencies of certification have allowed previously their use, it will be prohibited completely from 2005 onwards.	Pyrethrum extracted from *Chrysanthemum cinerariaefolium*	Pyrethrum extracted from *Chrysanthemum sp* and *Pyrethrum sp* Restricted
Quassia from *Quassia amara*	Quassia extracted from *Quassia amara*	*Quassia amara* Restricted
Rotenone (*Derris elliptica*, *Lonchocarpus spp. Tephrosia spp.*)	Rotenone extracted from *Derris* spp, *Lonchocarpus* spp and *Tephrosia* spp.	Rotenone extracted from *Derris* spp, *Lonchocarpus* spp and *Tephrosia* spp Restricted
Ryania (*Ryania speciosa*)	———	Ryania Restricted
Sabadilla (*Schoenocaulon officinale*)	———	———
Preparations made from animals and oils from vegetables	———	Preparations from animals and oils. Restricted
Repellents based on plants	———	Repellents from plants. Free
Preparations made from seaweed	———	———
Quitine-containing preparations for nematode control	———	———
Preparations based on fungi, bacteria (e.g. *Bacillus thuringiensis*) or virus (e.g. granulosis virus)	Preparations based on fungi, bacteria (e.g. *Bacillus thuringiensis*) or virus (e.g. granulosis virus)	Preparations based on fungi, bacteria (e.g. *Bacillus thuringiensis*) or virus (e.g. granulosis virus) Restricted
Liberation of parasites, predators and sterilized insects	———	Liberation of parasites and predators of pest insects. Restricted

It's important to mention that certifying agencies often allow or restrict different biopesticides. Internationally, the most relevant norm is the one established by IFOAM. Using this as a base, the national norms have established their own lists including the Peruvian regulation for organic agriculture. Table 1 compares the regulatory status of selected biopesticides allowed in organic agriculture according to IFOAM, Biolatina (the most important Peruvian certifier) and CONAPO (Peruvian national regulation).

The Commerce of Biopesticides in Peru

For Peru, the most important rules governing the use of biopesticides are the ones established by the certification agencies and the National Norm CONAPO which was approved in May 2003. The most important certification agency in Peru is Biolatina whose certification criteria are primarily based on the regulations of IFOAM, OMRI and the European Union.

Many years ago, the government started promoting the use of biopesticides giving rise to what today is the National Program on Biological Control. Today, the program counts with 60 laboratories for biopesticide production, which have grown into a network of small enterprises. Additionally, private initiatives, e.g. the asparagus industry, are also establishing laboratories for the production of biopesticides for their own particular needs. Also the non-governmental (NGO) sector has developed comprehensive promotional initiatives on biopesticides, including information and technology transfer for different clienteles. The positive experience of RAAA's support in the Cañete Valley for a small enterprise that markets biological pesticides is an example of successful collaboration with NGOs.

Nevertheless, one of the main obstacles for the spread of biopesticides is the registration process which subjects bioproducts to the same rules as synthetic pesticides.

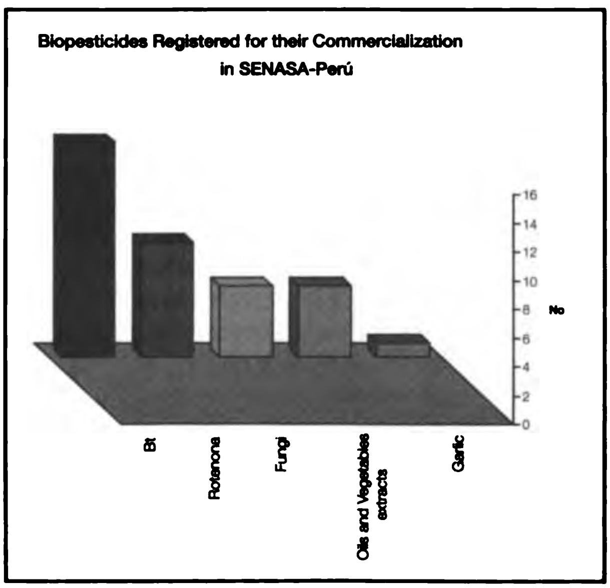

Figure 1. Bopesticides registered in Peru (SENASA, 2003). The numbers are the numbers of different commercial products in each category.

Currently, there are 34 biopesticides that are registered with SENASA, Peru, for their commercialisation (Figure 1). Among them, the most important are 15 products derived from *Bacillus thuringiensis*, followed by products based on rotenone (8), fungi (5), oils and vegetable extracts (5) and garlic (1).

Recommendations

The experiences with the development and use of biopesticides, as well with their characterization and regulation, suggest the following topics for future work:

- The registration process for biopesticides in the countries should be simplified by means of a special norm.
- Commercial biopesticides should have an organic certificate to facilitate the organic certification process.
- The managerial capacities of producers and producer groups need to be strengthened to promote organic production, and, consequently, stimulate the use and commercialisation of biopesticides.
- Certification requirements should be standardized, at least by groups of countries, as in the case of the initiative to establish an Andean Norm for biopesticides.

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Annex

LIST OF BIOPESTICIDES REGISTERED IN SENASA - PERU			
Common name	**Commercial name**	**Class**	**Registering company**
Bacillus thuringiensis	Bactucide	Biological insecticide	Comercial Agrícola del Perú S.A.
Bacillus thuringiensis	Ecotech	Biological insecticide	Aventis Cropscience, Perú S.A.
Bacillus thuringiensis	Biobit HP WP	Biological insecticide	Tecnología, Química y Comercio S.A.
Bacillus thuringiensis	Vendaval BT	Biological insecticide	Pineral Andina S.A.
Bacillus thuringiensis	Batumex	Biological insecticide	SERFI S.A.
Bacillus thuringiensis var. *kurstaki/aizawai*	Xexntari WDG	Biological insecticide	BAYER S.A..
Bacillus thuringiensis var. *kurstaki*	Javelin WG	Biological insecticide	Conagra S.A.C.
Bacillus thuringiensis var. *kurstaki*	Dipel 2X	Biological insecticide	BAYER S.A..
Bacillus thuringiensis var. *kurstaki*	Turilav WP	Biological insecticide	SERFI S.A.
Bacillus thuringiensis var. *kurstaki*	BT-2X	Biological insecticide	SERFI S.A.
Bacillus thuringiensis var. *kurstaki*	Biocillus	Biological insecticide	SERFI S.A.
Bacillus thuringiensis var. kurstaki/aizawai	Agree 50 WP	Biological insecticide	Conagra S.A.C.
Bacillus thuringiensis var. *kurstaki/aizawai*	Turex 50 WP	Biological insecticide	Química Suiza, S.A.
Endotoxina de *Bacillus thuringiensis*	MVP II	Biological insecticide	Conagra S.A.C.
Endotoxina de *Bacillus thuringiensis*	MVP	Insecticide	Conagra S.A.C.
Rotenona	Atoxin 15 CE	Insecticide	Laboratorios Regis, S.A.
Rotenona	Rote-Biol	Insecticide	FarmagroS.A.
Rotenona	AGROSAN 8% PM	Insecticide	Consorcio Exportador S.A.
Rotenona	Rothenox 10 CE	Insecticide	Ecopro S.A.
Rotenona	Rothenox X-SP 10 CE	Insecticide	Ecopro S.A.
Rotenona	Extracto-L	Insecticide	Serfi S.A.
Rotenona	Extracto	Insecticide	Serfi I S.A.
Rotenona	Rothenox 8 PM	Insecticide	Ecopro S.A.
Beauveria bassiana	Naturalis L	Insecticide	Serfi S.A.
Beauveria bassiana	Bracaril	Biological insecticide	Serfi S.A.
Enthomophora virulenta	Vektor	Biological insecticide	Serfi S.A.
Gliocladium virens	Soil gard	Fungicide	Conagra S.A.C.
Verticillum lecanii	Vertisol	Biological insecticide	Serfi S.A.
Azadirachtina	Neemix 4.5	Insecticide	Conagra S.A.C.
Vegetable Extracts	Hunter	Biological nematicide	Impagro E.I.R.L.
Corn oil	Super Crop Oil	Insecticide	Conagra S.A.C.
Neem Oil	Trilogy 70	Fungicide, insecticide, acaricide	Conagra S.A.C.
Refined fish oil	Ecoprol 3000 OIL	Insecticide	Ecopro S.A.
Vegetable Oil	Golden Natural Oil	Insecticide, aracida	Stoller PERU S.A.
Garlic (*Allium sativum*)	Garlic Con	Insect Repellent	Conagra S.A.C.

The CATIE/GTZ Information System on Biopesticides

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Abstract
In 2000, the GTZ project "Promotion of non chemical crop protection methods through the private Sector, Central America" started to develop an information system on biopesticides in Costa Rica, Nicaragua and Honduras. The system is based on the Internet page www.bioplaguicidas.org

The website features information on registered biopesticides that are available in Central America, as well as on active ingredients, technical details on BP use and the companies behind the products. The site has a database linking crop protection problems with products available and offers support on questions of registration. It contains an expanding number of documents related to biopesticides, publishes an updated calendar of relevant events and provides links to national, regional and international institutions involved in non chemical crop protection.

Introduction to www.bioplaguicidas.org

Since 2000, the GTZ project "Promotion of non chemical crop protection methods through the private Sector, Central America" started to develop an information system on biopesticides in Costa Rica, Nicaragua and Honduras. The information is updated twice per month and posted on the internet under www.bioplaguicidas.org. This website is the first and principal information platform in Latin-America designed for the promotion of registered biopesticides for sale in the three countries covered by the Project (Costa Rica, Nicaragua and Honduras).

The target groups for which this page has been designed include professionals in agriculture of the public and private sector, agriculture students, university professors. However, the website invites also other persons interested in promoting their products for the biopesticide market.

The webpage shares information about commercial products which is available from the registering company and/or the biopesticides traders. This information has been cross-checked by the project technicians with the respective ministries of agriculture. The website also provides complementary technical information derived from research by the project staff, as well as from updated information compiled through national and regional workshops and symposia. Further information is provided via a CD with the information of an initiated extension program with sale and extension's points of the public sector from which the information can be entered offline.

Contents of the Page

The website provides specific information on the following:

- **Biopesticides Products:** Contains information on all registered biopesticide products, as well as their availability for the sale in the markets of Costa Rica, Nicaragua and Honduras. Each product is presented with a photo of its commercial presentation, and with information about the manufacturer and distributor as well as with technical data about the active ingredient.

- **Biofertilizer Products:** this recently added section is still in the process of being completed; it offers, similar to the biopesticides section, information about the manufacturer and/or distributor, technical data of the product and a photograph of the commercial presentation of the products.

  - **Library:** this section provides the following information and services:
  - **Books:** this section provides the PDF files of all books written or published by the project staff. A central document is the **Guide of Active Ingredients in Central America** which, for the first time, compiles 69 technical records of active ingredients in the commercial biopesticides registered in the region. These records on active ingredients can be downloaded individually or as the complete guidebook which can also be found in the main bookstores.
  - **Training:** this section provides, free for all users, the summaries and complete presentations given by project personnel during selected training courses during the last three years.
  - **Economic studies:** this section presents economic studies on stem coffee and sugar cane a general study on biopesticidas.
  - **Legal Base:** this section presents information on the current regulations in each of the three project countries that are relevant for the registration of biopesticides. Several components of relevant regulations which today are in the process of approval by the corresponding authorities in Central America have been elaborated and promoted by the project in close collaboration with the private sector, This section has also become an important venue for the exchange of opinions among interested persons.
  - **International Companies:** a listing of European and North American Companies, mainly of those which distribute biopesticides in Central America.
  - **Data Base:** this system has been designed using the "Flash" environment to allow for easy and rapid browsing of the users. For example for Costa Rica, the database includes seven important agricultural crops, their principal pests and diseases, as well as the recommended biopesticides for their control.
  - **"Other Links"** lists many relevant public and private institutions, including universities and Ministries of Agriculture from which users can obtain more information.

- **Events:** this section provides information on training courses, product fairs, and other relevant events in Central America that are offered to the general public. This section invites the publication of events by all institutions that want to promote their products.

- **Organic Agriculture:** this new section offers information related to certifying companies, regulations and requisites for the organic certification of farms. For Costa Rica, the section provides a detailed list of certified organic crops at national level. Further information includes documents from workshops dedicated to identify advances and product supply of different Latin-American countries.

¿Who can Promote the Products in Our Page?

We invite all companies that have biopesticides which are registered under the current legislation of the country where the products are to be sold to submit information for the website. The information should include details on the manufacturer and/or distributor of the product, as well as a label and an original pamphlet or copy of the product. Prior to inclusion in the website the information will be evaluated and verified by a project expert.

Based on our experiences and company feedback, the site www.bioplaguicidas.org has been of great utility for many private companies, particularly for those companies that are small and often family enterprises with no capacity for the promotion of their products. Many of these companies have been able to increase their sales through their presence on the website. As an additional benefit each company can be provided with an individual e-mail address linked to bioplaguicidas.org, which facilitates the contact with their customers.

The rapidly growing number of visits of the website by different users during the past three years (Figure 1) illustrates clearly the growing importance of this internet page.

