The CGIAR Systemwide Program on Integrated Pest Management

Regulatory challenges for biological control

Hoeschle-Zeledon, I., P. Neuenschwander and L. Kumar




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About SP-IPM

The Systemwide Program on Integrated Pest Management (SP-IPM) is a global group of scientists and institutions that spearheads forward-looking research and outreach programs on crop pest and disease management by bringing together the individual strengths and expertise of several CGIAR centers and their partners around the world.

SP-IPM has been involved in development of knowledge and technologies for innovative crop protection to increase and secure the production of safe food in an environmentally and economically sound way.

SP-IPM strives to gain a better understanding of the diverse biotic and abiotic interrelationships between the different components of agricultural biodiversity. A holistic approach to IPM is taken by examining important plant interactions with both detrimental and beneficial organisms in the environment in which they flourish. These research areas will be further strengthened by multidisciplinary cooperation with other scientific disciplines and by expanding knowledge on IPM technologies through capacity building in the National Agricultural Research Systems (NARS) in cooperating countries and at the farmer level.

One of the key areas of SP-IPM is to disseminate IPM research results and recommendations worldwide by coordinating online resources that provide information and learning experiences in plant protection to researchers, regulators, policymakers, extension agencies, farmers and other stakeholders at all levels of development, focusing on their needs and desires. SP-IPM Briefs are one of the products that serve the outreach purpose.

For more information about SP-IPM, visit www.spipm.cgiar.org

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Acronyms and Abbreviations

ACPACP	African, Caribbean and Pacific Group of States
BCA	Biological control agent or biocontrol agent
CABI	Commonwealth Agricultural Bureau International
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Center for Tropical Agriculture
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
FAO	Food and Agriculture Organization
GMO	Genetically modified organism
IAPSC	Inter-African Phytosanitary Council
IITA	International Institute of Tropical Agriculture
IOBC	International Organisation for Biological Control
IPM	Integrated pest management
IPPC	International Plant Protection Convetion
ISPM	International Standards for Phytosanitary Measures
NARS	National Agricultural Research Systems
PRA	Pest Risk Analysis
SP-IPM	Systemwide Program on Integrated Pest Management
SSA	sub-Saharan Africa

Foreword

Biological control is a significant component of integrated pest management programs around the world. However, uncertainty about the risk of unanticipated effects on non-target organisms is one of the major concerns surrounding the release of biological control agents. This Brief has been prepared with the intention of:

- aiding scientists within the CGIAR, national programs and universities who develop, adopt or promote biological methods to control pests, pathogens and weeds;
- informing about the legal requirements in different countries for the import, release and commercialization of these agents; and
- increasing understanding among decision-makers in regulatory agencies of the risks and benefits associated with biological control programs.

This document also provides a list of various biological control agents adopted in different countries, as well as those currently under development, as a ready reference to new users. Biopesticides composed of non-living ingredients like plant products (e.g. neem extracts) or genetically modified organisms (GMOs) are not considered in this review. It is hoped that this document will facilitate the harmonization of regulatory procedures for import, production and release of biological control agents across countries in developing regions of the world and enable rapid interventions in situations of pest invasion and outbreak. This in turn will stimulate further research towards alternatives to chemical pest control methods, through biological control or the development and large scale application of readily available products, to the benefit of farmers, the environment, and society as a whole.

Introduction

The biological control of plant pests, diseases and weeds has become a major component of Integrated Pest Management (IPM) in most parts of the world, in the field as well as in horticulture under greenhouse. Compared to most other pest management techniques, biological control with live agents has the advantages of being self sustaining, cost effective and eco-friendly. Several hundred biological control agents (BCAs) (used to control pests, weeds and pathogens) and beneficial agents (used to improve the resilience of the host and environment) are being used worldwide against a wide range of pests and pathogens. Lists of the BCAs most often used in biological control programs worldwide are given in Annexes 1 and 2.

The CGIAR and associated Centers have executed a large number of successful biological control programs with releases of exotic agents in numerous countries (Neuenschwander 2004). They have also identified several plant beneficial microorganisms (e.g. endophytes) and natural antagonists of pathogens, pests and food contaminants for crop protection and food safety (see Annex 3). Some of these agents were extensively validated and released in biological control programs or commercialized after approval and registration by the authorities in the target countries (see Annex 3, part A). Together with good crop management practices, introductions of such agents have contributed to keeping pest levels, particularly of exotic invaders, under control, thereby reducing further pest control measures or making them altogether unnecessary. In this way, successful biological control leads to enormous and recurring savings (Neuenschwander 2004).

A full understanding of the regulations involved in the registration and release of BCAs is critical to their successful deployment. Many biological control options are, however, not being deployed because of poor awareness of adoption procedures and misplaced concerns about risks associated with BCAs. The approval and registration procedures differ between countries, but typically require a large dossier of scientific data on expected benefits, risks, biosafety considerations, and impact on the environment. The process generally involves different agencies, and decision-making is usually a slow process. Lack of information on or understanding of the risk of unanticipated effects is one of the bottlenecks that delays decision-making.

Information on any unexpected effects, or lack thereof, from countries which previously adopted the BCAs under consideration could hasten the decision-making process. The present document therefore presents a brief overview of biological control, concerns with its application, and examples of biological control programs executed in the CGIAR, together with guidelines to the relevant regulations adopted by some inter-governmental bodies and countries. Published and unpublished observations of unanticipated and non-target effects of BCAs released by the CGIAR Centers in collaboration with their national and international partners are also indicated.

What is biological control?

Biological control (also termed as biocontrol) is an integral component of IPM. It refers to the use of an organism to reduce the population density of another organism and includes the control of animals, weeds and diseases (van Lenteren 2011). It relies on predation, parasitism, herbivory or other natural mechanisms. BCAs of arthropod pests are predators, parasitoids and pathogens, while those of plant diseases are referred to as antagonists. BCAs of weeds include herbivores and plant pathogens.

Two types of biological control can be distinguished (Figure 1):

(i) Natural biological control: reduction of pest organisms by their natural enemies. This happens without human intervention and in all ecosystems. It is the most important form of biological control in agriculture and forestry (Hagen et al. 1971; Waage and Greathead 1988; van Lenteren 2011) and is at the root of the resilience of natural ecosystems.

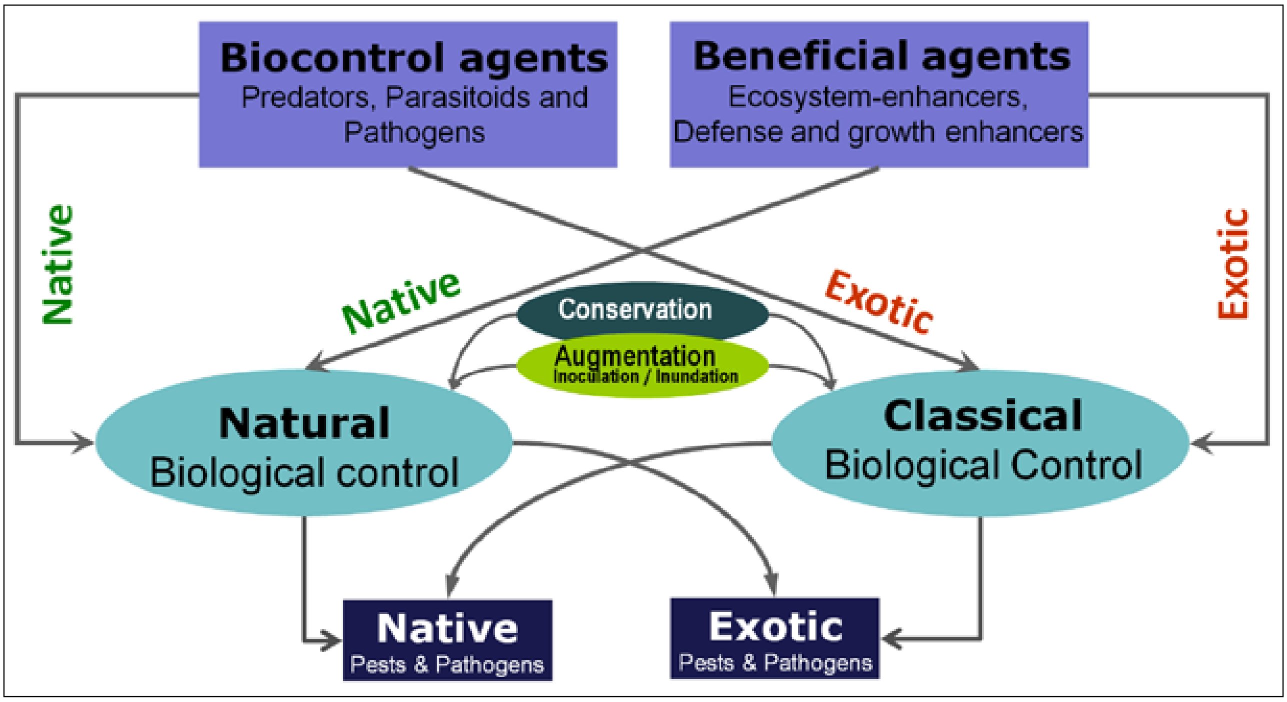

Figure 1. Functions and types of agents involved in the natural and classical biological control of native and exotic pests and pathogens

(ii) Classical biological control: introduction of a natural enemy to a locale where it has not been present before. This approach is usually used when the pest itself has been introduced. Essentially, co-adapted natural enemies from the pest's region of origin are introduced through quarantine. Natural enemies found in the original habitat of the pest are screened under quarantine conditions to prevent unwanted associated organisms before their introduction to the new environment. The behavior of the BCA is also monitored to determine its adaptation to the new conditions and ability to spread on its own (SP-IPM 2006). Once the introduced BCA becomes established, reproduces and spreads, no further intervention is needed for the agent to have its effect on the target pest. The introduced BCA effectively becomes a part of the natural biological control operating in the ecosystem (Cock et al. 2009).

The first case of classical biological control dates back to the year 1888, when the ladybird beetle *Rodolia cardinalis* was introduced to California to control the alien cottony cushion scale in citrus. Since then, classical biological control has been practiced to control hundreds of exotic pests, mostly insects and mites, in agriculture, horticulture and forestry. Over 6000 introductions have been made to control invertebrate pests, and about 1000 to control alien weeds (Julien and Griffiths 1998, Waage 2001). In hundreds of cases complete control has been achieved without the need for further intervention. Classical biological control is inexpensive to deploy, is self-sustaining, and does not demand difficult adaption by farmers.

To enhance the effectiveness and sustainability of both natural and introduced BCAs in an ecosystem it is sometimes necessary to provide supporting mechanisms that conserve and augment their populations. **Conservation** measures involve providing food sources and nesting sites, and reducing the presence of harmful pesticides to allow population numbers to increase (SP-IPM 2006). To augment a population of BCAs, the agents can also be mass produced and added periodically to the ecosystem. This method is often referred to as **augmentative biological control**. The addition of small numbers to gradually increase the natural population is termed 'inoculation', whereas the release of large numbers for a rapid effect on the pest organism is termed 'inundation' (SP-IPM 2006).

It is estimated that 170 species of invertebrate natural enemies are produced and sold worldwide for periodic release in augmentative biological control to manage more than 100 pest species. Augmentation is applied on 160,000 km^2 of land globally. The total 2008 world market for natural enemies used in augmentative control at the end-user level was estimated at about €300 million (Cock et al. 2010). A large share of augmentative biological control is used in greenhouses where mostly exotic BCAs are released that do not survive from one cropping cycle to the next (Cock et al. 2009).

Types of biological control agents

BCAs can be classified as follows:

- **Predators** are free-living species that consume large numbers of prey during their lifetime. Birds, lady beetles, mites and lacewings are examples. In most cases, predators are not prey-specific.
- **Parasitoids** are species whose immature stages develop on or within a single insect host, ultimately killing it. Most have a very narrow host range. Many species of wasps and certain flies and nematodes are parasitoids.
- **Pathogens** are disease-causing organisms and include bacteria, fungi and viruses. They kill or debilitate their host and are relatively specific.

In addition to BCAs, other agents have an indirect impact on pests, pathogens and other harmful organisms. These are often termed beneficial agents, and come in two types:

- **Ecosystem enhancers** competitively displace plant pathogens or toxin producing strains of microorganisms. Examples of the latter are several atoxigenic strains of *Aspergillus flavus* that, through the principle of competitive exclusion, reduce populations of aflatoxin producing strains. The primary mode of action of certain strains of the bacterium *Pantoea agglomerans* is competitive exclusion of a variety of bacterial and fungal plant pathogens, particularly fire blight and post-harvest fungal diseases in apple and pear and basal kernel blight in barley. In addition, some strains also contribute to disease control through the production of antibiotics.
- **Plant defense and growth enhancers** boost the inherent ability of plants to defend against the impacts of herbivors or infections. This induced or systemically acquired resistance is a mode of action of certain plant endophytes like specific non-pathogenic strains of *Fusarium oxysporum*, other soil-borne microorganisms like *Trichoderma* species, and even mild strains of pathogenic viruses that boost host defenses and protect from severe strains.

Opportunities and risks in implementing biological control

Opportunities

Biological control is a cost-effective, environmentally friendly approach that can solve alien pest (non-indigenous, exotic or non-native) problems in diverse ecosystems, including agriculture and forestry, natural, semi-natural and urban habitats, freshwater, etc. (Wittenberg and Cock 2001). The increased volumes of trade in agriculture and horticulture, new trade routes, and increased travel have heightened the associated risks of introducing alien pest species and are likely to increase the need for classical biological control (Waage 2001, Wittenberg and Cock 2001).

Most of the world's crops and many planted timber species are grown as alien species in most areas where they are planted today (Cock et al. 2009). One classic example is Cassava (*Manihot esculenta*), which was introduced from South America into Africa by the Portuguese in the 16th century. Subsequently, two pests native to Latin America, the cassava mealybug (*Phenacoccus manihoti*) and cassava green mite (*Mononychellus tanajoa*), spread to Africa and devastated cassava production until their natural enemies were introduced into Africa in acts of classical biological control (see Box 1 and Box 2). Thus, there remains great potential for pests from a crop's area of origin to be introduced into habitats where the crop is being grown as an alien.

Alien invasive species also pose a threat to the conservation of biological diversity. Under the Convention on Biological Diversity (CBD) treaty, countries are required to prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species (Waage 2001). In addition, the withdrawal of particular chemical pest control products from the market and the expansion of certified IPM and organic production systems will require more biological pest control approaches against organisms that have been kept in check, sometimes inadvertently, through the application of broad-spectrum insecticides. Hence the need for a comprehensive approach as described for IPM, including biological control (Neuenschwander et al. 2003).

In conclusion, biological control, well executed and following internationally agreed guidelines, remains the most cost-effective and promising tool for the sustainable control of pests, particularly invasive aliens. Furthermore, many biological control introductions have led to beneficial non-target effects through the restoration of previously invaded habitats (van Driesche et al. 2010).

Risks

Most releases of BCAs before 1990 were made under the notion of good professional practice. Early introductions of non-specific predators like birds, mammals, amphibians, fishes and snails have resulted in dire consequences for entire ecosystems. An example is the rosy wolfsnail *Euglandina rosea* released in the 1950s in many Pacific and Indian Ocean Islands to control the invasive giant African land snail, *Achatina fulica*. The introduction of this non-specific predator led to the extinction of many tree snail species in these places (Regnier et al. 2009).

Lessons from such cases have led to the development of binding legislation, regulation and risk assessment. Since these developments there have been few reports of negative effects. However, the perception that BCAs pose a risk to native flora and fauna has increased, and even organisms widely understood to be beneficial have received the label of invasive alien in some countries (Bale 2011).

Potential risks arising from the introduction of exotic BCAs include those to human and animal health, the economy, and the environment. A health risk may exist for personnel in the mass production and application process of some BCAs in the form of allergies, but this risk is not unique to exotic invertebrates. Economic losses can occur when the introduced BCAs attack previously released BCAs or other non-target organisms. These effects can be checked and taken into account during characterization of BCAs and in quarantine. Though the agents are usually highly specific and therefore pose little threat to non-target indigenous organisms, there remains some risk of indirect effects on the distribution and abundance of native organisms. Studies to determine such risks are complicated, particularly in the species-rich tropics, because related non-target species are not sufficiently known (van Lenteren et al. 2006).

In general, assessing the non-target risks remains the most difficult part of overall risk assessment in biological control. This includes assessment of the host range, establishment potential, dispersal, and direct or indirect effects on other organisms in the ecosystem (which can extend to non-target herbivores, intraguild predation, enrichment, vectoring pathogens or hyperparasitoids, competition with other natural enemies that use the same food source, and hybridization between BCAs and indigenous types of the same or closely related species). These effects are determined by environmental factors and the characteristics and biology of the BCA and other organisms in the ecosystem. A comprehensive environmental risk evaluation guideline applicable to all types of invertebrate BCAs has been developed (van Lenteren et al. 2006) and consists of a stepwise procedure as detailed in Figure 2.

No extinctions are known to have been caused through biological control with insects. Nonetheless, clear risks that have to be assessed (Louda et al. 1997; van Lenteren et al. 2006) include a large reduction in the population of a native organism, interference in the efficacy of a native natural enemy, transmission of pathogens harmful to native organisms, hybridization between close relatives, and any major shifts in the balance of native species – such as those caused by the recent controversial introduction of the lady beetle *Harmonia axyridis* in Aregentina, Canada, Europe, South Africa, USA and other countries (Roy and Wajnberg 2008).

The risks from introducing exotic BCAs have to be balanced against the already achieved damages from the accidental introduction of exotic organisms. For perspective, accidentally introduced organisms greatly outnumber intentionally introduced ones. About 50,000 organisms (plants, animals, microbes and others) have been unintentionally brought to the USA. Out of these, 10-50% have caused ecological problems

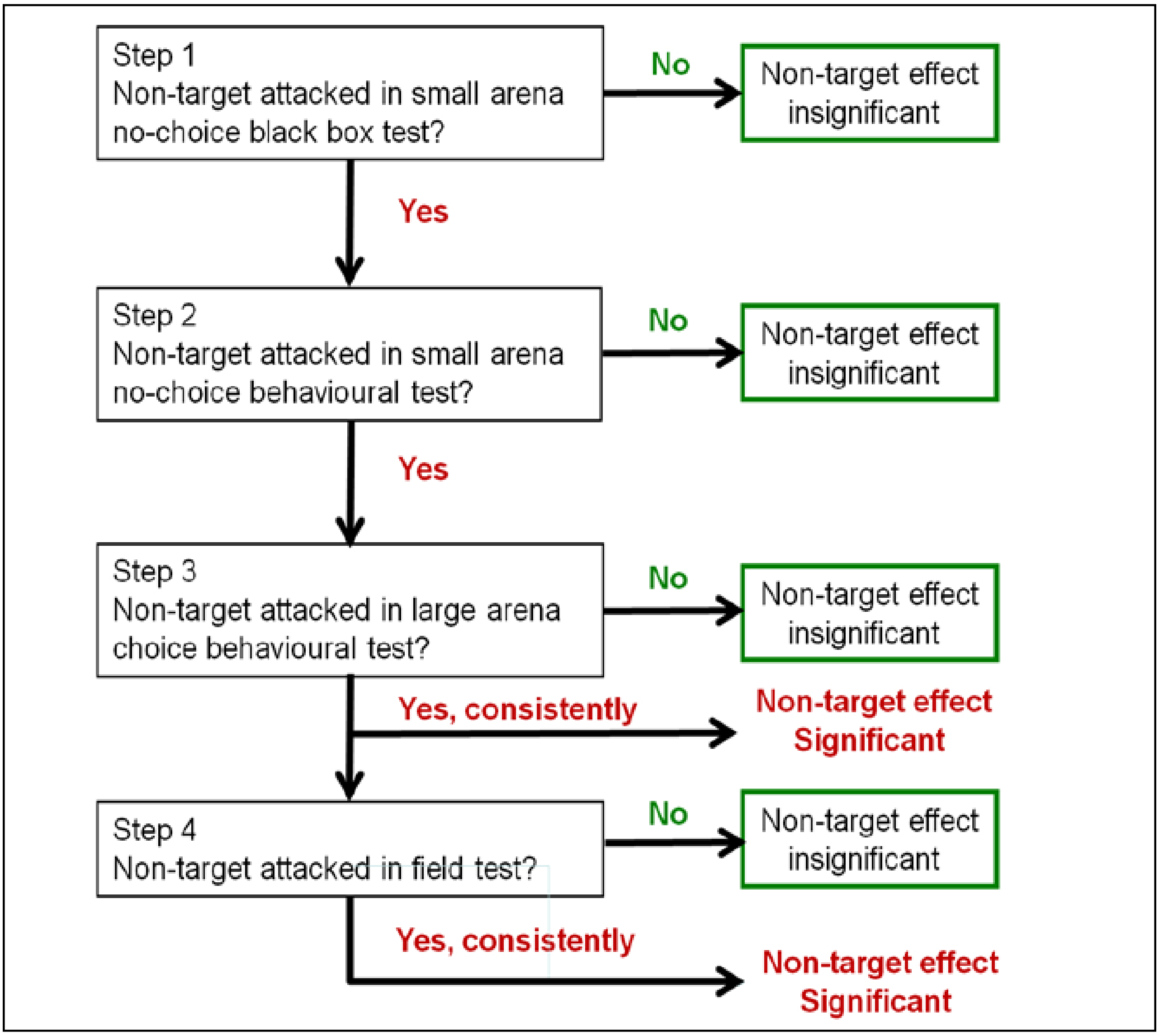

Figure 2. Scheme to assess non-target effects of biological control agents (Source: van Lenteren et al. 2006)

(Pimentel et al. 2002). Most intentional introductions have been of crop and ornamental plants, 2.2% of which have become troublesome weed (Pimentel et al. 1989, Sailer 1978). Of all non-indigenous insects in the continental US, over 50% are considered pests; however, only a few intentionally introduced insects have been reported to cause some sort of side effect. Though only a minority of cases have been carefully evaluated for non-target effects, the introduction of insects as BCAs must be considered particularly safe. Less than 1% appear to have caused measurable population-level effects on non-target organisms, while only 3-5% may have caused some minor effects. If strong non-target effects had appeared, they would have been noticed and reported (Lynch et al. 2001).

Transient effects on non-target species are common in inundative releases of arthropods, especially when polyphagous agents are used as BCAs. Such effects are also occasionally reported during the introduction phase of a parasitoid for classical biological control, but they have not been found to cause any lasting population-level effects (Lynch et al. 2001). The use of native organisms is one way to reduce the risks from releasing exotic species in augmentative biological control (van Lenteren et al. 2006; van Lenteren 2011). This also avoids extensive evaluation and registration demands. At present, about 65% of new natural enemies used in biological control are native (J. van Lenteren, pers. comm.).

In conclusion, specificity and efficacy of biological control introductions are important criteria in the selection of BCAs. Safety records of biological control control in agricultural production have been very good, and no invertebrate or microbial BCA that has been introduced following strict standard safety procedures is known to have become a significant agricultural pest (Waage 2001).

Constraints from over- and under-regulation

Procedures for assessing risk due to biological control, particularly to non-target organisms, are kept at a minimum to encourage screening and use of promising BCAs. Excessive and costly procedures can halt promising classical biological control projects. Evaluation of commercially produced BCAs for augmentative (inundative) release under legislation developed to screen synthetic pesticides would prevent the commercialization and use of BCAs, sustaining and even increasing farmers' dependence on environmentally harmful chemical pesticides (Neuenschwander and Markham 2001).

Misunderstood application of the Code of Conduct, the Guidelines on Environmental Risk Assessment, and national regulations can delay implementation of biological control (Bolckmans 1999). Guidelines could and should be simplified and harmonized wherever possible.

One approach is to adopt international legal frameworks, such as the FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents (FAO 2006) and the International Standards for Phytosanitary Measures No. 3, ***Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and other Beneficial Organisms*** (ISPM-3 2005), as a standard for all biological control introductions worldwide (see Annex 5). The ISPM No. 3 provides guidelines related to phytosanitary measures, as well as recommended guidelines for safe export, shipment, import and safe usage of BCAs and other beneficial organisms for all public and private bodies involved, particularly through the development of national legislation where it does not exist. Together with existing standards on pest risk analysis – ISPM No. 2, ***Framework for pest risk analysis*** (ISPM-2 2007) and ISPM No. 11, ***Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms*** (ISPM-11 2004) – it provides the appropriate fundamental processes for carrying out pest risk assessments for BCAs and other beneficial organisms to determine any possibilities of harmful effects on plant species or plant health in habitats or ecosystems.

Some countries or groups of countries like the EU have established specific regulations (van Lenteren et al. 2006) which are more or less in line with ISPM procedures, aside from significant differences in documentation and registration for on-farm use. Some examples are given in this section on Existing legislation.

Another major constraint that applies particularly to the development of classical biological control projects is the prevention of exploration for BCAs under Convention on Biological Diversity (CBD) treaties by some countries (van Lenteren et al. 2011). This issue, related to access and benefit sharing of BCAs, requires further discussion in order to find a mutually agreeable understanding that benefits countries of BCA origin as well as beneficiaries in other countries. The International Organisation for Biological Control (IOBC) is in a position to mediate the discussion on this matter.

The private industry involved in commercial production of BCAs is encountering lengthy and cumbersome procedures that lead to high costs for the marketing of BCAs. This will inevitably cause the loss of industry interest, meaning farmers and countries will miss out on a safe and cost-effective pest control option. Fast scanning methods could be applied to BCAs that are already in use elsewhere and white lists of supposedly safe species for particular regions could be developed (van Lenteren et al. 2006). For testing, decisions could be reached through a tiered system approach to avoid lengthy procedures.

Existing legislation

Inter-governmental

International Plant Protection Convention (IPPC)

The IPCC's International Standards for Phytosanitary Measures No. 3, *Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and other Beneficial Organisms* (ISPM-3 2005; see Annex 5) provides guidelines for risk management related to the export, shipment, import and release of biological control agents and other beneficial organisms. The standard addresses BCAs capable of self-replication, as well as sterile insects and other beneficial organisms (mycorrhizae, pollinators), and includes those packed or formulated as commercial products. The provisions also include the import of non-indigenous BCAs and other beneficials for the purpose of research in quarantined facilities.

The standards request governments to designate a National Authority responsible for implementation. This National Authority (usually a National Plant Protection Organization) should develop appropriate official procedures and administrative systems, taking into account official policies in support of biological control (OEPP/EPPO 2010).

The responsibility of the National Authority is to:

a. carry out pest risk analysis of BCAs and other beneficials prior to import or prior to release;
b. obtain, provide and assess documentation that is appropriate and relevant to the export, shipment; import and release of BCAs and other beneficial organisms;
c. ensure that biological control agents and other beneficials are taken either directly to the designated quarantine facilities or mass-rearing facilities or, if appropriate, passed directly for release into the environment;
d. ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with; and
e. encourage monitoring of release of BCAs or beneficials in order to assess impact on target and non-target organisms.

European and Mediterranean Plant Protection Organization (EPPO)

Regulations distinguish between a BCA for release or for first import for research. If the organism is to be imported for research or mass-rearing the notification procedure of EPPO Standard PM 6/1, *First import of exotic biological control agents for research under contained conditions*, is followed.

In the case of an organism already being imported and currently held in containment, or if the organism is being imported directly for release, the applicant has to prepare a dossier for submission to the National Authority. The dossier requires the following information.

- Part 1. Application information: Information on the applicant; purpose of application and use.
- Part 2. Information for indigenous and non-indigenous BCAs: Taxonomy and origin; product information.
- Part 3. Information requirements for intentional release of a non-indigenous BCA with reference to: Biology and ecology; assessment of risks and benefits; establishment; host specificity; dispersal; non-target effects.
- Part 4. Submission of forms and signature: Submission details; agreement; safeguards and signature.
- Part 5. Appendices, if appropriate.

The National Authority determines whether an organism is required to be subjected to pest risk analysis (PRA) in accordance with ISPM No. 2 (*Framework for pest risk analysis*) and ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*) before release. The National Authority also considers possible impacts on the environment, such as impacts on non-target invertebrates. These procedures also ensure that relevant national and international regulations are respected (for example, on the safeguard of natural resources or the movement of rare or endangered organisms).

During the release process the releasing organization has to ensure that:

(1) All appropriate safety procedures are put in place. In particular, all contaminants and hyperparasites should be absent.
(2) The release program is fully documented concerning identity, origin, numbers/quantity released, dates, localities and any other data relevant to assessing the outcome.
(3) Evaluation of the releases is planned in advance, to assess the impact of the organism on the target pest and non-target organisms.
(4) Authoritatively identified reference (voucher) specimens of the pests and natural enemies involved are deposited in appropriate collections, where they should be available for reference and study.
(5) Any problems encountered in post-release monitoring are reported. (OEPP/EPPO 2010).

European Union

Since June 2011, EU Regulation 1107/2009/EC (EU 2009a) regulates the registration of all plant protection products, including those based on microorganisms. It aims at harmonizing the process throughout the Community. It is based on a 2-tier system in which the active ingredient is assessed at the EU level for inclusion into a positive list (see EU 2011) while products are subsequently registered by the Member States. An active substance complying with the criteria is approved for a period not exceeding 15 years. These regulations, established on the principle of mutual recognition, stipulate that authorization granted by one member state should be accepted by other member states where agricultural, plant health and environmental (including climatic) conditions are comparable.

On the basis of Regulation 1107/2009/EC (EU 2009a) and Directive 2009/128/EC (EU 2009b), implementation of the principles of IPM is obligatory with priority given wherever possible to non-chemical methods of plant protection and pest and crop management. Member states have to develop National Action Plans with quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides.

There is no legislation at the EU level regarding the import and use of invertebrate BCAs. Regulation is at the discretion of member countries, and few countries have regulatory systems in place. Therefore, a BCA may be prohibited for release in one country with regulation but then released in another country without regulation. Among countries with regulation, there is no requirement for mutual recognition of environmental risk assessment data (Bale 2011).

The EPPO/IOBC Panel on safe use of biological control agents maintains a positive list of BCAs that are used within Europe, and developed the EPPO standard on Import and Release of Non-indigenous Biological Control Agents. Several EU-funded projects such as ERBIC (Evaluating environmental risks of biological control introductions into Europe) and REBECA (Regulation of biological control agents) have been implemented with the aim of harmonizing regulatory requirements across the EU so that costs to the biological control industry can be minimized without compromising environmental safety (Bale 2010).

Africa-wide biological control projects

Unlike in the EU, harmonized regulations for adoption of biological control are not in place in Africa. The large number of countries with porous borders and the weak development of quarantine facilities on this continent pose particular challenges for implementing Africa-wide biological control programs.

In the past, major biological control projects have been implemented under the umbrella of the Inter-African Phytosanitary Council (IAPSC), facilitated by a quarantine station based in Africa or even outside the continent. As a consequence, national quarantine authorities have been willing to issue quarantine permits on the basis of submitted documentation, but without testing the biological control organisms themselves (see Boxes 1 and 3). With an increase in the application of BCAs for pest and disease control, many countries are now adopting regulations for the registration and release of agents. A common set of regulations could play a dramatic role in enhancing the use of BCAs and eco-friendly pest and disease control in Africa, and IAPSC is well placed to lead discussions toward formulating such common practices.

Legislation in selected countries

Kenya

The Pest Control Products Board (PCPB) is the national authority responsible for registration of microbial pest control products. The PCPB has developed biopesticide-specific (BCAs being considered as biopesticides) registration pathways, including one for microbial pest control products. There is a distinction between indigenous and non-indigenous microorganisms. For registration of non-indigenous organisms, all applicants intending to import or export live organisms must seek clearance from the Kenya Standing Technical Committee on Imports and Exports of live organisms (KSTCIE) prior to initiating any in-country work with the organisms. If an indigenous organism is produced in Kenya and is intended for export, notification should be sent to the CBD. The broad role of the PCPB, the pesticide regulator, includes but is not limited to the following: evaluation of submissions for pesticide and biopesticide approvals; regulation of biopesticide production facilities in terms of safety and production quality; and final product quality control and labeling.

The PCPB will consider supporting data in the dossier that has been generated outside of Kenya, provided it was carried out to the required standards such as good laboratory practice. Toxicological data may be waived where there is sufficient evidence that the product is safe. This should be based on results of medical surveillance, published data, as well as actual studies of the product. Where no evidence is provided, or where there is insufficient evidence, toxicological studies have to be conducted in three tiers.

Waivers for ecotoxicological data may be granted on presentation of evidence that exposure to the particular non-target organism will not occur, or where effects of exposure are already documented. Selection of test non-target organisms will be on a case-by-case basis and according to mode of action and ecological relevance. Tier 1 studies report any observed pathogenicity/infectivity to the test species. Tier 2 studies are required on representative non-target species, if acute studies indicate that adverse effects would occur during routine application.

Regulations stipulate at least two seasons of efficacy trials of the product in Kenya. This trial work must be done by a PCPB approved contractor; a list of PCPB accredited contractors, with expertise in different crop groups, is provided on their website. The time from pre-consultation with the PCPB to approval and registration of a microbial pest control product varies with the complexity of the product, and can range from 2 to 4 years (Gwynn and Maniania 2010).

Brazil

A Certificate of Registration, granted by the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) after scrutiny by the National Health Surveillance Agency (ANVISA) and the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA), is required for all pesticides used in agricultural areas, forests and pastures. The Certificate of Registration authorizes the marketing of the pest control product in the country. Products for use in native forests and water environments must be registered with IBAMA after meeting the requirements established by the other two registration authorities. Biological products have been separated from chemical products and registration of products with low toxicity and environmental hazard has been given priority. Many tests required for chemical products are no longer required for biopesticides.

Testing on non-target organisms is divided into four tiers, with non-target organisms (birds, freshwater fish, non-target insects and others depending on the nature of the pathogen) being subjected to a single high dose in the first tier. If no adverse effect is observed in Tier 1, testing in Tiers 2 to 4 is unnecessary.

Furthermore, efficacy data resulting from field trials involving the subject crop and target pest must also be submitted. Once all of the documentation is delivered to the official agencies, IBAMA and ANVISA have up to four months to send their evaluations to MAPA. MAPA then has another 30 days to accept or reject the application for the Certificate of Registration.

Products which are considered non-formulated according to international literature have been registered, such as mycopesticides commercialized as fungus-colonized substrates. Once registered by a federal agency, registration at the state level where the product will be marketed is also required. This step is coordinated by the Department of Agriculture in each state, and is a fairly simple process (Rangel and Faria 2010).