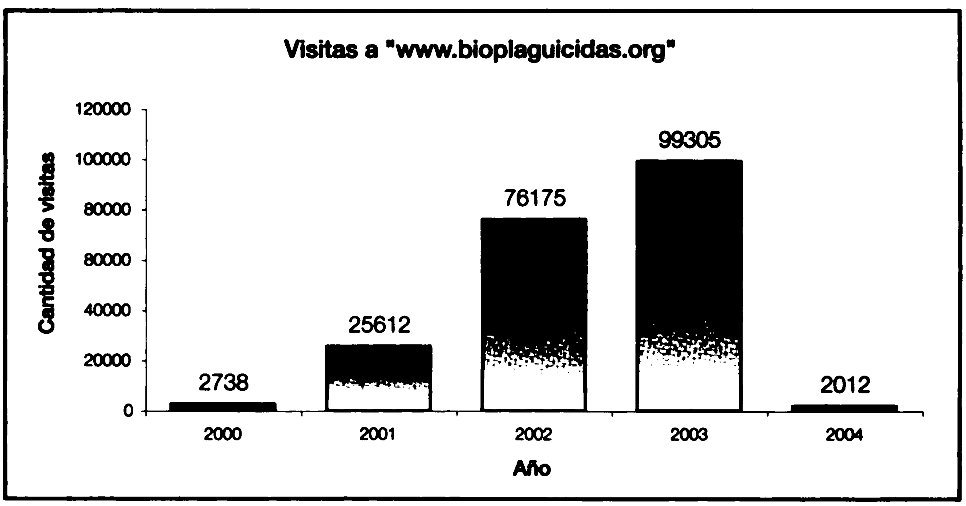

Figure 1. Visits to the website www.bioplaguicidas.org from 2001 to 2004 (Source: Biopesticide Project CATIE/GTZ, 2005)

EPA Information Systems for Biopesticides

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EPA Information System

The U.S. Environmental Protection Agency (EPA) maintains an Internet website for dissemination of information regarding all topics pertinent to the Agency [www.epa.gov], including biopesticides. The homepage for the Biopesticide and Pollution Prevention Division (BPPD) provides information on the history of the Division, the legal statutes granting authority for oversight of pesticides, definitions, tools for registration procedures, lists of active ingredients (by product and group - microbial or biochemical), fact sheets, and a list of Plant-incorporated Protectants (PIPs) [http://www.epa.gov/oppbppd1/biopesticides/].

Additionally, the biopesticides homepage contains links to supportive documents on legal matters, storage and disposal of pesticides and containers, food tolerances and documentation of adverse effects. A "Highlights" section provides access to more recent or highly significant documents that relate to biopesticide issues, including Pesticide Registration Notices (PR-Notices), which provide guidance to applicants wishing to register a pesticide and which communicate changes to current pesticide policy, which may affect registrants of pesticides. Another section allows for researching historical aspects of biopesticide registration and regulation.

BPPD is divided into three working groups or branches: the Biochemicals Branch, the Microbials Branch, and the newly formed Environmental Stewardship Branch (ESB). The EPA strives to maintain a transparent review process for biopesticides in that the toxicity data reviewed as part of the registration process are available, either in summarized form on-line, or as the original submission and review documents through a public docket, or through a Freedom of Information Act request. Typically, the only data that are not available are those which are considered as confidential business information, as defined by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The EPA publishes all significant registration actions in the Federal Register, the official publication of the U.S. Government. [http://www.gpoaccess.gov/fr/index.html]

The ESB is responsible for the Partners in Environmental Stewardship Program (PESP) which serves to foster the use of biopesticides and integrated pest management principles for agricultural and non-agricultural uses [www.PESP.org]. PESP is a voluntary public / private partnership committed to reducing the risks from pesticides in agricultural and non-agricultural settings, including farms, gardens, rights of way, schools, parks, public forests, etc..

The staff of the ESB provides educational materials for the public and serves as a liaison to various partner groups, which use pesticides or which can affect their overall utilization. The list of members of PESP can be found under [http://www.epa.gov/oppbppd1/PESP/members.htm]. In addition, there are "supporters" who do not actually use pesticides, however, they can serve to influence their use based on their position in business or as a public institution. Both groups are committed to environmental stewardship and support the reduction of pesticide risks while managing pests cost-effectively. The PESP also provides financial support for some of its objectives through competitive grant programs under the Regional Initiative Grants Program [http://www.epa.gov/oppbppd1/PESP/regional_grants.htm] and the National Foundation for Integrated Pest Management Education [http://www.ipm-education.org]. for Integrated Pest Management Education, and Demonstration Project grant mechanisms. While the criteria for the different grants vary, the goal is to promote the use of reduced-risk pesticides and to foster safer environmental practices.

Besides the website for information dissemination, the PESP publishes audience-specific pamphlets and booklets for instructional purposes. These include educational literature aimed at grammar-school-aged children. Some of these publications are available on-line at [http://www.epa.gov/oppbppd1/PESP/publications.htm]. While there is currently no information source in Spanish on the official Agency site for biopesticides, there are some related documents on pesticides at the two URLs listed below:

http://www.epa.gov/espanol/
http://www.cec.org/search/results.cfm?varlan=espanol&words=pesticidas&x=0&y=0

Other websites with information relevant for biopesticides are:

- http://www.epa.gov/pesticides/
- http://www.epa.gov/opptsfrs/OPPTS_Harmonized/885_Microbial_Pesticide_Test_Guidelines/Series/index.html
- http://www.epa.gov/docs/OPPTS_Harmonized/830_Product_Properties_Test_Guidelines/Series/
- http://www.biopesticideindustryalliance.org/

DISCLAIMER: The content and opinions expressed in this analysis are those of the author and do not in any way constitute the policy or endorsement of the U.S. Environmental Protection Agency, the U.S. Department of Agriculture or the Food and Drug Administration.

PAN Germany Online Information Service for Non-chemical Pest Management OISAT

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Abstract
The OISAT Online Information Service for Non-chemical Pest Management in the tropics is intended to spread information on non-chemical crop protection practices to users in developing countries, including poor and illiterate farmers. The project aims at providing an easy to understand and easy to use service based on validated information derived from local knowledge and research.

Introduction

The international NGO "Pesticide Action Network" (PAN) has played an important role in stimulating global awareness about the urgency for the reduction of synthetic pesticide use. PAN has played an important role in pesticide reduction efforts, including contributions to the FAO International Code of Conduct on the Distribution and Use of Pesticides, the Rotterdam Convention on Prior Informed Consent (PIC), and the Stockholm Convention on Persistent Organic Pollutants (POPs). Recently, the network has recognized the relevance of non-chemical pest management practices as an important component for successful pesticide reduction efforts. According to the analysis of PAN Germany, the mentioned international regulations can only be put into practice if effective, user-friendly and economically attractive alternatives are available for the users of environmentally dangerous synthetic chemicals.

Current Situation

Developing countries continue to face many problems caused by excessive use of pesticides and the use of highly toxic and dangerous substances which are often banned in the countries where they are produced. Over the past decades, knowledge on alternatives to chemical pest control has increased, often drawing on traditional and local knowledge and on applied research. However, this information is still rather scattered and is not easily available to the end users. An example are the many training and extension programmes in developing countries which often lack easy and low-cost access to relevant quality information on topics related to the conversion from chemical to non-chemical crop protection approaches and techniques (NCPAT).

Due to external pressures such as the imposition of the maximum residue level (MRL) for exporters of agricultural products, but also due to the growing health and environmental awareness, there is an increasing demand for information on ecological pest management and NCPAT. Access to information is an important factor contributing to reduce the application of chemical pesticides and to decrease health hazards to farmers and consumers, as well as negative ecological effects on ecosystems at large and natural enemies, microorganisms, and water quality in particular.

Objectives of the Information Service

The online information service for non-chemical pest management in the tropics, OISAT, has been initiated by PAN Germany to facilitate the access to information and knowledge on non-chemical pest management practices. The goal of OISAT is to employ modern information technologies in order to spread information on non-chemical crop protection practices in developing countries. With the help of this online service, existing information and knowledge will be made more visible and accessible. If the use of successful non-chemical control options by farmers is increased, the application of chemical pesticides will be reduced and the health as well as the socio-economic situation of smallholder farmers in developing countries is likely to be improved.

The project aims at converting existing information derived from local knowledge and research into a form and language that is easy to understand and that allows the reader to experiment immediately with a recommended practice. The information service should also serve as an interactive site for exchanging information and experiences among practitioners in the South and as a source of information for researchers. During the subsequent dissemination phase, the South-South exchange will be intensified by stimulating the integration of this information service into existing training and extension activities of relevant networks and by reporting back the information and experiences gained by the various collaborating groups and organisation to OISAT.

Target Group

The ultimate intention of OISAT is to reach very poor and even illiterate farmers in developing countries. However, since online information generally cannot reach these intended users directly, the information will be targeted primarily to training and extension programs and to researchers who work directly with the target group and its organizations. Wherever possible, direct access of farmers to OISAT is encouraged.

Main Steps

1. Collection of information from different sources, including publications, internet, practical experiences, project reports etc. which form the body of information for the website;
2. Development of a structure for the online presentation of the information, which is suitable for trainers and farmers, in consultation with international advisors and practitioners;
3. Programming and data input;
4. Development of a strategy with key partners for the effective use of the information service;
5. Creation of a multiplicator network with organizations and institutions active in training and extension;
6. Ensuring the maintenance and updating of the service for at least 3 years, and stimulating the South-South exchange of information and knowledge.

Currently, a follow-up project on dissemination strategies is being developed in close collaboration with key partners, who work actively at the interface between training and extension and poor producers.

Timeline

With the conclusion of the development phase which started in 2002, the online service was launched in July 2004. The dissemination phase is scheduled to run from July 2004 until June 2007. After these two phases, the service should be self-supported by the different collaborating networks.

Structure of the Website

PAN-Germany's approach to pest management is ecosystem-oriented. This means that PAN does not promote the substitution of chemical pesticides, but first of all a crop or farm management with a high degree of self-regulatory mechanisms to keep pest damage within acceptable limits while keeping populations of antagonistic organism high. Unfortunately, preventive measures alone are not always effective enough and therefore curative pest control practices are also needed as a complement. As a result of this, both preventive and curative pest management options are provided by the information service.

The online service presents an overview of pests for a wide range of important crops and fruits, including staple crops, vegetables and export crops (www.oisat.org/cropsmap.htm). For each crop, the system then guides the user to the important key pests for the major crop stages and plant parts (see Inset 1 for an example). This information, complemented by a section on the agroecology of the crop helps farmers, trainers and extension workers to identify the pests and appropriate non-chemical control methods along the cropping cycle.

Inset 1. Information provided by the OISAT website (www.oisat.org) illustrated by the example of cabbage. Clicking on a specific pest takes the reader to the pest profile, from which the user can access pages with recommendations on preventive and curative control methods. The website also provides detailed information on the agroecology of the crop, information on the recent developments. external links and references.

Cabbage
Scientific name: *Brassica oleracea var. capitata*
Family: Cruciferae

Growth stage and plant part	Pests
Seed	
Sown seeds	Ants
Seedling Stage	
Transplanted Seedlings	Aphids, Cabbage root maggot, Cutworm, Diamondback moth
Roots	Cabbage root maggot, Flea beetles
Stem	Cutworm
Leaves	Aphids, Cutworm, Diamondback moth, Flea beetles, Thrips
Vegetative Stage	
Stems	Cutworm Lygus bugs
Leaves	Aphids, Cabbage webworm, Cabbage white butterfly Cabbagehead caterpillar, Diamondback moth Flea beetles, Lygus bugs, Thrips
Reproductive Stage	
Head	Cabbage looper, Cabbage webworm, Cabbage white butterfly Cabbagehead caterpillar, Diamondback moth, Flea beetles,
Lygus bugs, Thrips	
Maturation stage	
Head	Cabbage looper; Cabbage webworm, Cabbage head caterpillar Diamondback moth, Flea beetles, Lygus bugs, Thrips
Postharvest and storage stage	

Agro-ecology

Cabbage when planted 14 days after tomatoes reduces the incidence of and damage by Diamondback moth (Makumbi, 1996). Cabbage intercropped with tomato, coriander or garlic, combined with the application of neem seed kernel extract protects plants from Diamondback moth in the field (Facknath, 1996). Indian mustard (Facknath, 1997), Chinese cabbage, and radish are good trap crops for controlling cabbage webworm, flea hopper, and mustard aphid when planted in every 15 rows of cabbage. The mustard row is either in the outermost or in the middle row to avoid caterpillars being blown by wind into the cabbage plants (Muniappan; Lali, 1997). To control cabbage head caterpillar, Indian mustard should be planted 12 days before *transplanting* cabbage (Cornell University, 1995). Do not plant cabbage or where members of the cabbage family have been grown for 3 consecutive years to avoid serious problems of pests and diseases. *Intercropping* with certain combinations will have a beneficial effect on reducing pest damage in crucifer areas. Where farm size is small, seedlings covered with row covers (fine nylon mesh) prevent moths from laying eggs on the leaves and or next to the plant (Agriculture and Agri-Food Canada, 2003).