India

Biopesticides fall under the Insecticide Act of 1968, under which any microbial organism manufactured or sold for pest and disease control should be registered with the Central Insecticides Board (CIB) of the Ministry of Agriculture. To promote registration, biopesticide products benefit from priority processing of registration, simplified registration procedures, and the acceptance of generic registration data for new products containing strains already registered (Kulshrestha 2004). Manufacturers can register their products temporarily or regularly. This system allows commercial producers of those microbial pesticides evaluated as generally safe to obtain provisional registration and continue to develop a market while the product is undergoing full registration; this reduces commercial barriers to product development. The data requirement for temporary registration is less stringent than for regular registration. Data on product characterization, efficacy, safety, toxicology and labeling must be submitted while applying for registration. The CIB's established quality standards must be met, with reference to content, virulence of the organism in terms of LC50, moisture content, shelf life and secondary non-pathogenic microbial load. Protocols for assessing these quality parameters have been prescribed (Rabindra 2005).

The Department of Biotechnology plays a key role in funding research and development of microbial pesticides, including the generation of toxicological data for registration purposes. The state governments play the main role in implementing IPM. The IPM programs implemented by the states have been vital to creating a market for and encouraging private commercial production of microbial pesticides (Rabindra and Grzywacz 2010).

Canada

Invertebrate BCAs are not registered by the Pest Management Regulatory Agency (PMRA). Nematodes require a rather simple approval for use issued by the Canadian Food Inspection Agency (CFIA), but macrobiologicals (predator insects), if exotic, require an extensive petition for release, North American-wide review and approval, and final authorization by the CFIA. Indigenous invertebrates for release have no regulatory oversight (Kabaluk et al. 2010).

The process for the registration of microbial pesticides is provided in DIR2001-02, *Guidelines for the registration of microbial pest control agents and products*. The cornerstone document of a submission for any pesticide registration is the Data Code (DACO) table. For microbial pesticides there is a separate and more generic DACO table which is used as a starting point to set data requirements for all microorganisms to be registered. The purpose of the DACO table is to itemize all the information, data and otherwise, that are required for registration. Testing on human health and environmental fate and toxicology are tiered, meaning that if the microbial pest control agent is found to produce no effect under the most opportune conditions, then no further testing is required. Data from existing scientific literature are acceptable. The DACO table provides the option of including information from foreign registration reviews (Kabaluk et al. 2010).

The DACO table for microbials is designed collaboratively by the PMRA and prospective registrant at a non-mandatory Pre-registration Consultation. During this consultation, prospective registrants are advised on data requirements congruent with the DACO table and on the option for data waivers if the registrant does not consider certain DACO items applicable to the target use. Advice is also given regarding the application procedure. Prospective registrants are required to provide additional information, e.g. on international registration status, which will aid PMRA in setting appropriate data requirements. The identification of the ecological zone in which the MCPA will be used is critical to implementing the tiered system of evaluation which determines the level of environmental testing that will be required (Kabaluk et al. 2010).

There is ongoing work with other countries to facilitate and encourage the Canadian registration of pest control products. Canada accepts registration data created in and submitted to regulators in other countries, provided they have been generated under conditions relevant for Canada. Further to the acceptance of data from OECD countries, in recent years, Canadian registration requirements for microbial pesticides and pheromones were essentially harmonized with those in the United States. PMRA and EPA undertake joint reviews of registration submissions for biopesticides, including microbials, semiochemicals and other biochemicals (Kabaluk et al. 2010).

In a regulatory context, microbial pesticides are afforded special concessions. Evaluation and risk assessment standards remain the same as for synthetic pesticides, but the review timeline is shortened. Timelines for Canada-U.S. joint reviews are negotiated, but are expected to be shorter than those for single-country reviews. To encourage registration submissions and increase the range of candidate reduced-risk pest control products, Canada has accepted the United States definition of a reduced-risk or biopesticide product. Biopesticides are exempted from the fees for pesticide registration and for the right to sell the product in Canada, except for the cost charged for reviewing the product label. Finally, there are generally no Maximum Residue Limits for microbial pesticides, negating the need for crop residue studies (Kabaluk et al. 2010).

United States of America

In the United States, the Environmental Protection Agency (EPA) is responsible for the registration of pest management products. There is a special division that regulates biopesticides. These include i) microbial pesticides, viral proteins and their genetic material, bacteria, fungi, protozoa and algae; ii) biochemicals, including food substances and food additives, pheromones, growth regulators, oils and numerous other substances found in nature; and iii) plant incorporated protectants (PIPs). In comparison with registration of conventional chemical pesticides, biopesticide registrations are usually faster, less complex, and less costly when adequate information already exists for consideration in the risk assessment process.

Like Canada, the US does not require registration of indigenous beneficial insects or entomopathogenic nematodes. Plant growth promoting rhizobacteria, nitrogen fixation, or similar types of microbial inoculants are also exempted from registration as long as they do not make a pest control claim.

The data required to register a microbial pesticide are divided into five groups of a) product analysis, b) residues, c) toxicology (health effects), d) non-target/environmental effects and e) environmental expression. Residue and environmental expression data are rarely required. In most cases, no maximum residue tolerances are associated with microbial pesticides. Data on environmental expression to demonstrate whether a microbial pest control agent (MPCA) is able to survive or replicate in the environment is also rarely required. Non-target testing includes avian oral, avian inhalation, wild mammal, freshwater fish and aquatic invertebrates, estuarine and marine animals, non-target plant and insect, and honeybee testing. In addition to the toxicology and non-target test guidelines, there are higher tier studies for toxicology.

Overall, acute oral and dermal, avian oral, non-target insect and honeybee testing are the data that are most frequently fulfilled by toxicology studies while most others are fulfilled by data waivers. Data waivers are a scientifically justified discussion of how the data is fulfilled due to existing knowledge about the organism or why exposure is unlikely to occur. Some of the factors in determining if the data requirement will need to be fulfilled by a toxicology study instead of a waiver include if there is known pathogenicity of the organism to man, animals and plants or proximal relationship to organisms of concern. Other factors include the type of microorganism (fungi, bacteria, virus, etc.), use sites such as food versus non-food crops, outdoor versus indoor application, and terrestrial versus aquatic application.

In order to facilitate the adoption of biopesticides, universities, EPA and USDA may assist small private companies technically and financially with the development and registration of biopesticides (Braverman 2010).

Germany

In Germany, the release of native and non-native natural enemies can be exempted from approval under the Federal Environment Protection Law. However, non-native species for the purpose of pest control then need to be licensed under the Plant Protection Law, taking into account their impact on native species. This procedure is not in place yet. Nevertheless, many non-native species have been released without negative impact on the ecosystem, but liability remains with the provider of the BCA and the plant protection advisor who recommended their release. For import of BCAs from non-EU countries, a written confirmation of the environmental safety of the BCA in terms of impact on native species, freedom from pathogens, type of species, and a declaration that it is not a protected species in the country of origin, needs to be presented to the plant protection service in the respective federal state (Hertz, Julius Kühn Institut, pers. comm.).

Biological control agents released around the world

At least 7,000 introductions of BCAs, involving almost 2,700 BCA species, have been made. The most widely used BCAs have been introduced into more than 50 countries. Invertebrate BCAs from 119 different countries have been introduced into 146 different countries (for a selection see Annex 1). Once a BCA has been used successfully in one country it has often been redistributed from there to other countries, but each move to another country requires a corresponding new quarantine permit.

More than 170 species of invertebrate natural enemies are produced and sold for augmentative biological control, with about 30 species making up more than 90% of the world market (Cock et al. 2009; Mathre et al. 1999, see Annex 2).

Complete lists of classical biological control programs are found in the publications by de Bach and Schlinger (1964), Clausen (1972; 1978) and others. These provide a historic view of biological control and show how regulations for introductions and releases have changed in time. CABI also maintains an updated electronic list (www.cabi.org) of all biological control projects starting with the printed books by Greathead et al. (for instance 1971). In addition, for most continents or regions, imports, releases, establishments and impacts of classical BCAs have been documented for different targets (for instance Julien and Griffiths 1998; Neuenschwander et al. 2003; Muniappan et al. 2009; Moran et al. 2011; Waterhouse and Sands, 2000). Capinera (2008) provides an easily accessible encyclopedia.

These lists can also serve to canvas the area to see which new pests are arriving and to take appropriate quarantine measures. Overall, preventing a pest organism from entering a country or region is always cheaper than combatting the same pest later through a biological control program, which quite often will only provide partial control. FAO through its FAO Plant Protection Bulletin and the IAPSC through its bulletins provide information about pest incursions and potential control options, including biological control, as a service to national organizations.

Unfortunately, many releases are not well documented and do not get published in an internationally accessible journal. Moreover, establishment, spread and, particularly, the impact of the BCA on the target host, on its target agricultural or silvicultural commodity, on farmers' income and well-being, and on the national budget are often lacking. This deprives biological control of its overall standing and impact as a discipline. This is all the more vexing because the impact of successful projects needs no further input and, with time, the initially severe damage by the targeted invasive pest gets lost in the public memory.

Biological control agents identified in collaboration with CGIAR Centers

Thirty-plus biological control agents have been released or are under investigation by CGIAR Centers (see Annex 3 and Boxes 3-6). These include invertebrates (mainly arthropods), fungi and viruses released in many countries in Africa, Asia and Latin America. No unintended negative effects have been observed with any BCAs released for field application. In one case, a positive side-effect was observed in that an introduced BCA was found to facilitate transmission of MaviMNP, a viral biological control agent used for the control of ***Maruca vitrata*** (Tamó, IITA, pers. comm.).

Summary and Conclusions

Bological control, well executed following internationally agreed guidelines, remains the most cost-effective and promising tool for the sustainable control of pests, particularly invasive aliens. Many biological control introductions have led to beneficial non-target effects through the restoration of previously invaded habitats (van Driesche et al. 2010). Generally, these positive effects remain unappreciated and should be publicized more widely as a way to demonstrate the benefits of biological control. Unsubstantiated negative effects should not become the reason for inaction while the pest continues to spread its own 'non-target' effects, and farmers continue unsustainable use of broad-spectrum pesticides with well known non-target effects of their own.

A vast number of microbial BCAs have been registered (listed in Annex 4). Green Muscle®, the ***Metarhizium***-based mycopesticide against locusts and grasshoppers developed by CABI, IITA and partners in Niger is one example of such an agent successfully adopted in several countries in Africa (see Box 5). For their commercialization, all such products have to fulfill the regulatory requirements. Regulatory procedures for pre-market assessment of pest control products are common in most countries (Kabaluk et al. 2010). An effective regulatory framework protects from harm while facilitating the availability of useful products. It recognizes the needs and interests of farmers, society and the registrants. Predictive and efficient regulatory processes ultimately allow registrants to begin to recover their research, development and registration costs in a timely manner following registration. This is important for industries in this sector, which are mainly small and medium enterprises for whom lengthy registration delays may act as a deterrent to investment in product development.

An effective regulatory system puts in place the following elements:

- A system of data requirements to guide the assessment of human health and safety, value (including efficacy) and environmental safety;
- Clear and predictable procedures for assessing the risk and value of pest control products, with sufficient flexibility to allow expert opinion to contribute to the assessment process;
- Mechanisms which afford opportunities for public and industry input into the decision making process, including the right to appeal decisions;
- Policies which establish reasonable timelines for assessment of various classes of products, and an agency with a good track record with regard to these timelines;
- The flexibility to modify regulatory procedures in line with new scientific information;
- Regulatory fees which are affordable to registrants; and
- Enforcement of legislation and regulations related to product use, sale, distribution and other regulatory requirements (Cuddeford and Kabaluk 2010).

International harmonization of regulatory frameworks with regards to data requirements, fees, timelines, criteria for approval and risk assessment is considered to help in streamlining and accelerating product registration. Major advances in this direction have been made among EU members, the United States, Canada and ACP countries. In many countries registration of BCAs follows the national legislation for synthetic pesticides with some modifications due to the specificity of microbial BCAs. Cuba, China and India have widespread biological control programs in place due to state support to production and appropriate regulatory legislation. In Africa, continental harmonization is loosely achieved by following the principles of FAO for pesticide registration (Cuddeford and Kabaluk 2010).

Recommendations

The present text demonstrates the importance of understanding and following legal regulations for the benefit of biological control, but demonstrates also the problems that arise from over-regulation. Two recent reviews provide a road map for adoption of BCAs (Ravensberg 2011; Ehlers 2011).

As concerns regulatory challenges in biological control within the CGIAR and its clients, the following recommendations are made:

1. Harmonize the regulatory procedures for import, production and release of biological control agents across countries of a region. Otherwise no advances are possible and potentially good products/agents will not find the needed size of market or cross-country public support.
2. Stimulate further research in biological control by reinvigorating the Ethiopian and other tropical sections of IOBC, with special reference to the understanding and respect of the existing legislation. Otherwise the scientific discipline will remain dependent on the good will of developed countries.
3. Include fellowships in biological control implementation at all levels in externally funded projects, which includes transfer of knowledge about the regulatory framework and notification of releases in international journals.
4. Support research in taxonomy, because without better knowledge of the fauna and flora it is sometimes impossible to discuss non-target effects. Otherwise unreasonable demands on non-target research will block further biological control programs.
5. Avoid regulatory problems by using indigenous species for mass-production as inundative biological control agents; but use exotics against exotic invaders – they will be better adapted.
6. Exempt registration of indigenous BCAs (for inundative biological control) as well as growth promoting rhizobacteria, nitrogen fixers, and similar types of beneficial microbial inoculants not known to have any pathogenic effects.
7. Keep regulators abreast of intended introductions and include them in the professional discourse. Otherwise delays can be expected. Remember: a regulator who says “no” takes no risks.
8. Document not only releases but also spread and impact at all levels. Remember, a non-documented impact will not be attributed to biological control, but to better varieties, weather or climate change.
9. Publicize impact of successful biological control and assist in bringing this knowledge to schools, universities and the general public.
10. Register the release of BCAs in the journals BioControl or Crop Protection, similar to the registration of breeder varieties.

Case studies

Box 1. Biological control programs on cassava save farmers millions

Cassava (*Manihot esculenta*; Euphorbiaceae) was introduced from South America to Africa by the Portuguese in the 16th century and today is consumed by more than 200 million people in sub-Saharan Africa. Cassava is a staple food that is rich in calories, highly drought tolerant, thrives in poor soils and is easy to store in the ground. This major source of carbohydrates came under threat from devastating pests, the cassava mealybug (*Phenacoccus manihoti*) and the cassava green mite (*Mononychellus tanajoa*; Acari: Tetranychidae).

In a combined effort involving IITA and partners (CABI, CIAT, national quarantine and research stations), a biological control agent, the parasitoid wasp ***Anagyrus lopezi*** (DeSantis) (Encyrtidae) was identified for the control of the cassava mealybug and introduced. The operation was so successful that throughout sub-Saharan Africa cassava mealybug is now under complete control and no longer poses a threat to cassava production. The program cost about US$ 27 million, while the savings are estimated at US$ 7.9 to 20.2 billion. Savings are so huge because of good control by an agent with good dispersal capacity, active on a staple food over an entire continent.

Working with 25 African countries, several international agencies under the umbrella of the Inter-African Phytosanitary Council (IAPSC) posed special regulatory challenges that were later useful for the development of the first FAO Code of Conduct.

Another biological control program by IITA and partners on cassava green mite has been released and established in 22 African countries and brought benefits worth more than US$ 1.7 billion to Nigeria, Benin, and Ghana alone. *Typhlodromalus aripo* was identified as one of the most efficient enemies against cassava green mite, and the introduction of *T. aripo* reduced pest populations by as much as 90 percent in the dry season when pest populations are usually high; in the wet season, pest attacks are not as severe.

Other benefits of these biological control programs include close South-South and international cooperation and a significant increase in the capacities in biological control and agricultural entomology in SSA; benefits to cassava growing smallholders, who are often unaware of the program or the parasitoid wasp; and increases to food security through improved harvests and to health through reduced pesticide use, both of which come at no cost to the smallholders, who nevertheless receive the full benefits.

Cock et al. 2009; Neuenschwander 2001; Zeddies et al. 2001; Yaninek and Hanna 2003.

Box 2. Thailand taps IITA expertise as cassava mealybug invades country

The Government of Thailand, through its Department of Agriculture based in Chatuchak, Bangkok, has requested the assistance of the IITA to help in the biological control of the cassava mealybug, *Phenacoccus manihoti,* which recently invaded the country and possibly also Laos and Cambodia.

The mealybug has already spread to over 160,000 hectares around the East and Northeastern provinces of Thailand, where cassava is an important export crop mainly for starch production and cattle feed.

To halt the spread of the mealybug, a stock rearing colony of *Anagyrus lopezi,* a natural enemy of the pest, was imported into Thailand from the IITA laboratories in Benin by an IITA Entomologist in September 2009.

The wasps were placed into rearing under quarantine conditions in Bangkok and released in November 2009 after release permits were issued. Further releases were made in January 2010.

In Thailand, the cassava mealybug was not immediately recognized because another closely related mealybug species common on cassava, presumably *Phenacoccus madeirensis*, confused the situation. The identification of the mealybug by a taxonomic authority cleared the path for classical biological control.

It is hoped that IITA's involvement in the mealybug control project in Asia will produce results within a much shorter time span and at much reduced costs than previously in Africa, as experts intend to leverage past experience and techniques that were responsible for the African success story in controlling the cassava mealybug pandemic.