Cabbage needs plenty of nutrients. NPK is needed for head formation. However, excess nitrogen (N) may cause loose head formation and internal decay. Potassium (K) deficiency can result in marginal *necrosis* and lower head quality, but its excess can cause the heads to open. It has high Sulfur requirement; and is sensitive to Magnesium and Boron deficiency. During land preparation, incorporate10-20 tons of manure/ha with NPK. NPK requirements are 55-75:40-80:80-110 kg/ha on prepared beds of 1-1.2 m width and 30 cm height. The distance between beds should be about 30-40 cm. Two weeks after transplanting another side dressing of 55-75 kg/ha of N should be applied. Alternatively, the same amount can be applied in split dosages as 1-2 % solutions at 3-4 days intervals starting 1-2 weeks after transplanting. Good timing in the split N applications is important for continuous vigorous growth (Siemonsma; Piluek, 1994: pp.130-113; 181-184). However, fertilizer recommendations based on soil analyses offer the very best chances of getting the right amount of fertilizer without over or under fertilizing. Ask for assistance from the local agriculturist office for *soil sampling* and *soil analysis* procedures.

If you have access to fresh seaweeds, rinse these seaweeds to remove the salt, and then apply them as mulch. Apply $^1/_2$ kg/100 sq feet area. Seaweed is a long-term soil conditioner and growth regulator. It contains micronutrients, amino acid and enzymes plus growth hormones that stimulate plant cell division (Card, et. al., 2002).

To help control fungal disease apply compost tea made from mature-based compost. The *microorganisms* present in the compost tea attack the fungi that cause cabbage disease such as Botrytis blight. To make your own compost tea, place 1 gallon of well-aged compost in a 5-gallon pail and fill it with water. Stir well and leave to stand for 3 days in a warm place. Strain the mixture which is then ready for application. Remove heavily diseased leaves before application. It is better to spray late in the afternoon so that the leaves remain damp for several hours. Check affected plants every 3-4 days and repeat applications if *symptoms* persist (Ellis; Bradley, 1996: p. 427).

Recent developments

The main *germplasm* collections of Brussels sprouts, kales, and kohlrabi are maintained in European countries and the USA. Kales are the main source of genes conferring resistance to environmental stress. Attempts are being made to breed annual cultivars to make seed production possible in tropical areas (CABI, 2000).

External links:

- AVRDC. Cabbage information. http://www.avrdc.org/LC/cabbage/home.html
- Cabbage Family Pest Information Links. Cabbage pest links. http://www.citygardening.net/cabpest/
- University of Kentucky College of Agriculture Cabbage pests. http://www.uky.edu/Ag/Entomology/entfacts/veg/ef300.htm
- Lerner, R. Purdue University. Cabbage. http://www.hort.purdue.edu/ext/senior/vegetabl/cabbage1.htm
- Ministry of Agriculture and Food, Ontario. Caterpillar pests of Cruciferous crops. http://www.gov.on.ca/OMAFRA/english/crops/facts/99-035.htm
- UC IPM. Cole crops. http://www.ipm.ucdavis.edu/PDF/PMG/pmgcolecrops.pdf
- Purdue University. Managing insect pests of commercially grown crucifers. http://www.entm.purdue.edu/Entomology/ext/targets/e-series/EseriesPDF/E-99.pdf
- IFA. Present fertilizer practices. Cabbage (*Brassica oleracea* L., Capitata group). http://www.fertilizer.org/ifa/publicat/html/pubman/cabbage.htm
- Texas A&M University Entomology. Vegetable insect pest index. http://vegipm.tamu.edu/indexbyvegetable.html

References:

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Muniappan, R.; Lali, T. (2000): Management of cabbage pests of the Asia Pacific lowland tropics. College of Agriculture and Life Sciences, University of Guam, Guam.

Siemonsma, J.; Piluek, K. (2000): Vegetables. Plant resource of Southeast Asia (PROSEA).

Talekar, N.; *et. al.* (2000): Intercropping and modification of irrigation method for the control of diamondback moth. Asian Vegetable Research and Development Center (AVRDC), Shanhua, Tainan, Taiwan, ROC

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Linked to the crop and pest profiles, the user can retrieve up-to-date information on preventive control options (natural enemies, pest monitoring, cultural and management practices) and on curative control options (botanicals or other substances, physical control and other methods). In addition, the website also provides general entomological information about the pests. The information on pest-controlling plants covers the following aspects: scientific name, plant parts used, mode of action, formulation, effects on humans, and effects on non-target organisms. Other options provided by the site are a library with full-text documents, external web links and a mechanism for information input & feedback by users of the site.

Dissemination

OISAT is a platform for information dissemination and information sharing and the integration of its online information into training and extension services. The close collaboration with relevant training and extension networks and other information platforms should help to ensure an effective and efficient information flow from the web to the field and back. The pest management practices presented in OISAT can be validated in the field by the various training and extension services using the system. Thus, more information and data can be generated and subsequently included into the information service.

Once OISAT is complete, it is hoped that also development agencies will recognize the benefits of a successful integration of OISAT with training and extension services. It is envisioned that this may lead to a subsequent large-scale outreach programme for the benefits of farmers. The learning process on the successful integration of OISAT into training and extension services will be undertaken collaboratively with partners from Africa and Asia.

Conclusions and recommendations

Partnerships and networking are key "ingredients" of the future dissemination strategy of OISAT which will involve not only training and extension networks but also policy makers. PAN Germany should actively pursue the collaboration with such networks and develop a communication strategy on the basis of transparency and participation and thus achieve the commitment of the collaborating partners.

References and websites

www.oisat.org
http://www.oisat.org/downloads/oisat_flyer.pdf
http://www.oisat.org/downloads/OISATReportKenya.pdf.

Section 4
Outlook and perspectives

Use of Biopesticides in Central America: Farmers' and Market Criteria

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Abstract
With a market share of less than 2%, biopesticides still represent a small fraction of the world market of pesticides. In Central America this pattern is similar, indicating that the availability of biopesticides to the region's farmers is very limited compared to that of synthetic pesticides. However, public awareness is increasing regarding the negative effects of synthetic pesticides in the form of residues in food products, water and the environment on the one hand, and recognizing the multiple environmental and health benefits of biopesticides on the other.

In order to promote the use of biopesticides among Central American farmers, it is vital to develop strategies that enhance their availability through local production and through the import of high-quality products linked to an efficient distribution chain.

Introduction
The Biopesticides Project of CATIE/GTZ is a regional initiative supported by GTZ/BMZ, Germany, to strengthen the capacity of the private sector in Central America to provide high-quality biological inputs to farmers. In 2003, the BP project interviewed centers that distribute agricultural inputs, as well as extensionist professionals and farmers to assess their knowledge about, their attitude towards and their use of biopesticides. The interviewed persons were also asked whether they would recommend biopesticides for wider use. This paper summarizes the responses of these three groups of users.

Factors that Determine the Acceptance of Biopesticides
The criteria that farmers use to accept or reject agricultural inputs such as biopesticides include the following:

Effectiveness of BPs
The relatively slow action of biopesticides compared to synthetic pesticides is often perceived as a negative aspect. A regional survey indicated that 70% of Costa Rica's farmers, 64% of Honduras' and 87% of Nicaragua's believed that the effect of biopesticides is slow (CATIE/GTZ, 2003). However, when asked about the reasons why they do not use biopesticides, only 41%, 25% and 35%, respectively, mentioned slow action as the reason to reject BPs (see Table 1). Of all the interviewed farmers, 11% of Costa Rican farmers and 7% of Honduran farmers said that biopesticides were not effective at all.

Among the possible causes for a low effectiveness may be the typically relatively short shelf lives of the products compared with synthetic alternatives. Use of products past their shelf life tends to reduce their effectivity. Furthermore, many bioproducts are very specific for certain pests or diseases, thus restricting their application spectrum.

Table 1. Farmers' perception of biopesticides in Costa Rica (CR), Honduras (HO) and Nicaragua (NI)

		% (1)	
¿How is the effect of biopesticides on pests?	CR	HO	NI
-Fast	10	32	6
-Slow	70	64	88
-Farmer does not know	16	4	6
¿What are the reasons why BP are not used more widely?			
-Products are ineffective	11	7	0
-Expensive	13	32	10
-Not available	26	19	48
-Slow action	42	25	36
-Others	4	5	0
¿Do you use the same application equipment?			
-Yes	38	57	36
-No	52	12	64
-no answer	10	8	0
¿What time of the day is best to apply BPs?			
-Morning	53	53	43
-Afternoon	19	23	38
-Night	5	16	4
-Unknown	19	6	15

(1) The numbers are the percentages of the 50 farmers interviewed in each country

Source: CATIE/GTZ 2003. Estudio sobre conocimiento, actitud y práctica hacia biopleguicidas entre agricultores, extensionistas y agroservicios. Proyecto Biopleguicidas CATIE/GTZ. Documento Interno. S.p.

High Specificity of BPs

The survey revealed that farmers criticize that some BPs, particularly microbials, are restricted to attacking only specific states of a pest and that their effectiveness to control pests is subject to the match between temperature and moisture conditions at application and their environmental requirements. These limitations can be significantly reduced through adequate formulation, e.g. in oil, by using ultraviolet light protectors, and by choosing the best conditions for the application. The best time to apply many BPs is either early in the morning or towards the end of the day, when the sunlight is relatively weak. In Costa Rica, Honduras and Nicaragua, between 43% and 53% of the farmers considered that the morning was the best time to apply BPs. For the majority of the other farmers, the next best option is the application during the afternoon (Table 1). These percentages show that there is little knowledge on the adverse effects of sunlight on the effectiveness of BPs.

Application Equipment

For the application of biopesticides, it is preferable to use different equipment than for the application of synthetic chemicals to avoid contamination by residues of synthetic pesticides. In some cases, even intense washing may not be sufficient to avoid effects of residual synthetic pesticides on the effectivity of biopesticides. According to the study, in Costa Rica, Honduras and Nicaragua, 52%, 12% and 64% of the farmers used different equipment to apply biopesticides or synthetic chemicals, while 37%, 56% and 35% use the same equipment (see Table 1).

Market Requirements

While many biopesticides can be used in organic agriculture, subject to restrictions established by agencies such as OMRI, IFOAM, the Codex Alimentarius and by certification agencies accredited in importer countries, not all BPs are automatically allowed in organic agriculture. However, there are no restrictions to their use in IPM programs and in conventional agriculture. Considering that the international markets are asking for cleaner products with fewer pesticide residues, and that exports to the United States and Europe are increasing, BPs encounter new possibilities, as more and more products must meet the international standards regarding food quality and residues in final products.

High Prices and Limited Availability

Biological pesticides are generally more expensive than synthetic chemicals, especially when compared with cheap generic products. Thirteen percent of Costa Rican and 32% of Honduran farmers claimed that BPs are not used because they are too expensive (Table 1). The main reasons for these higher prices are that, so far, most BPs are produced at small scales because of limited demand or difficulties to develop mass production technologies, and that many BPs, particularly microbials, have special storage requirements such as refrigeration.

In Costa Rica, Nicaragua, and Honduras, many of the interviewed farmers said that one of the main reasons why BPs are not used is due to the lack of information about BPs and due to their limited availability (Table 1). In the case of microbial products, their availability is also affected by a limited shelf and storage life. Hence, it is often easier and cheaper to buy synthetic agrochemical products, since they are available in almost every store.

Educational Level and Knowledge of the Farmers about BPs

The educational level of Central American farmers varies depending on the size of their production units, location and financial capacities. These factors also have a strong influence on farmer acceptance of BPs and on their willingness to change (Table 2). In the three mentioned countries, most of the farmers are willing to promote the use of BPs on the grounds of their benefits for human health, for the protection of the environment and, to a lesser degree, based on economic aspects.

In Costa Rica, 42% of the farmers indicated that they did not know much about biopesticides, although they claimed to know about their main benefits and that their effects are slow. Up to 76% of the interviewed farmers in Costa Rica, Nicaragua and Honduras mentioned that they did not know how to distinguish a particular biopesticide among several options. Even worse, many confuse BPs with synthetic chemicals (Table 2). Therefore, there is a considerable need for to provide information to the farmers on the following subjects: the risks to human and animal health, the risks of environmental pollution, the target range of the products, how and when the products should be used for maximum effectivity, how they are affected by different conditions, and where they are available.

Many Costarican farmers believed that the use of BPs will increase in the future. In this country, the principal information sources used by the farmers were publications (10%-20%), government institutions (20%-75%) and technicians (6%-44%).

Use of BPs by Farmers

Based on a study by CATIE/GTZ (2003) it is estimated that between 76% and 82% of the producers in Costa Rica and Honduras have used at least one biopesticide. Between 76% and 90% of the extension agents have recommended their use, and between 60% and 80% of the agrochemical stores have done so too. However, these figures do not imply that there is a high level of use, as producers tend to apply large amounts of synthetic pesticides. According to the information on pesticide imports, the import values of synthetic pesticides in Costa Rica amounted to approximately US-$ 58 million for the year 2002, compared to biopesticide imports worth US-$ 2 million. The most common applications of BP in that country are insect and worm control, mainly through the use of *Bacillus thuringiensis*.

Table 2. Knowledge and perception of Central American farmers towards BPs

		%[1]	
¿Which of these products are BPs?	CR[2]	HO	NI
-Fatty acids	17	12	2
-Endosulfan	4	15	2
-*Bacillus thuringiensis*	37	44	20
-Don't know	43	29	76
¿What types of BPs are found in agrochemical stores?			
-Against fungi	26	9	4
-Against insects	38	31	22
-Against weeds	7	22	2
-Against all types of pests	15	22	7
-Don't know	13	15	65
¿Would you promote the use of BPs?			
-Yes	89	90	98
-No	9	10	2
¿Why would you promote the use of BPs?			
-Economic	18	24	16
-Health	40	26	43
-Environment	34	43	39
¿Which are the benefits of using BPs?	34	30	34
-Healthy foods	19	35	35
-Reduce the risks of poisoning	29	26	27
-They do not pollute the environment	29	26	27
-Alternative to synthetic products	11	8	4

[1] The numbers are the percentages of the 50 farmers interviewed in each country
[2] Ho = Honduras, Ni = Nicaragua, CR = Costa Rica;

Source: CATIE/GTZ 2003. Estudio sobre conocimiento, actitud y práctica hacia bioplaguicidas entre agricultores, extensionistas y agroservicios. Proyecto Bioplaguicidas CATIE/GTZ. Documento interno. S.p.