G. Goergen (IITA), pers. comm.

Box 3. Striga research reaches the field

A series of witchweeds (*Striga* spp.) are causing great losses as parasites on crop plants in Africa. *Striga hermonthica*, the worst of them, attacks maize, sorghum and millet. It produces huge numbers of long-lived seeds, building up a substantial seed bank in the soil. Control methods include *Striga*-free planting material, crop rotation with selected non-host cultivars, *Striga*-resistant crop varieties, and where available, planting on suppressive soils. Biological control options include ethylene-producing bacteria, rhizobacteria and fungi, particularly *Fusarium oxysporum* f.sp. *strigae.* This species shows a proven ability and virulence to attack *Striga* in all its growth stages from seed to germination, from seedling to flowering shoot, thus protecting current crop yield and preventing *Striga* seed formation, dispersal and deposition. Reduction of *Striga* emergence by 90% and improvement of crop performance when used in combination with *Striga*-resistant varieties have been shown in experiments in Ghana and Nigeria. Large-scale field validation of economic benefit to crop yield using *Striga* BCAs across different agro-ecological zones is currently under evaluation in Nigeria and Kenya.

Fusairum oxysporum f.sp. *strigae* was tested and proven to be host specific to *Striga* (on 35 non- target plants, crops related to the cereal host, including crops that were known to be highly susceptible to different pathotypes of *Fusarium oxysporum*) and was shown not to produce mycotoxins harmful to human or livestock health.

Challenges that are being overcome to get this technology to farmers include the development of a genetic tool to monitor the distribution, spread and persistence of *Fusarium oxysporum* f.sp. *strigae* and the stimulation of a seed sector to manufacture inoculum and to coat and distribute maize seeds.

Berner et al. 2003; J. Kroschel, (CIP) A. Elzein, (IITA) F. Beed (IITA), pers. comm.

Box 4. Aflasafe: a biological control product for aflatoxin mitigation

Aflatoxins are highly toxic chemical poisons produced mainly by the fungus *Aspergillus flavus* in several food crops, including maize and groundnut. Treatment of fields with indigenous atoxigenic strains of *Aspergillus flavus* that are incapable of producing aflatoxins is a proven and effective aflatoxin control method used on hundreds of thousands of acres in the United States. These applied atoxigenic strains ‘push out’ their toxin cousins so that crops are less contaminated with aflatoxins in a process called ‘competitive exclusion’. IITA in partnership with the United States Department of Agriculture - Agricultural Research Service (USDA-ARS) and the African Agriculture Technology Foundation (AATF) developed the biocontrol product aflasafe™, which uses native atoxigenic strains of *A. flavus*. Field testing of aflasafe™ in Nigeria has produced extremely positive results: aflatoxin contamination of maize and groundnut was consistently reduced by 80-90%. Other countries are now pursuing similar research.

Aflatoxin biocontrol researchers have recognized that registration of aflatoxin biocontrol products with the regulatory authorities in each country can be a significant challenge. Given below are some of the approaches taken by IITA and partners to meet these challenges:

- Three regional biopesticide registration training workshops were conducted in Ethiopia, Kenya and Nigeria since several African countries do not have much experience in biopesticides registration. Procedures followed for registration of two aflatoxin biocontrol products in the United States by the Environmental Protection Agency were used as examples in these workshops. Regulators became familiar with efficacy and risk assessment procedures for the registration of aflatoxin biocontrol products, and also gained an understanding of the technology.
- Regulatory agencies and key senior policymakers were consulted and sensitized before initiation of biocontrol research in each country. It was emphasized that aflatoxin biocontrol is in the national interest of public health. These agencies were considered as partners in R&D. They were kept informed of key R&D steps and their advice was incorporated into the research process. These steps enabled building of trust.
- Regulators were made to understand that native atoxigenic strains are already present in the target areas, negating added risks of exposure.
- Research in each country was conducted in partnership with national program staff, encouraging a sense of ownership and championing by the national system, including the regulatory agencies.
- Efforts are currently underway to develop regional aflatoxin biocontrol products that contain atoxigenic strains that co-occur in all countries in a region. National biopesticide regulators are currently discussing procedures for regional harmonization of biopesticide registration protocols for expanded use of biocontrol products in a region.

R. Bandyopadhyay (IITA), pers. comm.; Probst et al. 2011.

Box 5. Green Muscle®, a registered biopesticide against locusts and grasshoppers recommended and used by FAO

Beginning in 1989, efforts were undertaken to develop a biopesticide based on the fungus *Metarhizium anisopliae* var. *acridae* to replace environmentally disastrous insecticide treatments against locusts as they had been applied during the largest known swarming of locusts in the 20th century in 1987 to 1989. Starting with basic research at CABI and following up with field research by IITA and national partners, particularly in Niger, the biopesticide Green Muscle® was developed, registered and approved by FAO in 1997. It has been commercialized since 2000 by Biological Control Products, Durban, South Africa.

The main problems during this development phase concerned the fact that locusts erupt only every 20 or so years. Thus the powdery product had to be storable for at least a matter of years. A patented oil based formulation that attached to the epidermis of locusts with the best performing strain, one from Niger, was shepherded through the international registration procedure using criteria that had been developed for chemical insecticides. It was field-tested in northern Benin, Niger, Mali and Senegal on Shelia grasshoppers and desert locust. As compared to chemical insecticides, mortality was slow – which had to be explained and accepted by farmers and extension agents – but lethal action lasted much longer, with some infections carrying over into the next year.

After the externally funded LUBILOSA (Biological control of locusts and grasshoppers) project ended in 2002, production of Green Muscle® continued in Senegal under a project that concluded in 2012. Today, only Becker Underwood (www.beckerunderwood.com) in South Africa still produces this product.

The development and commercialization of this product opened up new avenues for the CGIAR and were studied in some detail. A licensing agreement was prepared, with income accumulating at CABI for the declared benefit of future research and training in entomopathology. Today the product tops FAO's list of products to be used against new locust eruptions.

Lomer et al. 2001; Douthwaite et al. 1999; Wikipedia (en.wikipedia.org/wiki/LUBILOSA)

Box 6. Boosting natural defense system using *Fusarium oxysporum* V5w2 in East Africa

Fusarium oxysporum is a cosmopolitan soil fungus and is the most common naturally occurring endophyte in banana (*Musa* spp.) plants in East Africa. Banana in East Africa is plagued by a variety of soil borne pests and diseases, especially the burrowing nematode *Radopholus similis* (in Uganda), the root lesion nematode *Pratylenchus goodeyi* (in Kenya) and the banana weevil *Cosmopolites sordidus*.

Banana is traditionally propagated by means of field-obtained suckers or side-shoots, which are often contaminated with soil-borne diseases and pests. With the exception of fastidious bacteria and viruses, normally eliminated at the stock nurseries, tissue cultured (TC) plants provide a source of pest- and disease-free planting material. However, as a consequence of their aseptic and sterile production, TC plants are devoid of the beneficial microorganisms present in suckers and have untested defense mechanisms, though they are regularly planted into fields with high pest and disease burdens and abiotic constraints. Reintroducing such beneficial endophytes during the TC production process to provide an element of the plant's natural defense system has proved viable and beneficial.

Research has been carried out since 1995 at IITA, in collaboration with University of Bonn, University of Pretoria, Makerere University, Jomo Kenyatta University of Agriculture and Technology and University of Stellenbosch. Experimental on-farm trials have been conducted in Uganda with farmers. *F. oxysporum* V5w2 is being registered as a commercial biological control agent in Kenya, under the leadership of Jomo Kenyatta University of Agriculture and Technology and in cooperation with IITA.

Depending on field conditions and the endophyte strain inoculated, enhanced TC banana plants have outperformed nematicides, reducing root damage and decreasing populations of *R. similis* and *P. goodeyi* by 20-50%. Currently, the economic effects of endophyte-enhanced TC banana plants in smallholder farms are being investigated in Uganda, and preliminary results indicate that sometimes yields and revenues are greater than those from TC plants without enhancement.

Commercialization of the product is currently sought. Following registration, the Real IPM Company will be licensed to mass-produce the product for use in banana seed systems to control nematodes and weevils. In Uganda, endophyte technology has been embedded directly into commercial tissue culture companies, such as Agro-Genetic Technologies. In Central America, Bioversity International (formerly INIBAP), in cooperation with Fresh Del Monte Produce Inc., has carried out successful field trials testing the effectiveness of locally isolated banana endophytes to control nematodes in commercial plantations.

The risks associated with this biological control product are minimal: Firstly, *F. oxysporum* V5w2 is an endogenous strain and extensive technical studies have demonstrated that it is non-pathogenic. Nevertheless, apprehensions exist, particularly among non-experts who erroneously label all strains of the *F. oxysporum* group as pathogens.

T. Dubois (IITA), pers. comm.

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Annex 1. The most used biological control agents (BCAs) for classical biological control

BCA	Classification (insects except as indicated)	Origin	Target(s)	Number of countries where BCA was released
Ageniaspis citricola	Encyrtidae	SE Asia	Citrus leaf miner, *Phyllocnistis citrella*	23
Aphytis lingnanensis	Aphelinidae	SE Asia	Red scale, *Aonidiella aurantii*	23
Aphelinus mali	Aphelinidae	North America	Woolly apple aphid, *Eriosoma lanigera*	37
Apoanagyrus lopezi	Encyrtidae	Brazil, Paraguay, Bolivia	Cassava mealybug, *Phenacoccus manihoti* (see Box 1)	23 (natural spread observed in 3 other African countries)
Cotesia plutellae	Braconidae	Europe	Diamondback moth, *Plutella xylostella*	29
Cotesia flavipes	Braconidae	South Asia	Sugarcane stem borers (Crambidae)	38
Cryptolaemus montrouzieri	Coccinellidae	Australia	Mealybugs	58
Diachasmimorpha longicaudata	Braconidae	SE Asia	Fruit flies	49
Encarsia perniciosi	Aphelinidae	East Asia	San José scale, *Quadraspidiotus perniciosus*	29
Euglandina rosea[1]	Mollusca	USA	Other snails	35
Lixophaga diatraeae	Tachinidae	Caribbean	Sugarcane stem borers (Crambidae)	35
Neochetina bruchi	Curculionidae	Neotropical	Water hyacinth, *Eichhornia crassipes*	28
Neochetina eichhorniae	Curculionidae	Neotropical	Water hyacinth, *Eichhornia crassipes*	35
Lydella minense	Tachinidae	Brazil	Sugarcane stem borers, mainly *Diatraea* spp.	27
Paratheresia claripalpis	Tachinidae	Neotropical	Sugarcane stem borers, mainly *Diatraea* spp.	26
Rhinocyllus conicus	Curculionidae	Europe	Thistles, especially nodding thistle, *Carduus nutans* group	26
Rodolia cardinalis	Coccinellidae	Australia	*Icerya purchasi*	56
Teleonemia scrupulosa	Tingidae	Neotropical	Lantana weed, *Lantana camara*	39
Trissolcus basalis	Scelionidae	Widespread	Green stink bug, *Nezara viridula*	24
Typhlodromalus aripo	Phytoseiidae	Brazil	Cassava green mite, *Mononychellus tanajoa* (see Box 1)	22
Uroplata girardi	Chrysomelidae	Neotropical	Lantana weed, *Lantana camara*	31

[1]Withdrawn as a biocontrol agent due to non-target effect.
(Source: Cook et al. 2009)

Annex 2. The most important biological control agents (BCAs) used in augmentative biological control

BCA	Family (insects except as indicated)	Source area	Target (s)	Number of countries where used	Year of first use
Encarsia formosa	Aphelinidae	Central America	whiteflies	20	1926
Phytoseiulus persimilis	Phytoseiidae	Chile	mites	20	1968
Trichogramma evanescens	Trichogrammatidae	Europe	Lepidoptera	11	1975
Dacnusa sibirica	Braconidae	Europe	leafminers	20	1981
Neoseiulus barkeri (= *Amblyseius barkeri*)	Phytoseiidae	Europe	thrips	3	1981
Diglyphus isaea	Eulophidae	Europe	leafminers	20	1984
Heterorhabditis bacteriophora	Heterorhabditidae[1]	Europe	Coleoptera	14	1984
Leptomastix dactylopii	Encyrtidae	South America	mealybugs	15	1984
Steinernema carpocapsae	Steinernematidae[1]	Europe	Lepidoptera	9	1984
Steinernema feltiae	Steinernematidae[1]	Europe	Sciaridae	18	1984
Neoseiulus californicus (= *Amblyseius alifornicus*)	Phytoseiidae	Central America	mites, thrips	14	1985
Neoseiulus cucumeris (= *Amblyseius cucumeris*)	Phytoseiidae	Europe	thrips	20	1985
Chrysoperla carnea (= *Chrysopa carnea*)	Chrysopidae	Europe	aphids, whiteflies etc.	10	1987
Aphidoletes aphidimyza	Cecidomyiidae	Europe	aphids	20	1989
Cryptolaemus montrouzieri	Coccinellidae	Australia	mealybugs, scales	16	1989
Aphidius matricariae	Braconidae	Europe	aphids	3	1990
Episyrphus balteatus	Syrphidae	Europe	aphids	11	1990
Feltiella acarisuga (=*Therodiplosis persicae*)	Cecidomyiidae	Europe	mites	15	1990
Heterorhabditis megidis	Heterorhabditidae[1]	Europe	Coleoptera	14	1990
Aphidius colemani	Braconidae	Middle East	aphids	20	1991
Aphelinus abdominalis	Aphelinidae	Europe	aphids	14	1992
Delphastus catalinae (= *pusillus*)	Coccinellidae	America	whiteflies	3	1993
Iphiseius degenerans (= *Amblyseius degenerans*)	Phytoseiidae	Europe, Mediterranean	thrips	4	1993
Orius laevigatus	Anthocoridae	Europe	thrips	17	1993
Orius majusculus	Anthocoridae	Europe	thrips	3	1993
Macrolophus pygmaeus (= *nubilis*)	Miridae	Europe	whiteflies	20	1994
Eretmocerus eremicus	Aphelinidae	North America	whiteflies	13	1995
Stratiolaelaps miles (= *Hypoaspis miles*)	Laelapidae	Europe	Sciaridae	15	1995
Aphidius ervi	Braconidae	Europe	aphids	17	1996
Galeolaelaps aculeifer (= *Hypoaspis aculifer*)	Laelapidae	Europe	Sciaridae	16	1996
Neoseiulus fallacis (= *Amblyseius fallacis*)	Phytoseiidae	North America	mites	1	1997
Eretmocerus mundus	Aphelinidae	Europe	whiteflies	13	2001
Nesidiocoris tenuis	Miridae	Europe	whiteflies	3	2003
Amblyseius swirskii	Phytoseiidae	Israel	whiteflies, thrips, mites	20	2005

[1]Entomopathogenic nematode
(Source: Cook et al. 2009)

Annex 3. Biological control projects by CGIAR Centers

Biocontrol agent	Target	Country of origin	Country of release	Year of release	Current Status	Impact achieved	Unexpected effects on target, nontarget and environment
A. Large-scale biological control projects by CGIAR Centers							
Anagyrus lopezi Formerly: *Epidinocarsis, Apoanagyrus* Plus some exotic coccinellids, which established locally, but had no impact	Cassava mealybug, *Phenacoccus manihoti* (see Boxes 1 and 2)	Paraguay, Brazil	25 countries in Africa, plus recently Thailand Project led by IITA; releases by IITA in collaboration with national programs (see Boxes 1 and 2)	Over 150 releases between 1983 and 1995 in Africa 2010 in Asia	150 releases in Africa and spread at over 100 km per year, established in all cases	Quantitative impact assessment on mealy-bug, plant growth, yield and the economy undertaken Reduction of mealybug populations 10-fold, to below economically significant levels, except in 5% of fields, all with sandy, unmulched soils, where only better farming brings relief	No non-target effects because *Phenacoccus manihoti* only attacks *Manihot* (2 spp. in Africa); *A. lopezi* only known from this host. A few cases of erroneous parasitism by other, indigenous *Anagyrus* spp. observed. Initial heavy attack by polyphagous indigenous hyperparasitoids is reduced as soon as biological control takes effect (within 2-4 years). Then hypers and indigenous coccinellids mostly disappear because of host density dependence effects.
Ceranisus femoratus	Bean flower thrips larvae, *Megalurothrips sjostedti*	Cameroon	Bénin, Ghana, Nigeria By IITA in collaboration with national programs	2001–2003	Agent established in Southern and Central Bénin and Ghana and on the Ibadan campus (no follow up surveys yet in South Western Nigeria)	In Bénin ecological impact on thrips populations measured on wild host plants; on average 43% reduction of larval population	None noted so far
Cyrtobagous salviniae	Water fern, *Salvinia molesta*	Originally South America; received from South Africa, directly sent to the Congo, as Benin does not harbor this pest	Congo (by IITA), Ghana, Côte d'Ivoire, Senegal, Mauritania (by RSA institutes) Old Project led by USDA in Florida; world-wide collaboration	Between 1999 and 2001 (by IITA) Releases out of local rearing stations	Established in all sites and dispersed along the rivers	Surveys and qualitative impact assessment undertaken Reduction of water fern populations often to local extinction levels in less than 2 years; overall to below economically significant levels	No non-target effects because of total specificity of the predator under natural conditions
Encarsia guadeloupae and *Encarsia dispersa (?haitiensis)*	Spiralling whitefly, *Aleurodicus dispersus*	The Pacific Islands	Bénin, spread to many other countries Project in Africa by IITA	Spontaneous establishment observed in 1993 just before parasitoids were ordered from the Pacific	Established along the coast, then spread to the north (525 km)	Quantitative impact assessment undertaken Reduction of whitefly populations within a few years, overall to below economically significant levels	No non-target effects because of total specificity of both parasitoids (though not tested)

Annex 3. Contd

Biocontrol agent	Target	Country of origin	Country of release	Year of release	Current Status	Impact achieved	Unexpected effects on target, nontarget and environment
Gyranusoidea tebygi and *Anagyrus mangicola*	Mango mealybug, *Rastrococcus invadens*	India	15 countries in Africa, Thailand In Africa first in Togo with GTZ, then across the continent by IITA in collaboration with national programs	1987 to about 1990	*G. tebygi* 48 and *A. mangicola* 57 released in West and Central Africa, established in all cases	Quantitative impact assessment on mealybug, plant growth, yield and the economy undertaken Reduction of mealybug populations sometimes to local extinction, overall to below economically significant levels	No non-target effects because both parasitoids are only known from mango mealybug Initial heavy attack by polyphagous indigenous hyperparasitoids is reduced as soon as biological control takes effect (within 1 year). Then hypers and indigenous coccinellids mostly disappear because of density dependent population effects.
Metarhizium anisopliae var. *acri*dae	Desert locust, *Schistocerca gregaria* Senegalese grasshopper, *Oedaleus senegalensis* Brown locust, *Locustana pardalina* Variegated grasshopper, *Zonocerus variegatus*	Niger strain used to develop Green Muscle®	Niger, Mali, Senegal, Benin, Zambia, South Africa, and others Project by CABI, IITA and national programs	Test releases since about 1990, then ever larger field trials	In use as a registered mycopesticide, Green Muscle®, which is approved and recommended by FAO Commercialization outside funded projects remains a problem and at present there exists only one producer, in South Africa	In huge plots at 50 g/ha, 80-90% mortality within 2-3 weeks; some carry-over to next season possible	For its commercial registration Green Muscle® had to be tested by external agencies for its lethal action on humans, mammals, fishes and other wildlife according to international norms usually applied to chemical insecticides; all tests were passed
Neochetina eichhorniae and *Neochetina bruchi* In addition a moth was released, but did not establish	Water hyacinth, *Eichhornia crassipes*	Originally South America; received from CSIRO, Australia	Bénin, Nigeria, Congo, Ghana, Côte d'Ivoire, Tanzania, Uganda by IITA in collaboration with national programs (Senegal, Ghana, East Africa also by institutes from RSA) Old Project led by USDA in Florida; world-wide collaboration	Between 1991 and 1995, and again in 2010	Both established in most sites, but *N. eichhornia* is dominant in West Africa in the lowlands, and *N. bruchi* in the Victoria Basin and East Africa	Quantitative impact assessment undertaken Reduction of water hyacinth populations within 8 years in West Africa and 4-5 years in East Africa, overall to below economically significant levels, except in highly eutrophic or brackish waters and where winters are cool	No non-target effects because of total specificity of both predators under natural conditions
Neohydronomus affinis	Water lettuce, *Pistia stratiotes*	Originally South America; received from South Africa	Bénin, Nigeria, Congo, Ghana, Côte d'Ivoire, Burkina-Faso, Senegal by IITA, national programs and RSA institutes Old Project led by USDA in Florida; world-wide collaboration	Between 1994 and 1998 Releases out of local rearing stations	Established in all sites with dispersal of up to 150 km in <2 years	Quantitative impact assessment undertaken Reduction of water lettuce populations often to local extinction levels in less than 3 years; overall to below economically significant levels	No non-target effects because of total specificity of the predator under natural conditions
Nuclear Polyhedrosis Viruses (NPVs)	Cotton bollworm, *Helicoverpa armigera* Tobacco caterpillar/ Cotton leafworm/ Tobacco cutworm, *Spodoptera litura*	India	By ICRISAT in India		In use	Proven impact A critical option in Indian IPM programs	None

Annex 3. Contd

Biocontrol agent	Target	Country of origin	Country of release	Year of release	Current Status	Impact achieved	Unexpected effects on target, nontarget and environment
Teretrius nigrescens	Larger grain borer, *Prostephanus truncatus*	Central America	Togo, Ghana, Kenya, Tanzania, Guinea-Conakry, Zambia, Malawi by GTZ and national programs Benin by IITA	1992	Agent established in all release countries	Impact assessment best in Benin by means of pheromone traps Impact as a BCA is discussed controversially and the importance of reservoir outside grain stores is unclear despite >10 years of intensive studies by many institutes	Preys also on other storage pests, but specificity given by the diameter of frass tunnels in maize kernels caused by prey larvae
Typhlodromalus aripo Several more phytoseiid species were released, some established, but with no great dispersal or impact	Cassava green mite, *Mononychellus tanajoa* (see Box 1)	North-Eastern Brazil	22 countries in Africa Project led by IITA; releases by IITA and national programs	1993 in Benin	Established in all release sites except in the cool highlands of Zambia	Yield loss reduction by 40-50%, less so in dry conditions	No non-target effects because of niche segregation: *T. aripo* is found in the shoot tips while the indigenous predatory mites occupy the lower leaves
B. Biological Control agents under investigation by the CGIAR Centers							
Aflasafe (a mixture of four atoxigenic L-strains of *Aspergillus flavus* native to Nigeria)	All strains of *A. flavus* that contaminate maize grains and groundnut kernels to produce aflatoxin on crop products (see Box 4)	Nigeria	Nigeria, in collaboration with USDA and National program; testing, development and commercialisation by IITA	2009-2012	Currently used under Experimental Use Permit (conditional registration) on more than 1,000 ha Construction of demonstration-scale manufacturing plant (capacity 5 tons per hour) underway at the IITA campus in Ibadan, Nigeria Funds in place from AgResults initiative of G-20 to upscale technology to 200,000 ha in four years beginning 2013 Commercialization model for distribution and adoption under field testing	Aflatoxin reduced in maize grains by up to 90% at harvest and up to 99% during storage Aflatoxin reduced in groundnut kernels by up to 98% at harvest and up to 99% during storage	None
Aflasafe SN01 (a mixture of four atoxigenic L-strains of *Aspergillus flavus* native to Senegal)	All strains of *A. flavus* that contaminate groundnut kernels to produce aflatoxin on crop products	Senegal	Senegal, Nigeria, in collaboration with USDA and national program; testing, development and commercialisation by IITA	2010-2012	In use for efficacy testing purposes; area-wide application in two villages in Senegal	Aflatoxin reduced in groundnut kernels by up to 90% at harvest and up to 98% during storage	None
Aflasafe BF01 (a mixture of four atoxigenic L-strains of *Aspergillus flavus* native to Burkina Faso)	All strains of *A. flavus* that contaminate maize grains and groundnut kernels to produce aflatoxin on crop products	Burkina Faso	Burkina Faso, in collaboration with USDA and national program; testing, development and commercialisation by IITA	2012	In use for efficacy testing purposes	Test results in groundnut not available; data analysis in progress	None
Aflasafe KE01 (a mixture of four atoxigenic L-strains of *Aspergillus flavus* native to Kenya)	All strains *of* *A. flavus* that contaminate maize grains to produce aflatoxin on crop products	Kenya	Kenya, in collaboration with USDA and national program; testing, development and commercialisation by IITA	2012	In use for efficacy testing purposes	Test results in maize not available; data analysis in progress	None

Annex 3. Contd

Biocontrol agent	Target	Country of origin	Country of release	Year of release	Current Status	Impact achieved	Unexpected effects on target, nontarget and environment
Alternaria eichhorniae	Water hyacinth, *Eichhornia crassipes*	Benin (and other African countries)	Benin (and other African countries); first tests in Africa with IITA	2002	Undergoing field testing towards registration in collaboration with regulatory authorities	Under evaluation	Synergy with weevils determined and no mycotoxins shown to be produced
Apanteles taragamae	Larval parasitoid of the Legume pod borer, *Maruca vitrata*	Taiwan, from AVRDC	Bénin, Ghana, Nigeria, limited experimental releases only; by IITA in collaboration with national programs	2008	No direct evidence of establishment; indirect evidence through the finding of MaviMNPV infected larvae around experimental release sites	None so far	**Positive unintended effect:** the female wasp *A. taragamae* can effectively transmit the entomopathogenic MaviMNP to *M. vitrata* larvae through host probing and oviposition
Apanteles subandinus	Potato tuber moth, *Phthorimaea operculella*	Peru	Nepal, by CIP in collaboration with national programs	2010	Rrecovered, but no proof of establishment yet	Not yet	Not expected
Chrysocharis flacilla	Potato/pea leafminer fly, *Liriomyza huidobrensis* Vegetable laefminer fly *L. sativae* Serpentine laefminer fly *L. trifolii*	Peru	Kenya, by *icipe* in collaboration with CIP and national programs	Not yet	Development/ quarantine; to be released in 2013	–	No information
Copidosoma koehleri	Potato tuber moth, *Phthorimaea operculella*	Peru	Nepal, by CIP in collaboration with national programs	2009	Recovered, but no proof of establishment yet	Not yet	Not expected
Entomo-pathogenic virus *Maruca vitrata* Multiple Nucleopolyhedro-virus MaviMNPV	Legume pod borer, *Maruca vitrata*		Limited field testing in Bénin, Burkina Faso, Ghana, Niger and Nigeria, by IITA in collaboration with national programs	2009–2010	In Bénin rare occurrence of MaviMNPV infected *M. vitrata* larvae near experimental release sites of *A. taragamae* previous to field testing; systematic surveys planned for 2011	Under experimental field conditions up to 36% reduction of *M. vitrata* larval population in cowpea fields	**Positive unintended effect:** Interactions with the parasitoid *A. taragamae* (see above)
Fusarium oxysporum	Banana weevil, *Cosmopolites sordidus* Banana nematodes (see Box 6)	Uganda	Scientific testing: Burundi, Costa Rica, Kenya, Uganda Testing in world-wide collaboration. In Uganda by IITA.	Pandemic taxon Burundi: 2008 (on-station field trial) Kenya: 2006 (lab, screenhouse and field trials)	Pandemic taxon; not used in classical biological control Established Registration (eco-tox dossier + registration field trial) in progress with Kenyan authorities (PCBP); registration in Burundi and Uganda not applicable as no guidelines exist, although recent guidelines have been established for Uganda for which we now need to apply	Depending on pest status and management practices, 50-20% reduction of nematode populations (*Radopholus similis*) and damage; 0-20% increase in yield	Pandemic taxon; not used in classical biological control None

Annex 3. Contd

Biocontrol agent	Target	Country of origin	Country of release	Year of release	Current Status	Impact achieved	Unexpected effects on target, nontarget and environment
Fusarium oxysporum f. sp. *strigae*	Witchweeds, *Striga hermonthica* (see Box 3)	Ghana / Nigeria	Nigeria and Kenya; world-wide collaboration, releases with national programs	2012	Undergoing field validation towards registration in collaboration with regulatory authorities	Under large-scale evaluation in Nigeria	Proven to not produce mycotoxins harmful to human or livestock health; host specific to *Striga* Genetic characterization has proven its unique DNA constitution is different from other forms of *F. oxysporum* deposited in GenBank, known to cause disease on crops, a fact that enabled its classification as a new *forma specialis* (f.sp. *strigae*)
Halticoptera arduine	Potato/pea leafminer fly, *Liriomyza huidobrensis* Vegetable laefminer fly *L. sativae* Serpentine laefminer fly *L. trifolii*	Peru	Kenya, by CIP in collaboration with national program	2012	Recovery surveys ongong. Establsihment confirmed from most of the release sites.	Not yet	No information
Orgilus lepidus	Potato tuber moth, *Phthorimaea operculella*	South America	Nepal, by CIP in collaboration with national programs	2010	Recovered, but no proof of establishement yet	Not yet	Not expected
Phaedrotoma scabriventris	Potato/pea leafminer fly, *Liriomyza huidobrensis* Vegetable laefminer fly *L. sativae* Serpentine laefminer fly *L. trifolii*	Peru	Kenya, by *icipe* in collaboration with national program	2010 and 2011	Establsihed in pilot sites in high, mid nad low altitudes on Keya	Higher parasitism rates and abundance obtained in low altitudes. In mid and high alritutes abundance and parasitrism rates are so far low.	None

Annex 4. Microbial pesticides registered in selected countries

Type	Taxus	Products	Targets	Country
A. Bactericides				
Agrobacterium radiobacter	Bacterium	Crown Gall Inoculant	Crown gall	South Africa
Aureobasidium pullulans	Bacterium	Blossom Protect	Fire blight, postharvest diseases in apples	EU
Agrobacterium radiobacter K84	Bacterium	Dygall	Crown gall (*Agrobacterium tumefaciens*)	Canada
Agrobacterium radiobacter K84	Bacterium	Galltroll - A	Crown gall disease	US
Pantoea agglomerans C9-1	Bacterium	BlightBan C9-1	Fire blight	Canada
Pantoea agglomerans C9-1	Bacterium	BlightBan C9-1	Fire blight	US
Pseudomonas fluorescens A506	Bacterium	BlightBan A506	Fire blight, fruit russeting	Canada
Pantoea agglomerans E325	Bacterium	Bloomtime	Fire blight	
Bacteriophage of *Pseudomonas syringae* pv. tomato	Virus	AgriPhage	Bacterial speck	US
Bacteriophage of *Xanthomonas campestris* pv. *vesicatoria*	Virus	AgriPhage	Bacterial spot	US
B. Fungicides				
Bacillus subtilis 101	Bacterium	Shelter	Root and leaf diseases	South Africa
Bacillus subtilis 102	Bacterium	Artemis	Root and leaf diseases	South Africa
Bacillus subtilis 246	Bacterium	Avogreen	Root and leaf diseases	South Africa
Bacillus subtilis QST 713	Bacterium	Serenade	*Botrytis* spp.	South Africa
Bacillus subtilis MBI 600	Bacterium	HiStick N/T Subtilex Integral	*Aspergillus*, *Fusarium*, *Rhizoctonia*, *Pythium*	Canada
Bacillus subtilis MBI 600	Bacterium	Histick N/T Pro-Mix with Biofungicide	Damping off	US
Bacillus lichenformis SB3086	Bacterium	EcoGuard	Fungal diseases	US
Bacillus mycoides isolate J	Bacterium	BacJ	*Cercospora*	US
Bacillus pumilus GB 34	Bacterium	GB34	Seedling diseases- *Pythium* and *Rhizoctonia*	US
Bacillus pumilus QST 2808	Bacterium	Sonata Ballad Plus	Powdery mildew, downy mildew and rusts	US
Bacillus subtilis GB03	Bacterium	Companion Kodiak	*Fusarium*, *Pythium*, *Rhizoctonia*	US
Bacillus subtilis subsp. *amyloliquefaciens* FZB24	Bacterium	Taegro	*Fusarium* and *Rhizoctonia* wilt diseases	US
Pseudomonas fluorescens	Bacterium	ABTEC Pseudo Biomonas Esvin Pseudo Sudo Phalada 104PF Sun Agro Monus Bio-cure-B	Plant soil borne diseases	India
Pseudomonas aureofaciens Tx-1	Bacterium	Spot-Less	Turf fungal diseases	US
Pseudomonas chlororaphis 63-28	Bacterium	At-Eze	Soil and seed borne fungi	US
Pseudomonas syringae ESC 11	Bacterium	Bio-Save 11LP	Post harvest diseases	US
Phlebiopsis gigantea (several strains)	Bacterium	Rotstop	Conifer root rots	EU
Pseudomonas chlororaphis	Bacterium	Cedomon Cerall	*Pyrenophora teres, Pyrenophora graminea, Tilletia caries, Septoria nodorum, Fusarium* spp.	EU
Pseudomonas sp. DSMZ 13134	Bacterium	Proradix	Root rots	EU
Pseudomonas syringae ESC-10	Bacterium	Bio-Save 10 LP	Blue mold (*Penicillium expansum*), blue mold fruit rot (*Penicillium italicum*), dry rot (*Fusarium sambucinum*), green mold fruit rot (*Penicillium digitatum*), grey mold fruit rot (*Botrytis cinerea*), mucor fruit rot (*Mucor* spp.), silver scurf (*Helminthosporium solani*), sour rot (*Geotrichum candidum*)	Canada
Pseudomonas syringae ESC 10	Bacterium	Biosave 10LP	Post harvest diseases	US
Streptomyces griseoviridis K61	Bacterium	Mycostop	*Fusarium* wilt, *Botrytis* grey mold, root rot, stem rot, stemend rot, damping off, seed rot, soil borne damping off, crown rot, *Rhizoctonia*, *Phytophthora*, wilt, seed damping off, early root rot	EU
Streptomyces griseoviridis K61	Bacterium	Mycostop	*Botrytis* grey mold (*Botrytis cinerea*), crown rot, damping off, early root rot, *Fusarium* wilt, *Phytophthora*, *Rhizoctonia*, root rot (*Fusarium*, *Phytophthora*, *Pythium*), seed damping off, seed rot (*Fusarium*, *Alternaria*, *Phomopsis*), soil borne damping off, stem rot (*Fusarium*), stem-end rot (*Phomopsis*), wilt	Canada