Environmental and Health Aspects

Environment and health are very important aspects that should influence the selection of BPs. However, this is not necessarily happening. The continuing extensive use of chemical pesticides and their consequences for the environment and health give evidence that these considerations play only weak roles for the buying decisions. Nonetheless, the interviewed farmers mentioned that BPs are helpful agents to prevent or reduce risks such as water and soil pollution and human intoxication related to chemical residues in food.

About one third of the farmers in Costa Rica, Honduras and Nicaragua said that BPs are useful to produce healthy goods, to reduce poisoning, and to reduce contamination of the environment. However, fewer than 10% of the farmers considered BPs to be effective alternatives to synthetic pesticides (Table 2).

National Policies Regarding BP (regulations, subsidies)

In Central America, the development of several regulatory proposals aimed at eliminating toxic substances provide new opportunities to increase the use of BPs. However, the shift towards biological alternatives is currently limited, because the approval of BPs for marketing in most countries is subject to a lengthy and costly registration process which originally was designed for registering chemical pesticides. However, advances are being made to approve regulations suitable for botanical and microbial pesticides. In the future, increasing pressure from the region's governments, as well as from conscious consumers, producers and other sectors will likely stimulate the use of biopesticides.

Position of the Chemical Sector

Until now, the participation of the pesticide industry in the development of BPs has been marginal. During its history, this industry has concentrated on fast-acting products, which are often, but not always, highly effective and which tend to require repeated applications in the future. In contrast, the promotion of BPs is not considered as an interesting source of profit, because the production costs are still relatively high and the application frequency is, ideally, reduced with time. Also, the development of new synthetic products of higher specificity towards the target organisms may contribute to reduce the negative side effects of synthetic products. If successful, this shift towards less toxic synthetic chemicals may compete with the development of BPs.

Development, Quality Control, Registration and Distribution

The development and distribution of biopesticides must confront a number of obstacles before they can be integrated successfully into normal agricultural practices. For example, farmers often trust big companies more than small enterprises that produce BPs. In many cases, small BP producers sell their output directly without going through normal quality control and commercialisation channels. In some cases, these biopesticides may have a low effectiveness or have expired, resulting in a loss of credibility of BPs among farmers. Another important obstacle for the development of BPs is the presence of generic synthetic products, usually of low cost, which compete directly through prices and effectiveness.

In Costa Rica, there were 113 biopesticides registered in 2002, representing 9.5% of all the pesticides (excluding herbicides) registered (Table 3). Given that the percentage of registered BPs is low, the percentage of those that actually make it to the market is even lower (Table 4), because many products are not available through the established distribution channels of agricultural inputs. In the year 2002, 62% of the registered BPs were indicated to control insects, 17% to control fungi and 12% to prevent bacterial infections. In that same year, 95% of the agrochemical stores sold also biopesticides. Among these retailers, 53% offered between one and five varieties of BP, 23% had between six and ten and 19% sold more than ten kinds of biopesticides (Table 4).

Table 3. Registered Pesticides in Costa Rica between the years 2000 and 2003

Type	YEAR			
	2000	2001	2002 (Oct)	2003
Synthetic pesticides (# of products)	971	1035	1076	1104
Biopesticides (# of products)	89	98	113	117
Total pesticides (# of products)	1060	1.133	1.189	1.221
Biopesticides as fraction of all pesticides (%)	8,4	8,6	9,5	9,6

Source: CATIE/GTZ, 2003. Monitoreo de bioplaguicidas. Proyecto Bioplaguicidas CATIE/GTZ. Documento Interno. S.p.

Table 4. Number and percentage of biopesticides available in the agrochemical stores in Costa Rica during 2003.

Product / No of products available	0	1 - 5	6 - 10	>10
Agrochemical distribution centers selling BPs (# of stores)	2	25	11	9
Proportion of agrochemical distributors selling BPs (%)	4	53	23	19

Source: CATIE/GTZ, 2003. Monitoreo de bioplaguicidas. Proyecto Bioplaguicidas CATIE/GTZ. Documento Interno. S.p.

Knowledge of Extension Officers

Many agricultural extension officers have a basic knowledge about BPs. However, often they do not have the conviction and sufficient information to recommend them to farmers. Consequently, most extension professionals tend to use and advise on the utilization of synthetic products. The answers of extension agents to questions regarding their capacity to differentiate biopesticides from synthetic chemicals indicate an overall acceptable capacity, although insecurities persist (Table 5). The majority of the interviewed persons had accurate knowledge of the type of biopesticides that are found in agrochemical stores (Table 5). In the three countries officers indicated mainly products to control insects, followed by those to control fungi.

Although all extension officers said that they would be interested in promoting BPs, this topic currently is not a priority in the extension programs of the Ministries of Agriculture. According to the survey, extensionists said that they would promote the use of BPs for their benefits to health (44%) and the environment (44%), as well as for economic (11%) reasons. Finally, extension officers expressed that they would be willing to promote BPs among farmers through demonstration plots and field demonstrations (Table 5), indicating that they have a positive attitude towards BP.

Table 5. Perception of extension officers towards biopesticides

	% (1)		
¿Which of these products are BPs?	CR 2)	HO	NI
-Fatty acids	15	6	0
-Endosulfan	0	3	0
-Bacillus thuringiensis	86	75	97
-Don't know	0	16	3
¿Why would you promote the use of BPs?			
-Economic	12	16	20
-Health	44	40	38
-Environment	44	44	43
¿How do you or would you promote the use of BPs?			
-Demonstration plots	30	34	45
-Training	32	30	29
-Demonstrations	32	33	21
¿What type of BPs do you find in the agrochemical stores?			
-Against fungi	25	29	26
-Against insects	65	49	58
-Against weeds	2,5	0	5
-Against all types of pests	2,5	12	7
-I do not know	5	7	5
-No answer	0	2	0

1) CR = Costa Rica, Ho = Honduras, Ni = Nicaragua.
2) In each country, 30 extension specialists were interviewed

Source: CATIE/GTZ 2003. Estudio sobre conocimiento, actitud y práctica hacia bioplaguicidas entre agricultores, extensionistas y agroservicios. Proyecto Bioplaguicidas CATIE/GTZ. Documento interno. S.p.

Conclusions: Prospects For BPs

For the future, most of the agrochemical stores expect the use of biopesticides to increase in the coming years (Table 6), and most store representatives expressed their willingness to promote the use of BP. Among the most important reasons to do so they indicated health and environmental benefits. Yet they also pointed to factors such as high prices, limited availability and slow effects as obstacles for expanding the use of BPs.

Finally, most of the representatives of this sector mentioned that they had a generally positive attitude towards BPs and that they were willing to be educated about BPs (Table 6). This general positive attitude towards BPs was also shared by extension officers who indicated that the use of BP will increase in the future and that they would promote their use for the same reasons and with the same methods as the agrochemical stores. Therefore, the sector of biopesticides is likely to become more important in the future, particularly if government agencies establish and support policies aimed at promoting BPs.

Table 6. Perception of representatives of agrochemical distribution centers and of extension officers with respect to BPs in Costa Rica, Honduras and Nicaragua.

Attitude towards BP	Agrochemical stores sector			Extension specialists		
	CR [1]	HO	NI	CR	HO	NI
How will the use of BP change in the future?	% [2]	%	%	%	%	%
-It will increase	70	73	67	96	77	50
-It will stay at the same level	11	3	18	3	13	30
-It will decrease	6	7	14	0	3	10
Persons who would promote the use of BP	81	87	100	100	100	96
Reasons why you would promote BPs?						
-Health	42	28	39	44	40	37
-Environment	40	46	37	44	43	43
-Economical	9	19	24	12	16	20
How would you promote BPs?						
-Demonstration plots	24	30	33	30	34	44
-Technical training	42	23	38	32	29	29
-Demonstrations	23	25	29	32	33	20
Reasons why BPs are not used						
-Expensive	15	27	22	19	23	16
-Not available	22	20	39	37	30	51
-Slow action	33	32	22	23	30	26
Persons interested to be informed about BPs	90	100	100	100	100	100

[1] CR = Costa Rica, Ho = Honduras, NI = Nicaragua.
[2] In each country, 30 extension specialists were interviewed

Source: CATIE/GTZ 2003. Estudio sobre conocimiento, actitud y práctica hacia bioplaguicidas entre agricultores, extensionistas y agroservicios. Proyecto Bioplaguicidas CATIE/GTZ. Documento interno. S.p

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Biopesticides and Integrated Pest Management (IPM): Recent Developments and Future Needs in Central America

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Abstract
Integrated Pest Management (IPM) systems have been developed over more than 20 years in Central America (including Panama and the Dominican Republic). Today, most of the seven countries have incorporated the IPM concept into their national crop protection strategies. The use of biopesticides and non-chemical methods has always been part of IPM. However, over the past 15 years, IPM in Central America has been adopted by the pesticide industry, and today many chemical products are sold under the IPM banner.

Beginning around the year 2000, new and more potent biopesticides as alternatives to chemical products of synthetic origin have begun to appear more frequently in the markets of Central America. These products are either produced by small and medium companies in Central America and the Caribbean or imported from Europe or the United States. Although interest in these products is high, their availability for farmers is still relatively low. Transnational companies are still cautious about biopesticides even though the framework conditions in Central America have changed in favor of biopesticides. Globalization and growing consumer awareness in Europe, the United States and Central America have raised the demand for healthy, residue-free food and products from organic production. Importing countries have complemented their legislation and trade standards (e.g. Safe Food Act, 1997 and EUREPGAP, 2001) and have begun to apply stricter limits for chemical residues in food. Parallel to this, the health sector (OPS and WHO) is looking for nontoxic alternatives for the control of the vectors of Malaria and Dengue. These changes open new opportunities for biopesticides.

From 2000 to 2003, the market for biopesticides in Central America has grown dynamically with growth rates ranging from 3% to 10% annually. The number of registered biopesticides has nearly doubled in Costa Rica and Honduras within this period, growing to a market share (by value) of 4.4 % in Costa Rica and 6.5 % in Honduras.

In the current situation, the market for biopesticides in Central America will continue to grow. However, biopesticides will not substitute chemical products on a large scale soon. For this, a change of attitude in the pesticide industry would be necessary – which is not likely to happen in the near future.

Integrated Pest Management in Central America (1975 – 2003)

Integrated Pest Management (IPM) is the careful integration of a number of available pest control techniques that discourage pest population development and keep pesticide and other interventions to levels that are economically justified and safe for human health and the environment. IPM emphasizes the growth of a healthy crop with the least disruption of agro-ecosystems, thereby encouraging natural pest control mechanisms (FAO, 1994).

Chemical pesticides have always been part of this IPM concept, but should only be used when no other alternative is available (minimal intervention). But IPM also had an significant impact on microbial insecticide research (Dent, 1995). The use of biopesticides in IPM generates two complementary benefits:

a) From a **technological perspective:** Biopesticides can replace chemical products, which often have higher toxicities and a larger ecological impact.
b) From an **ecological perspective:** Biopesticides can increase the number and effectivity of natural enemies, beneficials and local species.

The second benefit is specific to the application of living biological control agents in the form of biopesticides, as the establishment of these organisms tends to reduce the number of future applications resulting in economic savings for the end-users. Unfortunately, this benefit for farmers and the environment is not always in the interest of the private sector which gains little from offering products which will be less needed with time.

The IPM Implementation Period (1975 – 1995)

Between the years 1975 and 1995, food security was the most important issue in the agricultural sector of the Central American countries. At the beginning, national crop protection services either were in their initial stages or non-existent, favoring the establishment of new pests and diseases. Diseases like *Monilia roreri* or *Phytophthora palmivora* nearly wiped out the cocoa production in the Caribbean lowlands of Costa Rica, Nicaragua and Honduras. In the 1970s, Central America was invaded by the coffee berry borer (*Hypothenemus hampei*) and by the coffee leaf rust (*Hemileia vastatrix*), two substantial threats to the coffee production of the whole region. As a consequence, national crop protection and quarantine systems were created or strengthened in the region, focusing primarily on the current phytosanitary problems. A number of international development agencies and research institutions like USAID, DANIDA, NORAD, CIRAD, USDA and GTZ supported these national efforts. As a result of the strong increase of synthetic pesticide use, the Ministries of Agriculture promoted IPM as a new paradigm for crop protection, combining economic and ecological objectives. National extension services were trained to forward IPM methodologies to their clients, the farmers. Participatory extension strategies were tested in Costa Rica and Nicaragua but never reached a comparable impact as the IPM farmer's field school approach in Asia (Gallagher, 1992). During this period, the first programs on biopesticides were organized. Neem (*Azadirachta indica*), a tree introduced from Asia to Central America for its insecticidal potential, was considered the solution for an environmentally sound approach on the small farmer's level. In Nicaragua and the Dominican Republic, production and extension programs were created to enhance the production and use of neem on the farm level.