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Streptomyces lydicus WYEC108	Bacterium	Actinovate	*Alternaria*, anthracnose, *Botrytis*, downy mildew, *Erwinia,* greasy spot, *Monilinia*, powdery mildew, *Sclerotinia*, soilborne plant diseases (*Pythium*, *Rhizoctonia*, *Phytophthora*, *Verticillium*, *Fusarium*), cotton root rot (*Phytomatotricum omnivorum*), *Aphanomyces*, *Monosporascus*, *Armillaria*, *Sclerotinia*, *Postia*, *Geotrichum*	Canada
Streptomyces griseoviridis K61	Bacterium	Mycostop Biofungicide Mycostop Mix	Fungi causing damping off, stem and crown rots	US
Streptomyces lydicus WYEC 108	Bacterium	Actinovate Actino-Iron	Fungi causing damping off, stem and crown rots	US
Ampelomyces quisqualis AQ10	Fungus	Bio-Dewcon	Powdery mildew	South Africa
Ampelomyces quisqualis	Fungus	Bio-Dewcon	Powdery mildew	India
Ampelomyces quisqualis AQ10	Fungus	AQ10	Leaf diseases	EU
Ampelomyces quisqualis M10	Fungus	PowderyGon	Powdery mildew	US
Aspergillus flavus AF36	Fungus	Aspergillus flavus AF36	*Aspergillus flavus* producing aflatoxin	US
Aspergillus flavus NRRL 21882	Fungus	Afla-guard	*Aspergillus flavus* producing aflatoxin	US
Candida oleophila strain O	Fungus	–	Post harvest diseases	EU
Coniothyrium minitans C ON/M-91-05	Fungus	Contans WG	*Sclerotinia sclerotiorum, Sclerotinia minor*	EU
Coniothyrium minitans CON/M-91-05	Fungus	Contans	*Sclerotinia sclerotiorum*, *Sclerotinia minor*, *Sclerotinia trifoliorum*	Canada
Coniothyrium minitans CON/M/91-08	Fungus	Contans	*Sclerotinia minor*, *Sclerotinia sclerotiorum*	US
Gliocladium catenulatum J1446	Fungus	Prestop	Seed borne and soil borne diseases	US
Gliocladium catenulatum J1446	Fungus	Prestop Prestop Mix	Damping off, gummy stem blight, grey mold, root rot, stem rot, wilt, storage diseases, foliar diseases, seed rot	EU
Gliocladium catenulatum J1446	Fungus	Prestop	Damping off (*Pythium*, *Rhizoctonia*), foliar diseases (*Botrytis*, *Didymella*, *Rhizoctonia*, *Pythium*, *Phytophthora*, *Fusarium*, *Verticillium*, *Alternaria*, *Cladosporium*, *Helminthosporium*, *Penicillium*, *Plicaria*), gummy stem blight (*Didymella*), grey mold (*Botrytis*), root rot, seed rot, stem rot, storage diseases (*Helminthosporium*, *Rhizoctonia*), wilt (*Alternaria*, *Cladosporium*, *Fusarium*, *Penicillium*, *Phytophthora*, *Plicaria*, *Pythium*, *Rhizoctonia*, *Verticillium*)	Canada
Muscodor albus QST 20799	Fungus	Arabesque	Post harvest diseases	US
Ophiostoma piliferum D97	Fungus	Sylvanex	Anti sap-stain of timber products	Canada
Pseudozyma flocculosa PF-A22 UL	Fungus	Sporodex	Powdery mildew	US
Pseudozyma flocculosa PF-A22 UL	Fungus	Sporodex	Powdery mildew	EU
Pythium oligandrum	Fungus	Polyversum	Root rots	EU
Trichoderma sp. A-55 (strain for tobacco) (INISAV)	Fungus	Trichosav-55 (use permit only)	Soil borne diseases (*Rhizoctonia solani, Phytium aphidermatum, Phytophthora parasitica, P. capsici, Sclerotium rolfsii, Fusarium* spp.)	Cuba
Trichoderma asperellum	Fungus	Trichotech	Soil fungal diseases	Kenya
Trichoderma aspellerum (ICC012) (T25) (TV1) (formerly *T. harzianum*)	Fungus	Tenet	Fungal infections (*Pythium, Phytophthera, Botrytis, Rhizoctonia*)	EU
Trichoderma asperellum (T34)	Fungus	–	*Fusarium* spp.	EU
Trichoderma asperellum ICC 012 and *Trichoderma harzianum* (*gamsii*) ATCC080	Fungus	Tenet Bioten Remedier	Soil borne diseases	US
Trichoderma atroviridae IMI 206040 (formerly *T. harzianum)*	Fungus	Binab T Pellets	*Botrytis cinerea,* pruning wound infection, *Chondrostereum purpureum*	EU
Trichoderma atroviride I-1237	Fungus	Esquive	Fungal infections (*Pythium, Phytophthera, Botrytis, Rhizoctonia*)	EU
Trichoderma gamsii (formerly *T. viride*) (ICC080)	Fungus	Remedier	Fungal infections (*Pythium, Phytophthera, Botrytis, Rhizoctonia*)	EU
Trichoderma harzianum	Fungus	Eco-77 Eco-T Promot Romulus Rootgard Trichoplus	Root diseases	South Africa
Trichoderma harzianum	Fungus	Trichodermil SC 1306	*Rhizoctonia solani, Fusarium* spp.*, Sclerotinia* spp.*, Pythium* spp.*, Botrytis cinerea, Phytophtora infestans*	Brazil
Trichoderma harzianum 39	Fungus	Trichodex	Root diseases	South Africa
Trichoderma harzianum DB103	Fungus	T-Gro	Root diseases	South Africa
Trichoderma harzianum Root	Fungus	Eco-T Rootgard Promot (temporary registration)	Fungal diseases	Kenya

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Trichoderma harzianum	Fungus	Biozim Phalada 105 Sun Agro Derma H	Soil borne pathogens	India
Trichoderma harzianum A-34 (strain for vegetables and ornamentals) (INISAV)	Fungus	Trichosav-34 (use permit only)	Soil borne diseases (*Rhizoctonia solani, Phytium aphidermatum, Phytophthora parasitica, P. capsici, Sclerotium rolfsii, Fusarium* spp.)	Cuba
Trichoderma harzianum Rifai T-22 (KRL-AG2)	Fungus	RootShield Rootshield Drench	*Cylindrocladium*, *Fusarium*, *Pythium*, *Rhizoctonia*, *Thielaviopsis*	Canada
Trichoderma harzianum ATCC 20476	Fungus	Binab	Wound healing	US
Trichoderma harzianum Rifai T-22	Fungus	PlantShield RootShield T-22 Planter box	Seed and foliar diseases	US
Trichoderma harzianum T-39	Fungus	Trichodex	Soil and foliar diseases	US
Trichoderma harzianum Rifai T-22 ITEM 108 or KRL-AG2	Fungus	Trianum P	Root diseases	EU
Trichoderma harzianum Rifai T-39 (IMI 206039)	Fungus	Trichodex Rootshield	*Botritis cinerea, Collectotrichum* spp., *Fulvia fulva, Monilia laxa, Plasmopara viticola, Pseudoperonospora cubensis, Rhizopus stolonifer, Sclerotinia sclerotiorum*	EU
Trichoderma polysporum and *T. harzianum*	Fungus	Binab T Vector	Fungal pathogens, fairy ring, *Botrytis, Verticillium, Pythium, Fusarium, Phytophthora, Rhizoctonia, Didymella, Chondrostereum, Heterobasidion*	EU
Trichoderma polysporum ATCC 20475	Fungus	Binab T	Soil and foliar diseases	US
Trichoderma stromaticum	Fungus	–	*Moniliophthora perniciosa*	Brazil
Trichoderma viride	Fungus	Monitor Trichoguard NIPROT Bioderma Biovidi Eswin Tricho Biohit Tricontrol Ecoderm Phalada 106TV Sun Agro Derma Defense SF	Soil borne pathogens	India
Ulocladium oudemansii U3	Fungus	BOTRY-Zen	*Botrytis* and *Sclerotinia*	US
Verticillium albo-atrum (WCS850) (formerly *Verticillium dahliae*)	Fungus	Dutch Trig	Dutch elm disease	EU
Verticillium albo-atrum WC S850	Fungus	Dutch-Trig	Dutch elm disease (*Ophiostoma ulmi, O. novo-ulmi*)	Canada
Verticillium albo-atrum WC S850	Fungus	DutchTrig	Dutch elm disease	US
Bacteriophage of *Pseudomonas syringae* pv. tomato	Virus	AgriPhage	Tomato leaf spot	US
Candida oleophila O	Yeast	NEXY	Post harvest fruit molds	US
C. Fungicides/bactericides				
Bacillus subtilis	Bacterium	Defender	Soil borne fungi and bacteria	South Africa
Bacillus subtilis	Bacterium	–	Soil borne pathogens	India
Bacillus subtilis QST 713	Bacterium	Serenade	Fire blight, *Botrytis* spp.	EU
Bacillus subtilis QST713	Bacterium	Serenade	Foliar fungal and bacterial diseases	US

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Bacillus subtilis QST 713	Bacterium	Serenade Rhapsody Serenade Garden	Label common names: Angular leaf spot, anthracnose, bacterial fruit blotch, bacterial leaf spot, bacterial soft rot, bacterial spot, bitter rot, black rot, black spot of rose, bot rot, brooks spot, brown patch, bull's eye rot, canker, cedar apple rust, dollar spot, downy mildew, early leaf spot, flyspeck, fruit brown rot, greasy spot, grey mold, gummy stem blight, head and leaf drop, late leaf spot, melanose, mummy berry, onion purple blotch, pink rot, post bloom fruit rot, powdery mildew, rust, scab, shot hole, sigatoka, silver scurf, sooty blotch, sour rot, southern corn leaf blight, southern blight, target spot, white mold Label Latin names: *Acidovorax avenae*, *Alternaria* spp., *Aspergillus niger*, *Bipolaris maydis*, *Blumeriella gaapi*, *Botrytis* spp., *Botrytosphaeria dothidea*, *Bremia lactucae*, *Cercospera* spp., *Cerosporidium personatum*, *Cladosporium berbarum*, *Cochliobolus heterostrophus*, *Colletotrichum* spp., *Corynespora cassiicola*, *Diaporthe citri*, *Didymella bryoniae*, *Diplocarpon rosae*, *Elsinoe fawcetti*, *Entomosporium* spp., *Erwinia* spp., *Erysiphe* spp., *Eutypa lata*, *Fusarium* spp., *Gloeodes pomigena*, *Gymnosporangium juniperivirginianae*, *Helminthosporium* spp., *Lanzia* spp., *Leveillula taurica*, *Moellerodiscus* spp., *Monilinia* spp., *Mycosphaerella* spp., *Myrothecium* spp., *Neofabraea* spp., *Oidiopsis taurica*, *Oidium* spp., *Penicillium* spp., *Peronospora* spp., *Phoma cucurbitacearum*, *Phomopsis viticola*, *Phragmidium* spp., *Phytophthora* spp., *Plasmopara viticola*, *Podosphaera* spp., *Pseudomonas* spp., *Pseudoperonospora cubensis*, *Puccinia* spp., *Pythium* spp., *Rhizoctonia* spp., *Rhizopus arrhizus*, *Schizothyrium pomi*, *Sclerotinia* spp., *Sclerotium rolfsii*, *Septoria* spp., *Sphaerotheca* spp., *Uncinula necator*, *Venturia* spp., *Wilsonmyces carpophilus*, *Xanthomonas* spp.	Canada
Ampelomyces quisqualis AQ10	Fungus	Bio Dewcon	Powdery mildew	Kenya
Pantoea agglomerans E325	Fungus	Bloomtime Biological FD	*Botrytis cinerea*, *Sclerotinia sclerotiorum*, fire blight	Canada
D. Herbicides				
Bacillus cereus BP01	Bacterium	MepPlus	Plant growth regulator	US
Lactobacillus spp. (several species and strains)	Bacterium	Organo-Sol	Clovers, black medick, bird's foot trefoil, wood sorrel	Canada
Alternaria destruens 059	Fungi	Smolder	Herbicide - dodder	US
Colletotrichum gloeosporioides f.sp. *aeschynomene* ATCC 202358	Fungus	LockDown	Herbicide - northern jointvetch	US
Chondrostereum purpureum PFC2139	Fungus	Control	Resprouting inhibition of cut alder	Canada
Chondrostereum purpureum PFC 2139	Fungus	Chontrol Paste	Herbicide - stump sprout inhibitor	US
Puccinia thlaspeos woad (dyer's woad rust)	Fungus	Woad Warrior	Herbicide - Dyer's woad	US
Sclerotinia minor IMI 344141	Fungus	Sarritor	Dandelion	Canada
E. Insecticides				
Bacillus thuringiensis subsp. *aizawai*	Bacterium	Florbac Xentari	Coffee giant looper	Kenya
Bacillus thuringiensis subspp. *aizawai* and *kurstaki*	Bacterium	Agree	Lepidopteran larvae	South Africa
Bacillus thuringiensis subsp. *israelensis*	Bacterium	VectoBac	Mosquito	South Africa
Bacillus thuringiensis subsp. *israelensis*	Bacterium	Tacibio Technar	Lepidopteran pests	India
Bacillus thuringiensis subsp. *israelensis*	Bacterium	Bacticide	Mosquito larvae	Kenya
Bacillus thuringiensis subsp *israelensis*	Bacterium	BMP	Mosquito and blackflies	US
Bacillus thuringiensis subsp. *kurstaki*	Bacterium	DiPel Rokur Thuricide	Lepidopteran larvae	South Africa
Bacillus thuringiensis subsp. *kurstaki*	Bacterium	Bio-Dart Biolep Halt Taciobio-Btk	Lepidopteran pests	India

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Bacillus thuringiensis subsp. *kurstaki*	Bacterium	Biolep DiPel Halt Thuricide	Thrips, African bollworm, *Helicoverpa armigera*, *Spodoptera exigua,* Lepidopteran larvae, diamond black moth	Kenya
Bacillus thuringiensis subsp. *kurstaki*	Bacterium	Thuricide Thuricide Forestry Wilbur-Ellis BT 320 Dust Dipel Deliver Biobit HP Foray Javelin WG Green Light Hi-Yield Worm Spray Ferti-Lome Bonide Britz BT Worm Whipper Security Dipel Dust	Lepidopteran larvae	US
Bacillus thuringiensis subsp. *kurstaki* H7	Bacterium	Florbac WG	Lepidopteran larvae	South Africa
Bacillus thuringiensis subsp. *kurstaki* SA11	Bacterium	Delfin	Diamond black moth, coffee giant looper	Kenya
Bacillus thuringiensis subsp. *aizawai* GC-91	Bacterium	Turex	Lepidopteran pests	EU
Bacillus thuringiensis subsp. *aizawai* GC-91	Bacterium	Agree WG	*Plutella*	US
Bacillus thuringiensis subsp. *israelensis* AM65	Bacterium	VectoBac	Sciarids	EU
Bacillus thuringiensis subsp. *kurstaki* HD-1	Bacterium	Dipel WP	Lepidopteran pests	EU
Bacillus thuringiensis subsp. *kurstaki* ABTS 351, PB 54, SA 11, SA12, and EG 2348	Bacterium	Batik Delfin	Lepidopteran pests	EU
Bacillus thuringiensis subsp. *kurstaki* EG2348	Bacterium	Condor	Lepidopteran larvae	US
Bacillus thuringiensis subsp. *kurstaki* BMP 123	Bacterium	BMP 123 Prolong	Lepidopteran pests	EU
Bacillus thuringiensis subsp. *kurstaki* BMP 123	Bacterium	BMP123	Lepidopteran larvae	US
Bacillus thuringiensis subsp. *tenebrionis* NB 176	Bacterium	Novodor	Coleopteran pests	EU
Bacillus thuringiensis	Bacterium	Agree Bac-Control Bactur Dipel Thuricide Xentari	Lepidopteran pests	Brazil
Bacillus thuringiensis subsp. kurstaki BT-32 (INICA 050-04)	Bacterium	BT-32	Lepidopteran larvae	Cuba
Bacillus thuringiensis LBT-1 (INISAV 179-04)	Bacterium	Thurisav -1	Lepidopteran larvae	Cuba
Bacillus thuringiensis subsp. *kurstaki* LBT-24 and LBT-26 (INISAV)	Bacterium	Thurisav-24 (LBT-24) Thurisav–26 (LBT-26)	*Ascia monuste eubotea*, *Plutella xylostella* (also Strain LBT-1), *Spodoptera frugiperda*, *Heliothis* spp., *Spodoptera* spp., *Trichoplusia brasicae, T.ni*, *Diaphania* spp., *Erinnyis ello*, *Erinnyis alope*, *Davara caricae*, *Hedylepta indicate*, *Mocis* spp., *Liriomyza trifolii*, *Phyllocnistis citrella, Heliothis* spp. (LBT-26 only), lepidopteran pests	Cuba
Bacillus thuringiensis LBT-13 (INISAV)	Bacterium	Thurisav-13	*Polyphagotarsonemus latus*, *Tetranychus tumidus*, *Phyllocoptruta oleivora*, *Thrips palmi*, *Liriomyza trifolii,* Animal pest control (*Megninia gynglimura*, *Ornithonyssus sylvianum*)	Cuba
Bacillus sphaericus 2362 SC (LABIOFAM 116-03)	Bacterium	Griselesf	Mosquito larvae	Cuba
Bacillus thuringiensis subsp. *israelensis* serotype H-14 (LABIOFAM 100-04)	Bacterium	Bactivec	Mosquito larvae	Cuba
Bacillus sphaericus serotype H5a5b strain 2362	Bacterium	VectoLex	Mosquito (*Culex* spp., *Aedes vexans*, *Ochlerotatus melanimon* (*Aedes melanimon*), *Ochlerotatus stimulans* (*Aedes stimulans*), *Ochlerotatus nigromaculis* (*Aedes nigromaculis*), *Psorophora columbiae, Psorophora ferox*, *Ochlerotatus triseriatus* (*Aedes triseriatus*), *Ochlerotatus sollicitans* (*Aedes sollicitans*), *Anopheles quadrimaculatus*, *Coquillettidia perturbans*	Canada
Bacillus thuringiensis subsp. *israelensis* 65-52	Bacterium	VectoBac (Active Ingredient II)	Mosquito, blackfly, nuisance fly, nuisance midge	Canada
Bacillus thuringiensis subsp. *israelensis* SA3A	Bacterium	Teknar HP-D	Blackfly, mosquito	Canada