The impact of this period on the phytosanitary situation in Central America was significant. At the beginning of the new millennium, food security was no longer a major issue in most of the Central American countries, as the national crop protection systems were fully developed and connected to regional and international networks. IPM was accepted as the national crop protection strategy in most counties (Panama, Costa Rica, Honduras, Nicaragua, El Salvador) and on the regional level (OIRSA). However, during this period, biopesticides still did not reach a significant share of the pesticide market in Central America.

The IPM Consolidation Period (1995 – 2003)

Starting in the 1990s, globalisation, the liberalisation of markets and the development of non-traditional export products increasingly shaped also the agricultural sector of Central America. The discussion on quality standards related to exports started with new certifications such as ISO-9000 and 14000. This trend was intensified by the creation of the US Safe Food Act (1997) and more recently by the new EUREPGAP regulation on fruits and vegetables (www.eurep.org, 2001) It was also the time of the disappearance of many national extension services in Central America. The organic agriculture movement underwent a swift development phase in some countries like Costa Rica, Honduras, Guatemala, and Belize.

Pressure to reduce the excessive use of pesticides started to mount from the health sector too. In 2000, the Pan-American Health Organisation signed a treaty with all seven Health Ministries of Central America to ban the 12 most toxic pesticides from the markets. New and revised UN resolutions (International Code of Conduct on the Distribution and Use of Pesticides, revised version 2002, FAO; PIC-Convention, 1998, UNEP, FAO; Montreal Protocol on Substances that deplete the Ozone Layer, 1995, UNEP; Agenda 21, Rio 1992) were developed to foment the use of less harmful products in agricultural production. All these developments increased the demand for alternative non-chemical products, but there was no corresponding offer on the market.

In January 2000, a German project ("Promotion of non-chemical plant protection alternatives through the private sector") started in Costa Rica, Honduras and Nicaragua to contribute to improve this situation. Since then, biopesticides have become increasingly visible in the markets, reaching market shares of 2% to 4% in 2003. Even though this relatively small market share is still not strong enough to provoke a significant change in use of toxic pesticides, it demonstrates a clear trend towards the international agreements and increased environmental awareness.

Biopesticides in Central America

The development of the biopesticide sector in Central America depends on the following mayor stakeholders:

The **transnational pesticide industry** is well represented in all markets of Central America. It represents about 70% of the chemical pesticides' market. Another 28% is in the hands of national companies. The latter are especially involved in the sale of "generics", *i.e.* products that are no longer protected by patents. Both focus on substances of high toxicities and short-term return on their investments.

Both groups share their reluctance towards biopesticides. As in other parts of the world, research on biopesticides is usually funded piecemeal, largely by the public sector and rarely involves multidisciplinary teams (Dent, 1997). There is a growing tendency of transnational companies to shift to genetic engineering rather than working with the more complex mode of action of biopesticides. The advent of transgenic crops, capable of expressing the *Bacillus thuringiensis* cry protein: (Harris, 1997) could threaten the further development of biopesticides. In addition, the private sector is not interested in offering products that will be less needed, the more they are being used. This is the case with some biopesticides, particularly with living organisms which may reduce pest damage over long periods once they have been established.

As a strategy, transnational companies have adopted IPM not only in Central America, but worldwide. The Industry is selling an integrated solution package based on pesticides under the IPM image. Promotion and market forces of the chemical pesticide industry remain strong. As a result, sales of chemical pesticides in Central America have not dropped.

Due to different production models, the **biopesticides industry** in Central America is more diverse than the chemical pesticide sector. It can be found in the form of small- and medium-scale farm production/formulation (Costa Rica, Nicaragua, Honduras), as well as in the form of production in cooperatives (Cuba) or large-scale operations (Colombia, Cuba and Guatemala). The market shows registered products from private companies, regional research and training institutions (e.g. EARTH in Costa Rica, ZAMORANO in Honduras) and national governmental institutions such as universities.

Local producers are normally small companies with few resources. Registration processes for biopesticides take up to 3 years and are costly, but not as costly as the registration of chemical products of synthetic origin. Producers tend to concentrate on production and often do not see the need for adequate promotion. Little is known about the economy of biopesticides. Efficacy trials are mandatory, but thorough analyses of costs and benefits are rare. With few exceptions, marketing of biopesticides is in the hands of the same trading companies that sell chemical pesticides. They rarely understand the difference, and therefore, do not contemplate the advantages of biopesticides. The organisation of the biopesticide sector in chambers (Costa Rica) or associations (Honduras, Nicaragua) is just beginning in Central America.

The **public sector** is not yet actively involved in the development and promotion of biopesticides in Central America. At the ministerial level (Ministries of Agriculture or Health), no distinction is made between chemical and non-chemical products. As there still is no specific registration procedure for biopesticides, the same rules apply for biopesticides – which are often living organisms – as for chemicals. Quality control of registered products and standard procedures for chemical pesticides in most of the countries of Central America is not available due to a lack of laboratory facilities by the government. National agricultural extension services are widely defunct in Central America, practically leaving the pesticide users alone with the information provided by the chemical industry. The interaction between the private and public sectors is largely restricted to registration and regulatory issues. Participatory collaboration between the public and the private sector is still rare.

After more than 40 years of chemical pesticide use, **farmers**, as potential users of biopesticides, expect high effectivity and immediate results of pesticides and are used to frequent applications. Nearly 90% of the farmers know about the existence of non-chemical alternatives, but only a few have basic knowledge and even fewer have tried them out. However, there is a substantial willingness to try them out. As the government extension services have been reduced significantly in Central America, and only little promotion on biopesticides is available, farmers are left to somehow "sort it out" for themselves. Unfortunately, their main sources for information are the distribution centers for farm inputs, which are mainly under the influence of the chemical sector.

The **International Development Community** (e.g., USAID, FAO, NORAD, DANIDA, GTZ), in cooperation with national institutions (Ministries of Agriculture and Health) and regional Institutions (CATIE, ZAMORANO, OIRSA) has supported over the past 25 years the development and implementation of IPM systems in Central America. As a result, nearly all countries have effective crop protection control and regulation units, and risks for food security from existing or new pests and diseases are only a minor issue. IPM is the basis of most of the national crop protection strategies today. Consequently, most external support for IPM programs has ended or is being targeted towards more Integrated Crop Production (ICP) programs, focusing on sustainable agriculture. Of the mayor donors, only NORAD is still working on IPM in Nicaragua. A direct impact of the donors' approach with regards to biopesticides can only be seen in Nicaragua and the Dominican Republic where neem production was firmly established as a source of an effective botanical pesticide. However, the original approach to produce neem pesticides on the farm level has failed. In both countries, development of neem as a biopesticide was taken up by the private sector.

Current Markets of Biopesticides in Selected Countries of Central America

From 2000 to 2003, the supply of biopesticides in Central America has increased, both in the number of different products as well as in market share (Tables 1 and 2). While the number of products and the sales volumes differ among Costa Rica, Honduras and Nicaragua, the trend is the same in these three countries.

Costa Rica, with its strong orientation towards agricultural export and a fast growing organic agricultural movement, leads in the range of biopesticides and in the market volume. The market share of biopesticides, compared to chemical products has grown from 2.9% in 2000 to 4.4% in 2002. The private sector consists of five producers and 26 trading companies for biopesticides. In 2003, there were 177 registered biopesticides in the market with 19 active ingredients (Table 1). Several products, particularly pheromones are exported from Costa Rica to other countries. One problem in Costa Rica is a relative large "grey market" of unregistered products.

Table 1. Active Ingredients (AI) of biopesticides registered in Costa Rica 2003

Microbial AI:	*Bacillus thuringiensis, Bacillus subtilis, Beauveria bassiana, Metarrhizium anisopliae, Verticillium lecanii, Entomophthora virulenta,* Nuclear Polihedrosis Virus (PNV).
Botanical AI:	Extracts of neem, mustard, chili peppers, garlic, chrysanthemum, citrus and vegetable oil.
Pheromones:	against *Hypothenemus hampei, Rhynchophorus palmarum, Spodoptera sunig.,*
Bioactive substances:	Sulfur, calcium carbonate.
Macroorganisms:	*Cotesia flavipes.*

Table 2. Biopesticides market in Costa Rica 2000 – 2002 in relation to the pesticide market (% and value, Mio. US$)

Year	2000	2001	2002	2002
Chemical Pesticides	97.1%	96.5%	95.6%	Mio. US$ 128
Biopesticides	**2.9%**	**3.5%**	**4.4%**	**Mio. US$ 6**
Total	100%	100%	100%	Mio. US$ 134

In **Honduras**, the pesticide market included in 2002 a wide spectrum of biopesticides, which was comparable to Costa Rica's. A total of 58 registered products were sold in the market, most of them imported. The value of biopesticides in 2002 represented about 5.3% of all pesticides (imported and locally produced/ formulated) and was higher than in Costa Rica. The market share has only risen slightly since 2000. The private sector consisted of five producers and 18 trading companies dealing with biopesticides. (Tables 3 and 4)

Table 3. Active Ingredients (AI) of biopesticides registered in Honduras, 2003

Microbial AI:	*Bacillus thuringiensis, Bacillus sphaericus, Beauveria bassiana, Verticillium lecanii, Entomophthora virulenta, Trichoderma lingorum,* Nuclear Polihedrosis Virus (PNV).
Botanical AI:	Extracts of neem, chrysanthemum, Qassia amara and citrus .
Bioactive substances:	Sulfur.
Macroorganisms:	*Cotesia flavipes.*

Table 4. Biopesticides market in Honduras 2000 – 2002 in relation to the pesticide market

Year	2000	2001	2002
Chemical Pesticides	95,9%	95,3%	94,7%
Biopesticides	**4,1%**	**4,7%**	**5,3%**
Total	100%	100%	100%

Due to consistent economic hardship, agricultural activities did not grow as strongly in **Nicaragua** as in the neighboring countries during the period 2000–2003. The pesticide market, including the biopesticides segment, is the smallest of the three countries (Tables 5 and 6). The market offered only 33 registered biopesticides in 2003 with eight different active ingredients. Nicaragua had three local producers and eight trading companies dealing with biopesticides. A number of them are academic institutions, which try to improve their economic situation through the sales of biopesticides.

Table 5. Active Ingredients (AI) of biopesticides registered in Nicaragua, 2003

Microbial AI:	*Bacillus thuringiensis, Bacillus sphaericus, Metarrhizium anisopliae, Beauveria bassiana,* Nuclear Polihedrosis Virus (PNV).
Botanical AI:	Extracts of neem and citrus.
Bioactive substances:	Sulfur.
Macroorganisms:	*Trichogramma* sp.

Table 6. Biopesticides market in Nicaragua 2000 – 2002 in relation to the pesticide market (% and value, Mio. US$)

Year	**2000**	**2001**	**2002**	**2002**
Chemical Pesticides	95%	97%	94%	Mio. US$ 7.7
Biopesticides	**5%**	**3%**	**6%**	**Mio. US$ 0.5**
Total	100%	100%	100%	Mio. US$ 8.2

Considering that, relative to the promotion of synthetic pesticides, there is very little promotion for biopesticides, it is encouraging to see that the number of registered biopesticides has risen in all three countries at the same or even a higher rate than the number of conventional synthetic pesticides.

Table 7. Number of Biopesticides registered in Costa Rica, Honduras and Nicaragua, 2000 – 2002

Year	2000	2001	2002
Costa Rica	89	98	113
Honduras	40	49	58
Nicaragua	26	28	33

Success Stories of Biopesticides in Central America:

In general terms, the full potential of biopesticides has not yet been reached in Central America. Among the most promising experiences, we find the following:

Sugarcane (*Saccharum officinale*) which is covering millions of hectares in Central America does not have as many phytosanitary problems as other crops. In this context, Costa Rica and Nicaragua have adopted a non-chemical pest control approach. Using biological antagonists, the major insect pest, the sugar cane borer *Diatraea saccharalis*, is effectively controlled with the application of *Beauveria bassiana* and the release of a parasitic wasp (*Cotesia flavipes*). Another major pest, a plant hopper (*Aeneolamia postica*), is widely kept under the economic threshold level (ETL) by using *Metarrhizium anisopliae*.. In both cases, production and distribution is coordinated by the Sugar Board in Costa Rica and by a Sugar Cooperative in Nicaragua.

Coffee (*Coffea arabica*) in Central America is attacked by only a few insect pests. The most damaging, by far, is the coffee berry borer (*Hypothenemus hampei*), which affects considerably the quality and quantity of the harvest in infested areas. In Ecuador, between 1982 and 1990, a biological control strategy was developed based on an entomopathogenic fungus (*Beauveria bassiana*), a parasitic beetle (*Prorops nasuta*) and a parasitic wasp (*Heterospilus coffeicola*).

These organisms where produced and released by the Ministry of Agriculture over a period of three to four years, resulting in a considerable reduction in losses. Today, the coffee berry borer is no longer considered a mayor pest in Ecuador. Starting in 1995, these methods were adopted by Colombia, Guatemala and Nicaragua. Since the arrival of the coffee berry borer in Costa Rica (2000), the Costarican Coffee Institute and the Ministry of Agriculture (www.protecnet.co.cr) have promoted jointly the use of biopesticides in coffee in an effort to avoid the use of the insecticide Endosulfan as far as possible.

Conclusions and Outlook

The development of biopesticides in Central America since 2000 shows that these products have increased their market share substantially. However, they are still not able to substitute chemical pesticides on a substantial scale in the near future. This is largely due to the transnational pesticide industry wich most likely will continue to concentrate on products with a "rapid kill" effect and with large markets. Farmers in Central America do not have much choice of information and are often led to believe what the chemical industry is telling them (Waage, 1997). For a substantial change in favor of the use of biopesticides, the transnational pesticides industry would have to redefine their objectives, which is not very likely to occur.

The market share of biopesticides is likely to continue to grow, because agriculture in Central America is increasingly oriented towards export and the consumer awareness regarding pesticide residues in food is rising worldwide. Consequently, quality standards for export products are rising and the agricultural sector is starting to react.

Markets for organic food are evolving rapidly in North America, Europe and Japan, stimulating the ecological production in the region which demands increasing use of biopesticides in this sector. On the global scale, a number of synthetic pesticides of high toxicity and high environmental risks will be phased out in the coming years, either voluntarily by the industry or through international conventions. This change will force the search for less harmful or non-toxic alternatives. Finally, yet importantly, the development of a biopesticide tends to be less expensive than the development of a synthetic pesticide. This fact makes biopesticides even more attractive for small and medium companies willing to take the risk. Based on these observations, I consider that biopesticides will have a bright future in Central America.

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Abbreviations	
USAID	US Agency for International Development
DANIDA	Danish International Development Agency
NORAD	Norwegian Agency for Development
CIRAD	Centre de coopération internationale en recherche agronomique
USDA	US Department of Agriculture
OPS	Organizacional Panamericana de la Salud,
WHO	World Health Organisation
GTZ	Deutsche Gesellschaft fuer Technische Zusammenarbeit
CATIE	Centro Agronómico Tropical de Investigación y Enseñanza
ZAMORANO	Escuela Mesoamericano para la Agricultura
OIRSA	Organismo Internacional Regional de la Salud Agropecuaria

Biopesticides and Pest Management Systems: Recent Developments and Future Needs in Developing Countries of Southeast Asia

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Abstract
The present paper highlights the past and present of pest control in Asian countries, especially focusing on biopesticides. It is based on information publicly available or collected by previous projects of German Technical Cooperation (GTZ) and other institutions for the region. Conventional pest control in crop production using synthetic pesticides and their frequent misuse is still dominant in SE Asia. However, the pressure generated by the demand of export markets for residue-free primary agricultural products and processed foods is increasing and might pave the way for a wider distribution of biopesticides including microbials, macrobials, plant extracts and others. Various governments in SE Asia (e.g. Thailand, Vietnam, Malaysia etc) have adopted and introduced IPM programmes including the use of biopesticides to gradually change attitudes and practices of farmers and pesticide users. Yet, these changes in government policy have had a very slow impact on the users, still influenced by the legacy of two decades of promotion of cheap synthetic products. Biopesticides seem to have a chance for wider distribution, especially if the private sector assumes a more active role in promoting and distributing biopesticides. In February 2003, a new GTZ initiative called "Commercialization of Biopesticides in Southeast Asia", headquartered in Bangkok, has begun to provide more information on potential markets and examples of successful marketing of biopesticides in the region. For instance, in Thailand which is quite advanced with regard to the application of biopesticides, about seven companies are currently involved in the distribution of biological products for pest and disease control. The products include *Bacillus thuringiensis*, entomopathogenic fungi, the biological rodenticide *Sarcocystis*, baculoviruses and others. At the moment, these products account for only about 1% the total pesticide market in that country. Characteristically, most of these companies are small to medium-sized enterprises that cater for local and regional markets, predominantly vegetables. The advance of genetically modified crops (GMO) might become a threat to conventional biopesticides if target markets overlap. On the other hand, a wider use of GMO could also prove beneficial for biopesticides if they can be used as tools for resistance management. It is of vital importance for successful commercialization of biocontrol products that local producers become more serious about quality control and improvement of industrial scale production. As soon as farmers, including smallholders, get better profits for pesticide-reduced or organic produce, market prospects are likely to improve considerably.

Introduction

Conventional pest control in crop production using synthetic pesticides and their frequent misuse is still dominant in Southeast Asia (Jungbluth 1996, Harris 2000). However, the pressure generated by the demand of export markets for residue-free primary agricultural products and processed foods is increasing and might pave the way for a wider distribution of biopesticides including microbials (microorganisms and derived products), macrobials (beneficial insects etc.), botanicals (e.g. plant extracts) and semiochemicals (e.g. pheromones). This paper does not regard genetically modified organisms (GMO) as biopesticides, because GMOs are subject to different legal and technical standards.

Various governments in Southeast Asia (e.g. Thailand, Vietnam and Malaysia) have adopted and introduced IPM programmes including the promotion of biopesticides to gradually change the attitudes and practices of farmers and users towards pesticides. This tendency is also endorsed by ASEAN through its Strategic Plan of Action on ASEAN Cooperation in Food, Agriculture and Forestry 1999-2004. Yet these changes in government policy have had a very slow impact only on the users, who are still influenced by the legacy of two decades of intensive promotion of cheap synthetic products. Consequently, the current availability of commercial biocontrol products is still limited. However, if the private sector assumes a more active role in promoting and distributing biopesticides, their role for crop protection can be increased substantially.

Starting in February 2003, a new GTZ initiative called "Commercialization of Biopesticides in Southeast Asia" has begun to operate in that region with its head office located in Bangkok, Thailand. It is expected that during the course of this project more information on potential markets and examples of successful marketing of biopesticides in this region will become available. The project strategy is to support the local private industry in its efforts to establish biopesticides in the market in order to gain a wider distribution of environmentally friendly technology in the long term.

Pesticides: Past and Present

Of the global crop protection market of around US$28 billion, the market share of biopesticides is less than 1% (GreatRex *et al.* 2003). This holds also for Asia (Ellis, 2000). For the year 2003, forecasts predicted a market dominance of generica, *i.e.* synthetic products that are no longer protected by patents, with an estimated worth of about US$6 billion in eastern Asia (Ellis, 2000).

The reasons behind this strong market position of synthetic pesticides in developing countries are the extensive government promotion and production of these chemicals in the 1970s and 1980s. This has created a bias towards synthetics and has led to psychological as well as economical dependencies among growers and other users of pesticides. Often the information that growers received from the chemical companies or retailers was incomplete with regards to negative side effects. In most cases, village pesticide dealers were not well informed about safety and specific use and had a strong interest in maximising pesticide use (Anonymous, 1998).

In the 1990s, production and marketing was taken over by the private sector, which led to a greater range of chemical products available on the market. Currently, many governments in Southeast Asia favour IPM concepts and new farming practices like organic production. However, this IPM bias does not always coincide with the view of the industry, which still sees great potential in conventional products (Ellis, 2000; GreatRex *et al.* 2003). The rapid expansion of generica supports this notion.

Additionally, conventional pesticides are used at a much lower rate in developing countries (Vietnam: 1 kg/ha/yr) compared to developed countries like Korea (11.8 kg/ha/yr) or Japan (19.4 kg/ha/yr), which offers an enormous growth potential. Despite the acceptance of IPM concepts which promote the reduction of synthetics (Stern *et al.*, 1959), this approach is difficult to implement, because it supposedly distorts the free market for pesticide sales and distribution. Consequently, it is virtually impossible to coordinate pesticide use over a wide area, a basic strategy in IPM to avoid pest resistance to pesticides (Anonymous 1998).

The problems arising from misuse of synthetic pesticides are well known and documented for the region. Residue and health problems along the food chain are becoming more often barriers for crop export. Many examples of occupational poisoning have been published to raise awareness (Harris, 2000). Most countries in Southeast Asia have banned the "Dirty Dozen" (very hazardous) group of pesticides. However, some chemicals like DDT are still widely used for mosquito control and other public health programs, and their use is often expanded to non-approved sectors.

The search for options to replace synthetic pesticides and to develop new markets has lead multinational corporations to promoting transgenic crops and other GMOs. The industry sees a great potential for GMOs in Asia. The 2004 forecast for global cnsumption of GMO is about US$4.3 billion (GreatRex *et al.* 2003). GMOs, such as plants expressing *Bt*-toxins to repel insects, are currently grown in China and Japan, and field trials are under way in Thailand and the Philippines (Table 1). Genetic modification currently focuses on cotton, rice, tomato, corn, vegetables and cut flowers. Nevertheless, the advance of GMOs may become a threat to biopesticides if they are developed for niche markets, such as vegetables and fruits, which are usually good targets for biocontrol products. On the other hand, increased use of GMOs could also be beneficial for the distribution of biopesticides, as they may become important tools for resistance management, e.g. during bridging periods when the use of GMOs is not recommended.

Presently, GMO food products are imported by various Southeast Asian countries, while GMO planting is not permitted in most of them (Table 1). At present, it is still too early to tell whether or not GMO can affect the advance of biopesticides in any significant way.

Table 1. Status of GMO in ASEAN countries.

Country	GMO		Biosafety	Guidelines			Field	GMF	Public	Labelling
	Planting	Food	Legislation / Status	Food	Environ	Lab	Trials	Approved	Education	(Threshold)
Brunei	N	L	N	N	N	N	N	N	N	N
Cambodia	N	Y	N	N	N	N	N	N	N	N
Laos	N	Y	N	N	N	N	N	N	N	N
Indonesia	Y with restriction	Y	Y	N	Y	N	Y	Y	Y	Y (not decided)
Malaysia	N	Y	Expected June 2002	Y	Y	N	Y	Y	N	Y (3%)
Myanmar	N	L	N	N	N	N	N	N	N	N
Philippines	N	L	Expected 2002	N	Y	Y	Y	N	N	??
Singapore	N	Y	???	Y	N	N	N	N	N	N
Thailand	N	Y	Expected 2003	Y	Y	Y	Y	Y	Y	Y (5%)
Vietnam	Y/N	Y	Expected 2002	N	N	N	N	N	N	Y(not decided)

According to Bhumiratana (2003), National Science and Technology Development Agency (NSTDA), Thailand; N = No; Y = Yes, L = Limited, GMF = Genetically Modified Food, Lab = Laboratory

As the public discussion on food safety issues intensifies in several food-exporting countries of Southeast Asia, particularly in Thailand (Panyakul, 1998), the interest in products for environmentally friendly pest control is increasing. However, at present time, the local private sector is not well prepared to switch to such products.

Although the development cooperation of various donor countries including Germany (Foerster *et al.* 2001), international institutions, and local governments have actively promoted the use and production of biopesticides at the farm level, typically within IPM programmes, it seems that an increased demand for reliable high-quality biocontrol products can only be met in the long run by an appropriate industrial scale production and distribution.

The Case of Biopesticides

The availability of commercial biocontrol products is still limited in Southeast Asia and there are only a few companies that produce or trade in biopesticides. Preparations based on *Bacillus thuringiensis* (*Bt*) toxin clearly dominate the market with high-quality *Bt* being mostly imported and local companies functioning as distributors. Thailand offers currently the largest range of commercial biocontrol products, again with *Bt* as the clear market leader. *Sarcocystis* singaporensis, a protozoan parasite used to control rats, is a recent addition to the palette of commercial products in Thailand as a result of the collaborative effort between the Department of Agriculture in Thailand and the private sector.

German Technical Cooperation and Uniseeds Co. Ltd., a local company dedicated mainly to trading seeds, have taken over the task to market this product in Thailand and neighbouring countries and are currently investing in a mass production facility. A pilot plant for the production of nuclear polyhedrosis viruses against common insect pests (*Helicoverpa armigera*, *Spodoptera exigua*, *S. litura*) was established by the Department of Agriculture in 1996. However, there is a lack of a private partner for the commercialization of the product. The resistance against chemical pesticides of the cotton bollworm, H. armigera, has brought down the entire cotton industry in Thailand (from 160.000 ha in 1982 to less than 32.000 ha in 2001). An appropriate Baculovirus-preparation could revive this industry, yet technical bottlenecks concerning the up-scaling of production still prevent an implementation of such plans (van Frankenhuyzen, 1999).

Most of the local companies involved in the biopesticide business are distributors; only few of them have their own production, usually in cooperation with public or governmental institutions that provide the scientific input for this heavily knowledge-based business. Therefore, in-house research capabilities are rarely developed, which is a major obstacle to efficient quality control and further expansion of the product portfolio. Under these conditions, only companies which can complement their work with biopesticides with core business such as the export of crops and processed food have the potential to become important players as distributors and/or producers. A strong base of contract farmers can serve as an appropriate distribution channel for new biocontrol products. The biological products currently registered for use in plant protection in Thailand, the Philippines and Vietnam are listed in Table 2.

With regard to registration, the Philippines have relatively advanced guidelines, specifying procedures for semiochemicals, biochemical products, microbial products and macrobials. Thailand mainly adheres to the procedures recommended by FAO (FAO, 1988). In Vietnam, as in other countries, the Ministry of Agriculture and Rural Development is the agency responsible for registering plant protection products. Due to a still poorly developed private sector, plant protection is still mainly under government control. Many of the registered biopesticides are small 'side businesses' of researchers employed by state research institutions like the National Institute of Plant Protection (NIPP) or the Vietnam Agricultural Science Institute (VASI) in Hanoi.

Table 2. Biopesticides Registered for Use in Plant Protection in Thailand, the Philippines and Vietnam (2003).