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Bacillus thuringiensis subsp. *israelensis* serotype H14	Bacterium	Teknar Summit Bti Briquets Mosquito Dunks VectoBac (Active Ingredient I)	Drain fly, filter fly, mosquito, mosquito larvae, psychodid fly	Canada
Bacillus thuringiensis subsp. *kurstaki* HD-1	Bacterium	Bioprotec Foray Dipel	Brown spanworm, cabbage looper, cherry fruitworm, cranberry fruitworm, diamondback moth, *Duponchelia fovealis*, early and late season oblique banded leafrollers, eastern hemlock looper, bagworm, eastern spruce budworm, elm spanworm, Essex skipper (European skipper), European corn borer, fall cankerworm, fall spanworm, fall webworm, forest caterpillar, forest tent caterpillar, fruitworm, green spanworm, Gypsy moth, hemlock looper, hornworm, imported cabbageworm, leafrollers (fruittree-, European-, oblique banded-, three-lined-, omnivorous-), pine budworm, range caterpillar (*Hemileuca*), rangeland caterpillar, satin moth, spring cankerworm, sunflower moth, tent caterpillar, tomato fruitworm, tomato hornworm, western spruce budworm, Jack pine budworm, white marked tussock moth, winter moth	Canada
Bacillus thuringiensis subsp. *kurstaki* SA-11	Bacterium	Safer Bt Caterpillar Killer Thuricide 48 LV	Alfalfa caterpillar, armyworm, bagworm, black cutworm, budworm, cabbage looper, cabbageworm, webworm, California oak moth, codling moth, cotton bollworm, cranberry blossomworm, cranberry fruitworm, cutworm, diamondback moth, Douglas fir tussock moth, eastern hemlock looper, elm spanworm, fall cankerworm, fall webworm, forest tent caterpillar, fruittree leafroller, green cloverworm, Gypsy moth, hornworm, Jack pine budworm, leafroller, fireworm, looper, *Mimosa* webworm, navel orangeworm, oriental fruit moth, peach twig borer, pecan nut casebearer, southwestern corn borer, European corn borer, pine butterfly, podworm, redhumped caterpillar, saltmarsh caterpillar, soybean looper, spanworm, cankerworm, *Sparganothis* fruitworm, spring cankerworm, Essex/European skipper, spruce budworm, tent caterpillar, tobacco budworm, tomato hornworm, tufted apple bud moth, velvetbean caterpillar, walnut caterpillar, webworm, western tussock moth	Canada
Bacillus thuringiensis subsp. *kurstaki* SA-12	Bacterium	Thuricide 48 LV Forestry Thuricide HPC	Alfalfa caterpillar, almond moth, bagworm, elm spanworm, banana skipper, budworm, cabbage looper, citrus cutworm, cotton bollworm, diamondback moth, easter spruce budworm, elm spanworm, Essex skipper, fall cankerworm, fall spanworm, fall webworm, filbert leafroller, forest tent caterpillar, fruittree leafroller, grape leaffolder, green cloverworm, Gypsy moth, imported cabbageworm, Indian meal moth, Jack pine budworm, oak moth, omnivorous leafroller, omnivorous looper, orange tortrix, orangedog, podworm, rangeland caterpillar, redbanded leafroller, redhumped caterpillar, rindworm complex, roughskinned cutworm, soybean looper, spring cankerworm, tent caterpillar, tobacco budworm, tobacco hornworm, tomato fruitworm, tomato hornworm, tufted apple bud moth, variegated leafroller, velvetbean caterpillar, western avocado leafroller, western spruce budworm	Canada
Bacillus thuringiensis subsp. *tenebrionis* HB 176	Bacterium	Novodor	Colorado potato beetle (*Leptinotarsa decemlineata*), elm leaf beetle (*Pyrrhalta leutola*)	Canada
Bacillus popilliae	Bacterium	Milky Spore Powder	Japanese beetle grubs	US
Bacillus sphaericus Serotype H5a5b strain 2362 ATCC 1170	Bacterium	VectoLex	Mosquito larvae	US
Bacillus thuringiensis subsp. *aizawai* NB200	Bacterium	Florbac	Moth larvae	US
Bacillus thuringiensis subsp *israelensis* EG2215	Bacterium	Gnatrol Aquabac	Mosquito, flies	US
Bacillus thuringiensis subsp. *aizawai* delta-endotoxin in killed *Pseudomonas fluorescens*	Bacterium	M-Trak	Colorado potato beetle	US
Bacillus thuringiensis subsp. *kurstaki* EG7841	Bacterium	Crymax	Lepidopteran larvae	US
Bacillus thuringiensis subsp. *tenebrionis*	Bacterium	Novodor	Colorado potato beetle	US
Bacilus thuringiensis subsp. *kurstaki* EG7826	Bacterium	Lepinox WDG	Lepidopteran larvae	US

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Beauveria bassiana	Fungus	Bb Plus Bb weevil Sparticus	Thrips, weevils, whiteflies	South Africa
Beauveria bassiana	Fungus	Myco-Jaal Biosoft ATEC Beauveria Larvo-Guard Biorin Biolarvex Biogrubex Biowonder Veera Phalada 101B Bioguard Bio-power	Coffee berry borer, diamondback moth, thrips, grasshoppers, whiteflies, aphids, codling moth	India
Beauveria bassiana	Fungus	Boveril PL 63	Coleoptera (Curculionidae), Acari Tetranychidae	Brazil
Beauveria bassiana ATCC 74040	Fungus	Naturalis L	Thrips, whiteflies, mites	EU
Beauveria bassiana GHA	Fungus	Botanigard	Whiteflies, aphids, thrips	EU
Beauveria bassiana GHA	Fungus	Mycotrol ES Mycotrol O Botanigard 22WP BotaniGard ES	Various insects	US
Beauveria bassiana GHA	Fungus	Botanigard	Aphid (bean-, cabbage-, cowpea-, green peach-, greenbug-, hop-, melon-, cotton-, pea-, potato-, rose-, Russian wheat, spotted alfalfa-), leafhoppers and plant hoppers (grape leafhopper, leafhopper, plant hopper, potato leafhopper, variegated leafhopper), mealybug (citrus-, grape-, buffalo grass-, longtailed-), plant pug (Heteroptera), chinch bug, lace bug, psyllid (pear-, tomato-, potato-), scarab beetle (*Atenius*, green June beetle, white grub), thrip (greenhouse-, Cuban laurel-, pear-, potato-, onion-, palmi-, western flower-), weevil (black vine-, strawberry root-, fuller rose-, root-, rose curculio, billbug), whitefly (banded-, winged-, citrus-, giant-, greenhouse-, silverleaf-, sweet potato-, tobacco-)	Canada
Beauveria bassiana GHA Botanigard	Fungus	Bio-power	Aphid, diamond black moth, sucking insect pests	Kenya
Beauveria bassiana HF23	Fungus	Balance	House fly	Canada
Beauveria bassiana HF23	Fungus	balEnce	House fly	US
Beauveria bassiana MB-1 (INISAV 182-04)	Fungus	Bibisav -2	*Atta insularis*, *Acromyrmex octospinosus*, *Attamyces bromatificus* (Formicidae)	Cuba
Beauveria bassiana LBB-1 (INISAV 180-04)	Fungus	Basisav-1	*Cosmopolites sordidus* (banana weevil), *Cylas formicarius* (weevil), *Lissorhoptrus brevirostris* (aquatic weevil), *Pachnaeus* spp. (Curculionidae), *Thrips palmi*, *Diatraea saccharalis*, *Hypothenemus hampei*, *Diabrotica balteata*, *Pseudacysta perseae*, *Lagochirus dezayasi*, *Corythucha gossypii*, *Tipophorus nigritus*, *Phyllophaga* spp.	Cuba
Beauveria bassiana 447 Baits	Fungus	Motel Stay-awhile	Ants	US
Beauveria bassiana ATCC 74040	Fungus	Naturalis L	Various insects	US
Lecanicillium muscarium (Ve6) (former *Verticillium lecanii*)	Fungus	Mycotal Vertalec	Whiteflies, thrips, aphids (except the Chrysanthemum aphid: *Macrosiphoniella sanborni*)	EU
Metarhizium anisopliae subsp. *acridum* IMI 330 189	Fungus	Green Muscle®	Locust	South Africa
Metarhizium anisopliae LBM-11 (INISAV 178-05)	Fungus	Metasav-11	*Lissorhoptrus brevirostris* (aquatic weevil), *Mocis* spp. (lepidopteran larvae), *Prosapia bicincta*, *Cosmopolites sordidus* (banana weevil), *Tagosodes oryzicola, Oebalus insularis, Spodoptera* spp., *Spodoptera* spp., *Pachnaeus litus*, *Thrips palmi*, *Plutella xylostella*, *Hypothenemus hampei, Diabrotica balteata* (Curculionidae)	Cuba
Metarhizium anisopliae	Fungus	ABTEC Verticillium Meta-Guard Biomet Biomagic Meta Biomet Sun Agro Meta Bio-Magic	Coleoptera and lepidoptera, termites, mosquitoes, leafhoppers, beetles, grubs	India
Metarhizium anisopliae	Fungus	Metarril E9	Hemiptera (Cercopidae), Acari (Ixodidae)	Brazil
Metarhizium anisopliae F52	Fungus	Met52	Black vine weevil	Canada
Metarhizium anisopliae F52	Fungus	Tick-Ex	Ticks and grubs	US

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Paecilomyces fumosoroseus	Fungus	Nemato-Guard Priority	Whitefly	India
Paecilomyces lilacinus	Fungus	Yorker ABTEC Paceilomyces Paecil Pacihit ROM biomite Bio-Nematon	Whitefly	India
Paecilomyces lilacinus	Fungus	Bio - Nematon	Root knot nematode	Kenya
Paecilomyces fumosoroseus Apopka 97	Fungus	Preferal WG	Greenhouse whiteflies (*Trialeurodes vaporariorum*)	EU
Paecilomyces fumosoroseus Apopka 97	Fungus	PFR-97	Whiteflies and thrips	US
Paecilomyces fumosoroseus Fe9901	Fungus	Nofly	Whiteflies	EU
Verticillium lecanii	Fungus	Verisoft ABTEC Verticillium Vert-Guard Bioline Biosappex Versitile Ecocil Phalada 107 V Biovert Rich ROM Verlac ROM Gurbkill Sun Agro Verti Bio-Catch	Whitefly, coffee green bug, homopteran pests	India
Verticillium lecanii Y-57 (INISAV 179-05 and 180-05)	Fungus	Vertisav-57	*Bemisia tabaci* (whitefly), *Bemisia argentifolia, Frankliniella* spp. *Aleurotracholus tracheoides*, *Aphis gossypii, Myzus persicae, Lipaphis erizini, Brevicoryne brassicae, Thrips palmi, Bophilus microplus*	Cuba
Heterorhabditis bacteriophora	Nematode	Nematop Nema- Green Terranem Larvanem Nemasys G B-Green Nematode HB Heteromask	Asiatic garden beetle (*Maladera castanea*), black vine weevil (*Otiorhynchus sulcatus*), cutworms, dung beetle (*Aphodius* sp.), European chafer (*Rhizotrogus majalis*), garden chafer (*Phyllopertha horticola*), ghost swift (*Hepialus lupulinus*), Japanese beetle (*Popillia japonica*), Japanese beetle grub (*Popillia japonica*), larvae of chafer grubs, larvae of curculionids (*Otiorhynchus sulcatus*, *Hepialus lupulinus*), May/June beetle (*Phyllophaga* spp.), oriental beetle grub (*Exomala orientalis*), strawberry root weevil (*Otiorhynchus ovatus*), Welch chafer (*Hoplia* sp.)	Canada
Heterorhabditis megidis	Nematode	Larvanem M Nematode HM Nemasys H	Black vine weevil (*Otiorhynchus salcatus*), strawberry root weevil (*Otiorhynchus ovatus*)	Canada
Steinernema carpocapsae	Nematode	Nemastar Nematac C Nematode SC Ecomask	Armyworm, black aetinius weevil, bluegrass billbug, caterpillar, cranberry girdler (*Chrysoteuchia topiaria*), cutworm, girdler, *Hylobius* weevil, leather jacket (European crane fly), mole cricket (*Gryllotalpa* spp.), pine weevil, red palm weevil, sod webworm, weevil grub	Canada
Steinernema feltiae	Nematode	Nemasys M Nemaplus Entonem Scia-Rid Traunem Nemacel/ Nemycel Nematode SF Nemasys Scanmask	Bibionid larvae, black vine weevil, crane fly, cucumber beetle, cutworm, fungus gnat (*Bradysia* spp.), sciarid fly larvae (Sciaridae), mushroom sciarids (*Lycoriella* spp.), onion maggot, root maggot, sciarid fly (*Lycoriella* spp.), sod webworm, western flower thrip (*Frankliniella occidentalis*), white grub	Canada
Steinernema kraussei	Nematode	Nemasys L	Black vine weevil (*Otiorhynchus sulcatus*)	Canada
Steinernema scapterisci	Nematode	Nematac S	Tawny mole cricket (*Scapteriscus vicinus*), southern mole cricket (*Scapteriscus borellii*)	Canada
Nosema locustae	Protozoan	Nolo Bait	Grasshopper	Canada
Nosema locustae	Protozoan	Nolo-Bait Semaspore Bait	Grasshopper and cricket	US
Adoxophyes orana BV-0001 granulosis virus	Virus	Capex	Summer fruit tortrix (*Adoxophyes orana*)	EU
Anagrapha falcifera nucleopolyhedrosis virus	Virus	CLV-LC	Lepidopteran larvae	US
Anticarsia gemmatalis nucleopolyhedrosis virus (AgNPV)	Virus	Baculo-Soja Baculovirus Nitral Coopervirus PM Protege	*Anticarsia gemmatalis*, lepidopteran pests	Brazil

Annex 4. Contd

Type	Taxus	Products	Targets	Country
Cydia pomonella granulosis virus	Virus	BioTepp	Codling moth (*Cydia pomonella*)	EU
Cydia pomonella granulosis virus	Virus	Virosoft	Codling moth (*Cydia pomonella*)	Canada
Cydia pomonella granulosis virus	Virus	CYD-X	Codling moth	US
Granulosis viruses	Virus	–	Lepidopteran larvae	South Africa
Gypsy moth nucleopolyhedrosis virus	Virus	Gypchek	Gypsy moth	US
Helicoverpa zea nucleopolyhedrosis virus (previously *Heliothis zea* NPV)	Virus	GemStar	Cotton bollworm, tobacco budworm	US
Helicoverpa armigera nucleopolyhedrosis virus (HearNPV)	Virus	–	*Helicoverpa armigera*	EU
Helicoverpa armigera Nucleopolyhedrosis virus	Virus	Helicide Virin-H Helocide Biovirus-H Helicop Heligard	*Helicoverpa armigera*	India
Indian meal moth granulovirus (*Plodia interpunctella* GV)	Virus	FruitGuard	Indian meal moth	US
Mamestra configurata nucleopolyhedrosis virus (107308)	Virus	Virosoft	Bertha armyworm	US
Neodiprion abietis nucleopolyhedrosis virus	Virus	Abietiv	Balsam fir sawfly (*Neodiprion abietis*)	Canada
Neodiprion lecontei nucleopolyhedrosis virus	Virus	Lecontvirus	Red-headed pine sawfly (Neodiprion lecontei)	Canada
Orgyia pseudotsugata nucleopolyhedrosis virus	Virus	Virtuss TM Biocontrol-1	Douglas fir tussock	Canada
Pseudomonas resinovorans bacteriophage	Virus	Agriphage	Insect pest control	South Africa
Saccharomyces cerevisiae	Yeast	Bull Run	Fly attractant	US
Spodoptera exigua nucleopolyhedrosis virus	Virus	Spod-X GH	*Spodoptera exigua*	EU
Spodoptera littoralis nucleopolyhedrosis virus	Virus	–	*Spodoptera littoralis*	EU
Spodoptera litura nucleopolyhedrosis virus	Virus	Spodocide Spodoterin Spodi-cide Biovirus-S	*Spodoptera litura*	India
Spodoptera exigua nucleopolyhedrosis virus	Virus	Spod-X	Beet armyworm	US
F. Nematicides				
Bacillus thuringiensis subsp. *kurstaki* LBT-3 (INISAV)	Bacterium	Thurisav-3	*Meloidogyne* spp., banana nematodes	Cuba
Bacillus firmus I-1582	Bacterium	BioNem	Nematodes	US
Pasteuria usgae	Bacterium	Econem	Nematodes	US
Tsukamurella paurometabola C-924 (CIGB 001-07)	Bacterium	HeberNem-L	Plant parasitic nematodes	Cuba
Tsukamurella paurometabola C-924 (CIGB 050-08)	Bacterium	HeberNem-S	Plant parasitic nematodes	Cuba
Myrothecium verrucaria	Fungus	Ditera	Nematodes	Kenya
Myrothecium verrucaria	Fungus	DiTera	Nematodes	US
Paecilomyces lilacinus	Fungus	Bio-Nematon	Nematodes	South Africa
Paecilomyces lilacinus	Fungus	PL Plus	Nematodes	Kenya
Paecilomyces lilacinus 251	Fungus	PL Plus	Nematodes	South Africa
Paecilomyces lilacinus 251	Fungus	MeloCon WG	Nematodes	US
Paecilomyces lilacinus PL 251	Fungus	BioAct WG	Common plant parasitic nematodes	EU
Verticillium chlamydosporium	Fungus	–	Nematodes	India
Pochonia chlamidospora subsp. *catenulate* (CENSA 047-09)	Fungus	KlamiC	Soil nematodes	Cuba
G. Rodenticides				
Salmonella enteriditis subsp. *danysz* (LABIOFAM 101-04)	Bacterium	Biorat G	Rats	Cuba
H. Virucides				
Zucchini Yellow Mosaic Virus, weak strain	Virus	Curbit	Yellow mosaic virus	EU

(Source: Kabaluk et al. 2010)

ISPM No. 3

Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms

(2005)

Produced by the Secretariat of the International Plant Protection Convention

Endorsement

ISPM No. 3 was first endorsed by the 28th Session of the FAO Conference in November 1995 as: Code of conduct for the import and release of exotic biological control agents. The first revision was endorsed by the Interim Commission on Phytosanitary Measures in April 2005 as the present standard, ISPM No. 3 (2005).