Country	Biopesticide	Companies
Thailand	*Bacillus thuringiensis* (*Bt*)	Thep Watana Chemical Co. Ltd.; Apply Chem (Thailand) Co. Ltd. and others
	Neem extract	Strong Crop Co. Ltd.; Global Crop Co. Ltd.; Rungsit Economical Agriculture Co. Ltd.; Greenleaf Co. Ltd.; Agro Co. Ltd.; Neem Thai Product Co. Ltd. and others
	Trichoderma harzianum (fungal biopesticide)	Apply Chem Co. Ltd.; Uniseeds Co. Ltd.
	Steinernema carpocapsae (entomopathogenic nematode)	Apply Chem Co. Ltd.; Agro (Thailand) Ltd. Co., Nematodic Co. Ltd.; Uniseeds Co. Ltd.
	Beauveria bassiana (entomophatogenic fungus)	Thep Watana Chemical Co. Ltd.
	Sarcocystis singaporensis (protozoan parasite used as biological rodenticide)	Uniseeds Co. Ltd.
	Nuclear Polyhedrosis Virus (NPV)	Department of Agriculture / National Institute of Genetic Engineering and Biotechnology
Philippines	*Bacillus thuringiensis*	Biostadt Mktg. Corp. ('Halt'); Cropking Chem. Inc. ('Dipel'; 'Xentari')
	Garlic extract	No information
	Paecilomyces lilacinus (strain 251)	Brain Inc. ('Bioact', nematicidal fungus), local distributor of Prophyta GmbH, Germany
	Salmonella enteritidis (+ Warfarin)	Mission Hills ('Biorat', biological rodenticide)
Vietnam	*Bt* var.Kurstaki	No information on companies available*
	Bt var. T36	
	Bt var. aizawai	
	Bt + Nosema sp. + *Beauveria bassiana*	
	Bt var. kurstaki + granulosis virus	
	Bt var. osmosisiensis	
	Beauveria bassiana	
	B. bassiana + *Metarhizium anisopliae*	
	Metarhizium anisopliae	
	Nuclear polyhedrosis virus (NPV)	
	NPV -S.1	
	NPV -Ha	
	Chaetomium cupreum ('Anthracnose', as natural enemy of fungi)	
	Salmonella enteritidis Isatchenko 7 F-4 ('Biorat')	

*applies to all products in Vietnam

Conclusions and Recommendations

The local private sector needs support and incentives for further investment in biopesticides which is the strategy followed by the new GTZ project on biopesticides in Southeast Asia. International support and development cooperation has strengthened the capabilities of local governments in IPM and crop management in general, and consumers in the region are becoming increasingly aware of food safety issues. Therefore, it seems that the time for promotion of biopesticides is right.

Economically competitive biocontrol products of good quality are still underdeveloped and rarely available on the regional market. Biopesticides need increased public funding, because the marketing prospects on a global scale are currently too small to attract multinational corporations. As soon as farmers, including smallholders, get better profits for pesticide-reduced or organic produce, market prospects are likely to improve considerably. However, the spread of genetically engineered crops in agricultural production could possibly affect the markets for biopesticides.

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Biopesticides in Pest Management Systems: Recent Development and Future Needs in Africa

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Introduction

The high input/high output agricultural systems practiced in developed countries, and increasingly deployed in developing countries, depend heavily on agrochemicals, especially synthetic pesticides. These practices are not sustainable and endanger biological diversity and environmental quality. The United Nations Conference on the Environment and Development, held in Rio de Janeiro in 1992, recognised integrated pest management, based on biological control, as a key element in reversing agriculture's hazardous dependence on synthetic pesticides and establishing a more environmentally friendly paradigm. Among the options, one is based on the use of pathogens to control arthropods. Microorganisms (bacteria, fungi, viruses, nematodes or protozoa) cause diseases in arthropod populations in nature and thereby contribute to natural regulation of pest populations. For the last three decades these microorganisms have been extensively studied and developed into microbial insecticides or biopesticides. In Africa, all of the four major groups of insect pathogens have been tested against some of the continent's major agricultural, and human and animal health arthropod pests (Cherry *et al.*, submitted). Many of these projects have generated successful candidate products but only few have found their way to the market. These include Green Muscle®, a *Metarhizium anisopliae*-based product developed by LUBILOSA (Lutte Biologique contre les Locustes et Sautériaux) for control of grasshoppers; *Bb* Plus and *Bb* Weevil, *Beauveria bassiana*-based products for the control of aphids and mites, and the banana weevil, respectively; *Pl* Plus, a *Paecilomyces lilacinus*-based nematicide for the control of root nematodes, and *Tricho* Plus for fungal disease control. All these products have been developed by Biological Control Products (BCP) in South Africa. Other products include T77, a *Trichoderma harzianum*-based product for the control of *Rhizoctonia* spp. on tobacco in Zimbabwe and Dudustop®, a product based on *Bacillus thuringiensis* for filth fly control in pit latrines, developed by the University of Helsinki, Finland, in collaboration with ICIPE. Unfortunately the production of this biopesticide has been discontinued, but may resume with the construction of a *Bt* factory at ICIPE.

Case Studies

Locusts and grasshoppers

Locusts and grasshoppers cause serious damage to crops in many parts of Africa and Asia. Locusts are well known for their potential of invading cropping areas in swarms of millions of individuals leaving behind devastated fields and plantations. Their invasions are infrequent and may be followed by long periods of recession. In contrast, grasshoppers form a more chronic problem causing serious yield losses in most years. Their control has relied on the use of persistent organic pollutant pesticides (POPs) such as dieldrin. Recently, less persistent pesticides have replaced it but they have to be applied more frequently in blanket treatments and in larger volumes. However, although these new products are less toxic than dieldrin, their environmental impact may still be serious, especially in outbreak situations.

The LUBILOSA project in Benin, West Africa, has developed a mycopesticide called Green Muscle® based on the spores of the insect pathogenic fungus *Metarhizium anisopliae* var. *acridum*. This fungus, which is specific to species of short-horned grasshoppers (Acridoidea: Acrididae and Pyrgomorphidae), is widely distributed in Africa and under favourable climatic conditions can cause local epidemics in grasshopper or locust populations (http://www.lubilosa.org). Its biological and physical properties make this fungus an ideal candidate for augmentative biological control. The efficacy of Green Muscle® has been demonstrated in many field trials carried out by LUBILOSA and its collaborators over the past seven years, including aerial application at an operational scale (Bateman, 1997; Lomer *et al.*, 1997). The biopesticide is now recommended by the pesticide referee group of FAO. Participatory rural appraisals (PRA) carried out in three countries of West Africa affected by a high risk of grasshopper attacks showed that farmers as well as plant protection agencies were supportive of the new technology (de Groote *et al.*, 1999).

Another isolate of *M. anisopliae* (SP9) is being developed for the control of the migratory locust, *Locusta migratoria*, in Madagascar by the USAID/AELGA locust biocontrol project, managed by Virginia Polytechnic and Virginia State University, USA. The specificity of Madagascar, with its unique fauna and flora, has necessitated the development of an indigenous isolate locust control. The registration of this isolate is in progress and waiting for results of field trials.

Thrips

The legume flower thrips, *Megalurothrips sjostedti*, the onion thrips, *Thrips tabaci*, and the western flower thrips, *Frankliniella occidentalis*, are major pests of vegetable and ornamental crops in Africa. Yield losses vary between 20 to 100% in cowpea (Singh and Allen, 1980) and up to 50% in onion crops (Sithanantham, unpubl.). Feeding damage by *F. occidentalis* can cause a flecking on growing leaf surfaces, flowers and fruits. Feeding on growing leaves causes distortion and mottling of the foliage while fully expanded leaves take on a characteristic silvery appearance as the dead cells are filled with air. In addition to direct damage, western flower thrips also serves as the vector of Tomato Spotted Wilt Virus (TSWV) and Impatiens Necrotic Spot Virus (INSV) which can cause the destruction of entire crops (Gill *et al.*, 1998).

Synthetic insecticides are the major control measures used against these three species of thrips. In most cases, and particularly on western flower thrips, applications are often repeated, causing residue accumulation and resistance problems. The western flower thrips is believed to have developed resistance to all the major classes of synthetic insecticides (Jensen, 2000), and resistance problems are on the increase with *M. sjostedti.* Horticultural industries in Africa are coming under increasing pressure to reduce pesticide residue levels in the production of these crops. For example, the European Union, the main importer of Kenya's horticultural products, has enforced residue level requirements for vegetable imports since 1996. Because of their sucking behaviour, the biopesticides of choice for thrips control are fungal-based as only these pathogens possess the necessary enzyme to penetrate the insect cuticle, and do not need to be ingested to infect their host. An isolate of *M. anisopliae* has been developed at ICIPE and its efficacy has been demonstrated in field trials against the three species of thrips (Ekesi *et al.*, 1998, 1999; Maniania *et al.*, 2001, 2003). Further field trials have been conducted in Benin, Uganda and Zimbabwe and have confirmed the potential of this product for the control of thrips. A tentative commercial name of Metathripol has been given to the product.

Armyworm

The African armyworm, *Spodoptera exempta*, is a serious sporadic pest of grasslands and cereal crops in eastern Africa and southern Africa. During periods of severe infestations, yield losses due to armyworms could be as high as 95% in Ethiopia and 70% in Kenya. For an infestation covering 65 km^2 of rangeland with larvae at a mean density of 28 larvae m^{-2}, it has been estimated that last-instar larvae can consume some 50 tonnes dry weight of herbage per day, a feeding rate equivalent to that of about 8,000 head of cattle (Gathuru *et al.*, 1991). Like locusts, armyworms are known to occur in solitary and gregarious phases. The solitary phase, present in very low densities over relatively large areas, is rarely observed. Outbreaks of the gregarious larvae are highly variable in time and space, and appear extremely suddenly.

Armyworm larvae are susceptible to many synthetic chemicals and, thus, not difficult to control. However, their infestations are generally detected when it is too late and larvae are already at advanced stages, which require blanket applications of synthetic insecticides on large areas. Forecasting the arrival of moths and armyworm infestations is an important tool in the management of this pest.

Insect pathogens (viruses and bacteria, especially *Bacillus thuringiensis*) are among the alternatives to synthetic insecticides. The Natural Resources Institute (NRI) and its partners are evaluating the effectiveness of a naturally occurring armyworm nuclear polyhedrosis virus (SeNPV) for use on smallholder cereal farms. Studies are also underway to determine the technical and practical feasibility of producing the virus locally, to reduce prices, to improve the availability of control options, and to reduce the environmental and health risks associated with the use of synthetic pesticides. With USAID funding, links have been made with EMBRAPA, Brazil, to draw on their expertise in virus production.

Tsetse fly

The tsetse fly (*Glossina* spp.), labelled as 'Africa's scourge or bane', is the one pest largely preventing full utilisation of the best agricultural/grazing lands on the continent (Offori, 1981; Rogers and Randolph, 1988; Cattand, 1995). About one-third of the continent or nearly 9 million km^2 is infested. The flies feed exclusively on vertebrate blood and are responsible for the transmission of protozoan parasites of the genus *Trypanosoma*, which cause human and animal trypanosomosis, otherwise referred to as sleeping sickness and nagana, respectively. Some of the control measures used for tsetse control over the years range from destruction of vegetation and vertebrate hosts to the application of different insecticides, all with varying degrees of success. More recently, less environmentally contaminating methods have been developed that involve the attraction of flies to traps or other devices which have been treated with insecticides.

Entomopathogenic fungi, whose infection occurs through the cuticle, offer a unique opportunity and this characteristic is being exploited. Such fungi are able to kill the insect and can be transferred from one individual to another by simple contact. Recently, a contamination device has been developed for use on the existing traps, by which flies attracted to the trap enter the system and get contaminated with fungal conidia before they return to the environment where they can spread the fungus in fly populations (Maniania, 1998, 2002). The prospects of using this technology for tsetse population suppression were tested under large-scale field conditions on islands in Lake Victoria in western Kenya. A substantial reduction of flies was observed in both 'trap and kill' and fungus-treated islands compared to the control treatment. The fungus treatment generally maintained a more consistently low population than the 'trap and kill' treatment (Maniania *et al.*, 2002).

Constraints to Microbial Control and Biopesticides in Africa

From the few cases studies described above (the list is not exhaustive), it is clear that there is no shortage of *R&D* investment in biopesticide initiatives or examples of the experimental use of microbial control agents on the African continent. So why is there an apparent gap between *R&D* and implementation, and hence why is the continent deriving little sustained benefit in the form of available biopesticides from this investment? The main constraints include (see Cherry *et al.*, submitted):

Scientific and Technical Constraints

The scientific and technical aspects of biopesticide development have generally been restricted to isolation and identification, pilot scale production, and laboratory and field validation. The scientific and technical aspects also encompass formulation and storage, but, in general, insect pathologists have not mastered these because the science involved does not fall within the biological but within the chemical and physical sciences. Therefore, there is a need to involve scientists from these domains. Biopesticide development is much more than just science and the multidisciplinarity required to take a product from its initial discovery to the point of sale currently does not exist in any one single institute in Africa.

Infrastructure Constraints

In Africa, without doubt, poor infrastructure puts a brake on most aspects of development, new technologies included. Poor transport and communication networks, lack of access to clean water and electricity are all factors which constrain the development of biopesticides as much as other technologies. Furthermore, inadequate storage facilities, where for example temperature can fluctuate widely and reach 50 °C, pose temperature problems to sensitive microorganisms and botanicals.

Social Constraints

This area encompasses biopesticide awareness and acceptance by farmers and the public. It is largely an issue of education and extension, and so could be considered under infrastructure and politics since it is often the lack of extension services, or inadequate training that leads to ignorance. A good example of how this should work is Brazil, where the commitment from government to the extension services was an important factor to allow the successful adoption of *Anticarsia gemmatalis* nuclear polyhedrosis virus (AgNPV) for soybean caterpillar control (Moscardi, 1999). Studies conducted by IITA showed that biopesticides are readily accepted by farmers to reduce the dangers inherent in the use of many of the standard synthetic pesticides used in Africa today. In addition, farmers were willing to pay for Green Muscle®.

Donor and Funding Constraints

Donors generally fund projects in 3-5 year cycles, which is in most instances enough only to isolate and identify, produce on a small scale, validate in the laboratory and perhaps in small experimental field plots. However, it took almost 10 years for the LUBILOSA project to take Green Muscle® to the shelf.

National Regulatory Constraints

In Africa, regulatory frameworks for biopesticides are few, but the field is developing with Kenya currently leading on this front. The few microbial products registered in Africa to date have passed through the synthetic pesticide procedure. For instance, Green Muscle® was registered in South Africa under the chemical pesticide regulations with certain requirements being waived and relaxed. However, this product has encountered difficulties to be registered with the Sahelian Pesticide Committee (CSP), even though the fungal isolate originated from the region.

While the cost of registration of a pesticide is not prohibitive, the cost of developing the required toxicology package represents a large investment. Since the national biopesticide markets are relatively small and the number of countries is large – there are about 50 countries in Africa - these financial constraints are hard to overcome, particularly if each of these countries develops separate regulations, and imposes requirements for registration. On these grounds, registration of biopesticides in multiple countries is unattractive for large manufacturers.

While the registration of indigenous pathogens seems to pose a relatively small problem, the importation of exotic species does cause considerable concern to the regulatory authorities. Whereas, on a regional or continental scale, this is a justified concern, the restriction of the transfer of indigenous pathogen isolates across political boundaries between neighboring countries is less justified. Yet it is a common occurrence, which, if maintained unaltered, would oblige manufacturers to develop local isolates in each country in which a biopesticide is registered. This would increase the financial burdens even more.

Economic Constraints

Many poor farmers are unable to pay for synthetic chemicals and the appropriate sprayer. This is even more so in the case of biopesticides, which often are even more expensive. It is important, however, to note that synthetic insecticides have hidden costs such as clean-up expenses and incineration, effects on non-target organisms and the hazard caused to the local population exposed to chemicals.

Commercial Constraints

Markets: There are three market sectors in Africa which consume pesticides: the cash sector producing export crops (cotton, coffee and cocoa), the peri-urban market (fruit, vegetables and basic grains), and the subsistence and traditional crops' market. Only the first two have significant buying power, and access to pesticide markets. Many projects of IARCs target the basic subsistence and traditional commodities which tend to be the priority of agricultural development donors who emphasize on poverty alleviation and basic commodities such as maize, cowpea, sorghum, millet. Unfortunately, these are the markets and people who can least afford to pay for biopesticides. Targeting others, wealthier and more influential markets may be a more effective way of bringing biopesticides to the market and having an impact.

Companies: Although there are a number of non-commercial and small-scale production units generally linked to IARCs (e.g., IITA, CIP, ICIPE and CABI), to date, there is only one commercial biopesticide company, namely BCP of South Africa, which produces biopesticides. Recently, ICIPE has built a factory for the production of *Bt* with financial support from the Chinese government.

Outlook: the Way Forward

- Biopesticides are not the solution to all the pest problems; they should be used as a component of an integrated approach and in cropping systems where they can work.
- New regulations should be elaborated within the framework of a declared policy for sustainable agricultural development.
- Biologists and biocontrol experts must become involved, specific ecological situations must be considered, and risks and benefits must be evaluated. Only projects that involve a multidisciplinary and product-oriented *R&D* team of relevant experts (in formulation, storage, population ecology, socioeconomics and marketing) with sufficient resources have a chance to succeed in developing microbial pesticides for commercial exploitation following the model of the agrochemical industry for the development of chemical insecticides.
- A recent analysis of the strengths, weaknesses, opportunities and threats (SWOT) of microbial pesticides identified a large potential to be explored (Gelernter and Evans, 1999).

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Recommendations of the Working Groups

The following information summarizes the results of the working groups. The information identifies principal problems, possible solutions, proposed actions and key actors. To facilitate access, the information is organized in the following six thematic sections:

1. Marketing and promotion,
2. Product quality,
3. Effectiveness and validation of BPs,
4. Registration,
5. Production, and
6. Cooperation

Problems	Solutions	Proposed actions	Key actors
I. Marketing/Promotion			
Still limited demand	Better information of producers and consumers about the potential and advantages of BPs will increase demand; a tax on synthetic chemicals due to damage to health & environment reduces attractiveness of conventional chemicals	1. Develop a promotion strategy and intensify promotion of BPs as an alternative to synthetic chemicals based on their environmental and health benefits; 2. Encourage the use of BPs as part of good agricultural practices and in organic farming; 3. Target the most influencial growers; 4. Provide a distinction for BP use that is compatible with exports; 5. Publicize success stories; 6. Raise consumer awareness about the dangers of pesticide residues in food; 7. Facilitate the strengthening of consumers' organizations; 8. Lobby funding bodies to allocate funds to BPs	Producers of BPs and farmers; public and private sector (promotion by regulatory agencies?)
Prices are relatively high for most products	Increased and improved production allows to reduce prices	1. Optimize production systems; 2. identify joint ventures to reduce redundancies and production costs; 3. identify public and private funding to facilitate initial development; 4. promote artesanal production with quality control protocols; clear cost-benefit analyses	Private sector: producers of BPs
Limited knowledge of extension and promotion agents	Better training	1. Provide information about production and use of BPs for different production systems (conventional, IPM, organic etc.) to extension specialists, agricultural colleges, universities (re-design of curricula) and sales agents; 2. demonstration farms/plots	Producers of BPs and other public and private groups

Problems	Solutions	Proposed actions	Key actors
Many potential users feel insecure regarding the use of BPs in organic production	Transparent and up-to-date information	1. For Central America (and other regions), develop a positive list of approved BPs for organic farming and 2. promote agroecological technologies	Public and private bodies including PAN-Peru and Agrecol Andes (www.raaa.org), MERCANET (??) and the information sites of INFOAGRO, and projects-derived databases such as www.bioplaguicidas.org or www.oisat.org
Low interest by "conventional" distributors due to lower profit margins compared to synthetic products	??? Promotion and awareness campaigns; alternative distribution channels	1. Information campaigns and incentives for distributors (but who pays for it? One option is the tax on synthetic chemicals considering their "externalities"); 2. create alternative distribution channels	Producers of BPs and public sector (including NGOs)
Low competitivity of BPs compared to synthetic chemicals is exacerbated by generic chemicals		1. Support the distribution, testing and adoption of BPs under the convention of POPs	Partners include: PAN-LA, cooraa@terra.com.pe Network on BPs
Incomplete information about markets	Market information	1. Analyze markets considering frameworks such as EUREPGAP, TLC, Nafta etc.	Private sector
II. Product quality			
Quality varies with production system and scale	Quality standards (many exist but are not well known)	1. Develop and apply quality standards; 2. Enforce good manufacturing practices (GMP)	Producers and regulatory organisms
Insufficient product stability and short shelf-life for many products	Extended shelf-life and easier handling	1. Cooling devices for transport and storage; 2. develop new formulation for extended shelf-life	Private sector: producers of BPs
III. Effectiveness/validation			
Often limited information on effectiveness and side effects under field conditions	Scientific information must substitute anecdotal information	1. Study and publish effectiveness and side effects/risks of BPs under field conditions and at commercial scales; 2. analyze the feed back of farmers and other end users; 3. strengthen the exchange of experiences (farmer to farmer etc.)	Producers of BPs and farmers with support from the scientific community
Often false expectations regarding effectiveness of BPs	Training of extension specialists, farmers and sales agents	1. Provide information about the mechanisms of action and the dynamics and indicators of effectivity; 2. also inform about the limitations for effectivity (climate, crops, pests dynamics etc.)	Producers of BPs, scientists, and farmers
In many countries no accredited laboratories for toxicity tests	Laboratories and networks	1. Establish accredited laboratories for toxicity tests and 2. facilitate the exchange and mutual recognition of toxicological information among laboratories and countries (networking?)	Public and private sectors

Problems	Solutions	Proposed actions	Key actors
IV. Registration			
In many countries, lack of clear registration guidelines	Guidelines	1. Develop and distribute guidelines (including exemptions for certain BPs) parting from frameworks such as the Cuban registration for microbiologicals, the Colombian ICA guide, the CILSS Mode (???), Codex Alimentarius, OECD guidelines, EPA, etc.	Public sector: regulatory bodies
Registration procedures for synthetic chemicals are only partially appropriate for biopesticides	Proper registration requirements and procedures for biopesticides	1. Simplify and communicate registration requirements: procedures should also allow small companies to register products; 2. identify the basic required and appropriate data set for BP registration as a potential guide for regional and international registration; 3. assure that regulatory offices have personnel with the necessary technical capacity to interpret and judge the performance of BPs correctly	Regulatory bodies and legislators
Different countries have different registration requirements	Harmonized rules and regulations	1. Harmonize rules and regulations among countries/regions (e.g. Central America, Asia); 2. Registration by crop and pest	Public and private sector: regulators and producers of BPs
High costs for registration	Reduced requirements and recognition of existing information	1. Reduce the requirements for registration to the minimum necessary; 2. facilitate the exchange and linkage of toxicological information for registration (networking).	Public sector: regulators
V. Effectiveness/validation			
Low vs. high technology or lab scale vs. industrial production	Clear definitions of quality requirements for commercial products allow free competition	1. Facilitate productions at different scales as long as quality requirements are met	Regulators and producers
VI. Cooperation			
Partners for international cooperation include: In Cuba, the Network for toxicological and ecological testing, the National Registration Office and INISAV; Larry Vaughan, Virginia Institute of Technology, the national ministries of agriculture, environment and health, OPS, OIRSA, CCDA, NGOs			

Acronyms

Acronyms

APC	Agricultural Production Cooperative
APHIS	Animal and Plant Health Inspection Service, USDA
ASEAN	Association of South-East Asian Nations
BBA	Federal Biological Research Centre for Agriculture and Forestry, Germany
BCA	Bio-Control Agent
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (Federal Ministry for Economic Cooperation and Development), Bonn, Germany
BPI	Bureau of Plant Industry, Ministry of Agriculture, Manila, Philippines
BPIA	Biopesticide Industry Alliance, USA
BPPD	Biopesticides & and Pollution Prevention Division, EPA, USA
CABI	Commonwealth Agricultural Bureau International, Wallingford, England
CETEX	Centre of Experimental Toxicology, Cuba
CFC	Chlorofluorocarbons
CIRAD	International Agricultural Research and Development Center of France
CREE	Cuban State Entomophages and Entomopathogens
DANIDA	Danish International Development Agency
ENRRI	Environmental and Natural Resources Research Institute, Sudan
EPA	Environmental Protection Agency, US
EU	European Union
EUP	Experimental Use Permits, US
FAMA	Agricultural and Environment Foundation, Dominican Republic
FAO	United Nation's Food and Agriculture Organization
FDA	Food and Drug Administration, US
FFDCA	Federal Food, Drug and Cosmetic Act, US
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act, US
FQPA	Food Quality Protection Act, US
GAPEC	Group of Action for the Protection of the Environment and Culture, Togo
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practices
GTZ	German Technical Cooperation Agency
IBMA	International Biocontrol Manufacturer's Association, France
ICA	Colombian Agricultural Institute
ICIPE	International Centre for Insect Physiology and Ecology, Nairobi, Kenya
ICM	Integrated Crop Management
ICONTEC	Colombian Institute for Technical Norms and Certifications
IITA	International Institute for Tropical Agriculture, Ibadan, Nigeria
INTA	Instituto Nacional de Tecnología Agropecuaria, Buenos Aires, Argentina
IOBC	International Organisation for Biological Control
IPM	Integrated Pest Management
LUBILOSA	Lutte Biologique contre les Locustes et Sautériaux (Biological control of locusts and grasshoppers), South Africa
MOI	Multiplicity of Infection
MRL	Maximum Residue Limit
NCPAT	Non-chemical Crop Protection Approaches and Techniques

NOP	National Organic Program of the U.S. Department of Agriculture
NORAD	Norwegian International Development Authority
NRC	National Research Council, US
NRI	Natural Resources Institute, England
OECD	Organization on Economic Cooperation and Development
OIRSA	International Organizaton of Research on Animal Health
OMRI	Organic Material Research Institute, US
PAHO	Pan-American Health Organization
PESP	Partners in Environmental Stewardship Program
PIP	Plant Incorporated Protectants
POP	Persistent Organic Pollutants
RAAA	Red de Acción en Alternativas al Uso de Agroquímicos (Action network for alternatives to pesticide use), Peru
RAPAL	Red de Acción en Plaguicidas y sus Alternativas para la Región Andina (Action network for pesticides and their alternatives for the Andean region), Peru
UNEP	United Nations Environmental Program
USDA	United States Department of Agriculture
WHO	World Health Organizaton