Introduction

Scope

This standard[1] provides guidelines for risk management related to the export, shipment, import and release of biological control agents and other beneficial organisms. It lists the related responsibilities of contracting parties to the IPPC ('contracting parties'), National Plant Protection Organizations (NPPOs) or other responsible authorities, importers and exporters (as described in the standard). The standard addresses biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), and includes those packaged or formulated as commercial products. Provisions are also included for import for research in quarantine facilities of non-indigenous biological control agents and other beneficial organisms.

The scope of this standard does not include living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control.

References

Convention on Biological Diversity, 1992. CBD, Montreal.

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.

Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest reporting, 2002. ISPM No. 17, FAO, Rome.

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

Definitions

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

Outline of requirements

This standard is intended to facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms. Responsibilities relating to this are held by contracting parties, National Plant Protection Organizations (NPPOs) or other responsible authorities, and by importers and exporters.

Contracting parties, or their designated authorities, should consider and implement appropriate phytosanitary measures related to the export, shipment, import and release of biological control agents and other beneficial organisms and, when necessary, issue related import permits.

As described in this standard, NPPOs or other responsible authorities should:

- carry out pest risk analysis of biological control agents and other beneficial organisms prior to import or prior to release;
- ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with;
- obtain, provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms;
- ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or mass-rearing facilities or, if appropriate, passed directly for release into the environment;
- encourage monitoring of release of biological control agents or beneficial organisms in order to assess impact on target and non target organisms.

Responsibilities of, and recommendations for, exporters include ensuring that consignments of biological control agents and other beneficial organisms comply with phytosanitary import requirements of importing countries and relevant international agreements, packaging consignments securely, and providing appropriate documentation relating to biological control agents or other beneficial organisms.

Responsibilities of, and recommendations for, importers include providing appropriate documentation relating to the target pest(s) and biological control agent or other beneficial organisms to the NPPO or other responsible authority of the importing country.

1 Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements. Provisions of other international agreements may be applicable, for example the Convention on Biological Diversity.

Background

The International Plant Protection Convention (IPPC) is based on securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and the promotion of appropriate measures for their control (Article I of the IPPC, 1997). In this context, the provisions of the IPPC extend to any organism capable of harbouring or spreading plant pests, particularly where international transportation is involved (Article I of the IPPC, 1997).

The IPPC (1997) contains the following provision in relation to the regulation of biological control agents and other beneficial organisms. Article VII.1 states:

"With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may: ...

c) prohibit or restrict the movement of regulated pests into their territories;

d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories."

Section 4.1 of ISPM No. 20 (Guidelines for a phytosanitary import regulatory system), contains a reference to the regulation of biological control agents; it states:

"Imported commodities that may be regulated include articles that may be infested or contaminated with regulated pests. ... The following are examples of regulated articles: ... pests and biological control agents."

This revision of ISPM No. 3 provides guidelines related to phytosanitary measures, as well as recommended guidelines for safe usage of biological control agents and other beneficial organisms. In some cases, the scope of these guidelines may be deemed to extend beyond the scope and provisions of the IPPC as described above. For example, although the primary context of this standard relates to phytosanitary concerns, "safe" usage as mentioned in the standard is intended to be interpreted in a broader sense, i.e. minimizing other non-phytosanitary negative effects. Phytosanitary concerns may include the possibility that newly introduced biological control agents may primarily affect other non-target organisms, but thereby result in harmful effects on plant species, or plant health in habitats or ecosystems. However, it is not intended that any aspects of this standard alter in any way the scope or obligations of the IPPC itself as contained in the New Revised Text of the IPPC (1997) or elaborated on in any of the other ISPMs.

The structure of this revised standard broadly follows the same structure of the original ISPM No. 3, and its content is based primarily on risk management relating to the use of biological control agents and other beneficial organisms. It is recognized that the existing standards on pest risk analysis (ISPM No. 2: Guidelines for pest risk analysis and ISPM No. 11: Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004) provide the appropriate fundamental processes for carrying out pest risk assessments for biological control agents and other beneficial organisms. In particular, ISPM No. 11 includes provisions for pest risk assessment in relation to environmental risks, and this aspect covers environmental concerns related to the use of biological control agents.

The IPPC (1997) takes into account internationally approved principles governing the protection of the environment (Preamble). Its purpose includes promoting appropriate phytosanitary measures (Article I.1). When carrying out pest risk analysis in accordance with this and other appropriate ISPMs, and in developing and applying related phytosanitary measures, contracting parties should also consider the potential for broader environmental impacts resulting from releasing biological control agents and other beneficial organisms[2] (for example, impacts on non-target invertebrates).

Most of this standard is based on the premise that a biological control agent or other beneficial organism may be a potential pest itself, and in this sense Article VII.1c of the IPPC (1997) applies because contracting parties may prohibit or restrict the movement of regulated pests into their territories. In some situations, biological control agents and other beneficial organisms may act as a carrier or pathway for plant pests, hyperparasitoids, hyperparasites and entomopathogens. In this sense, biological control agents and other beneficial organisms may be considered to be regulated articles as described in Article VII.1 of the IPPC (1997) and ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*.

Purpose of the standard

The objectives of the standard are to:

- facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms by providing guidelines for all public and private bodies involved, particularly through the development of national legislation where it does not exist.
- describe the need for cooperation between importing and exporting countries so that:
  - benefits to be derived from using biological control agents or other beneficial organisms are achieved with minimal adverse effects
  - practices which ensure efficient and safe use while minimizing environmental risks due to improper handling or use are promoted.

Guidelines in support of these objectives are described that:

- encourage responsible trade practices
- assist countries to design regulations to address the safe handling, assessment and use of biological control agents and other beneficial organisms
- provide risk management recommendations for the safe export, shipment, import and release of biological control agents and other beneficial organisms
- promote the safe use of biological control agents and other beneficial organisms.

2 Available expertise, instruments and work in international fora with competence in the area of risks to the environment should be taken into account as appropriate.

Requirements

1. Designation of Responsible Authority and Description of General Responsibilities

1.1 Contracting parties

Contracting parties should designate an authority with appropriate competencies (usually their NPPO) to be responsible for export certification and to regulate the import or release of biological control agents and other beneficial organisms, subject to relevant phytosanitary measures and procedures.

Contracting parties should have provisions for implementing appropriate phytosanitary measures for the export, shipment, import or release of biological control agents and other beneficial organisms.

1.2 General responsibilities

The NPPO or other responsible authority should establish procedures for the implementation of this standard, including for the assessment of relevant documentation specified in section 4.

The NPPO or other responsible authority should:

– carry out pest risk analysis prior to import or release of biological control agents and other beneficial organisms
– ensure, when certifying exports, that the regulations of importing countries are complied with
– provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms
– ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or, if appropriate, passed to mass rearing facilities or directly for release into the environment
– ensure that importers and, where appropriate, exporters meet their responsibilities
– consider possible impacts on the environment, such as impacts on non-target invertebrates.

The NPPO or other responsible authority should maintain communication and, where appropriate, coordinate with relevant parties including other NPPOs or relevant authorities on:

– characteristics of biological control agent and other beneficial organisms
– assessment of risks including environmental risks
– labelling, packaging and storage during shipment
– dispatch and handling procedures
– distribution and trade
– release
– evaluation of performance
– information exchange
– occurrence of unexpected and/or harmful incidents, including remedial action taken.

2. Pest Risk Analysis

The NPPO of the importing country should determine whether an organism is required to be subjected to pest risk analysis (PRA). The NPPO or other responsible authority may also be responsible for ensuring that other national legislative requirements are met; however, these may not be IPPC obligations.

Pest risk assessment should be conducted in accordance with ISPM No. 2 (Guidelines for pest risk analysis) and/or stage 2 of ISPM No. 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004) as appropriate, taking into account uncertainties, and potential environmental consequences, as provided for in those standards. In addition to conducting pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

Most contracting parties require PRA to be completed prior to import and technical justification, as described in ISPM No. 20 (Guidelines for a phytosanitary import regulatory system), such as through PRA, is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them. Where applicable, if pest risk assessment of the proposed organism has not been undertaken or completed prior to import, it should be completed prior to release (see section 7). However, it is recognized that biological control agents and other beneficial organisms may need to be imported for research and evaluation in secure facilities prior to release. ISPM No. 20 also states that contracting parties may make special provision for the import of biological control agents and other beneficial organisms for scientific research, and that such imports may be authorized subject to the provision of adequate safeguards. The NPPO should be prepared for such imports with the expectation that, where necessary, a full PRA in accordance with ISPM No. 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004) will be completed prior to release. When non-phytosanitary risks are identified, these may need to be referred to other appropriate authorities for possible action.

It may be important that further scientific investigations are carried out in the exporting country prior to importing the biological control agents or other beneficial organisms in order to verify the accuracy and reliability of the risk assessment. Among other options, and where appropriate, NPPOs or other responsible authorities may consider possibilities for such scientific investigations, in cooperation with the authorities of the exporting country and in accordance with relevant procedures and regulations.

3. Responsibilities of Contracting Parties prior to Import

3.1 Responsibilities of the importing contracting party

The importing contracting party or its NPPO or other responsible authority should:

3.1.1 Promote awareness of, and compliance with this standard and introduce necessary phytosanitary measures to regulate the import, shipment or release of biological control agents and other beneficial organisms in its country, and make provision for effective enforcement.

3.1.2 Evaluate the documentation on the target pest and on the biological control agent and beneficial organisms supplied by the importer (see section 4) in relation to the level of acceptable risk. The contracting party should establish appropriate phytosanitary measures for import, shipment, quarantine facilities (including approval of research facilities, and phytosanitary measures for containment and disposal) or release of biological control agents appropriate to the assessed risk. If the biological control agent or other beneficial organism is already present in the country, regulation may only be needed to ensure there is no contamination or infestation of this organism, or that interbreeding with local genotypes of the same species does not result in new phytosanitary risks. Inundative release may be restricted for these reasons.

3.1.3 Issue regulations stating requirements to be fulfilled by the exporting country, the exporter and the importer[3]. Where appropriate, these may include:

– the issuing of an accompanying authorising document (import permit or licence)
– phytosanitary certification, in accordance with ISPM No. 12: Guidelines for phytosanitary certificates
– a specific certification document
– authoritative identification of organisms during quarantine and provision of a reference specimen
– specification of the source of the biological control agent or other beneficial organism(s), including origin and/or point of production where relevant
– precautions to be taken against inclusion of natural enemies of the biological control agent or other beneficial organism and of contamination or infestation
– requirements regarding packaging for shipment during transport and storage
– procedures for the disposal of packaging
– means to validate documentation
– means to validate the contents of consignments
– conditions under which the package may be opened
– designation of point(s) of entry
– identification of the person or organization to receive the consignment
– requirements for the facilities in which the biological control agent or other beneficial organisms may be held.

3.1.4 Ensure that procedures are in place for the documentation of:

– pest risk analysis
– the import (identity, origins, dates)
– nurturing, rearing or multiplication
– release (quantities released, dates, locations), and
– any other relevant data.

Such records may be made available to the scientific community and the public, as may be appropriate, while protecting any proprietary rights to the data.

3.1.5 If appropriate, ensure entry of consignments, and processing where required, through quarantine facilities. Where a country does not have secure quarantine facilities, import through a quarantine station in a third country, recognized by the importing contracting party, may be considered.

3.1.6 Consider, through pest risk analysis, the risk of introducing other organisms associated with the biological control agent or beneficial organism. Considerations (keeping in mind the principles of necessity and minimal impact) should include phytosanitary measures requiring the culturing of imported biological control agents and other beneficial organisms in quarantine before release. Culturing for at least one generation can help in ensuring purity of the culture and freedom from hyperparasites and pathogens or associated pests, as well as facilitating authoritative identification. This is particularly advisable when biological control agents and other beneficial organisms are collected from the wild.

3.1.7 Where possible, ensure the deposition in collections of authoritatively identified reference specimens of the imported biological control agent or other beneficial organism (and host(s) where appropriate). It is preferable to deposit a series of specimens, where available, to accommodate natural variation.

3.1.8 In the case of sterile insect technique, the sterile insect may be marked to differentiate it from the wild insect.

3.1.9 Consider, through pest risk analysis (consistent with the principles of necessity and minimal impact), if, after a first import or release, further imports of the same biological control agent or other beneficial organism may be exempted from some or all of the requirements for import. The publication of lists of approved and prohibited biological control agents and other beneficial organisms may also be considered. If appropriate, biological control agents that are prohibited should be included in lists of regulated pests (established and updated by contracting parties in accordance with the IPPC (1997) and ISPM No. 19: *Guidelines on lists of regulated pests*).

3 Provisions of other international agreements may address the import of biological control agents or other beneficial organisms (for example the Convention on Biological Diversity).

3.2 Responsibilities of the NPPO of an exporting country

The NPPO of an exporting country should ensure that the phytosanitary import requirements of the importing country are satisfied and that phytosanitary certificates are issued in accordance with ISPM No. 12: Guidelines for phytosanitary certificates, where required by the importing country for consignments of biological control agents or other beneficial organisms, if these are considered as potential pests or pathways for plant pests.

The NPPO is also encouraged to follow the appropriate elements of this standard where the importing country has no legislation concerning the import of biological control agents and other beneficial organisms.

4. Documentary responsibilities of importer prior to import

4.1 Documentary requirements related to the target organism

Prior to the first importation, the importer of biological control agents or other beneficial organisms should provide information as required by the NPPO or other responsible authority of the importing contracting party. For all biological control agents or other beneficial organisms, this information includes accurate identification of the target organism(s), generally at the species level. Where a biological control agent intended to control a pest is being imported, the information on the target pest may also include:

- its world distribution and probable origin
- its known biology and ecology
- available information on its economic importance and environmental impact
- possible benefits and any conflicting interests surrounding its use
- known natural enemies, antagonists and other biological control agents or competitors of the target pest already present or used in the proposed release area or in other parts of the world.

For all biological control agents or other beneficial organisms, other information relevant to a PRA may also be requested by the NPPO or other responsible authority of the importing contracting party.

4.2 Documentary requirements related to the biological control agent or other beneficial organism

Prior to first import, the importer of biological control agents or other beneficial organisms should coordinate with the exporter to provide documentation, accompanied by appropriate scientific references, to the NPPO or other responsible authority of the importing contracting party with information on the biological control agent or beneficial organism including:

- sufficient characterization of the biological control agent or other beneficial organism to allow for its accurate identification, in general to the species level at minimum
- a summary of all available information on its origin, world distribution, biology, natural enemies, hyperparasites, and impact in its area of distribution
- available information on host specificity (in particular, a list of confirmed hosts) of the biological control agent or beneficial organism and any potential hazards posed to non-target hosts
- description of natural enemies and contaminants of the agent and procedures required for their elimination from laboratory colonies. This includes, where appropriate, procedures to identify accurately and, if necessary, eliminate from the culture the host upon which the biological control agent or beneficial organism was cultured. Information on any phytosanitary measures taken prior to shipment should also be provided.

4.3 Documentary requirements related to potential hazards and emergency actions

Prior to first importation, the importer of biological control agents or other beneficial organisms is encouraged to provide documentation to the NPPO or other responsible authority that:

- identifies potential health hazards and analyzes the risks[4] posed to staff operatives exposed when handling biological control agents or other beneficial organisms under laboratory, production and application conditions.
- details emergency action plans or procedures already in existence, should the biological control agent or beneficial organism display unexpected adverse properties.

4.4 Documentary requirements related to research in quarantine

An importer of biological control agents or other beneficial organisms proposed for research in quarantine should provide as much information as possible as described in points 4.1–4.3. However, it is recognized that field collected organisms imported by researchers in initial shipments of potential biological control agents may not be described with regard to their exact taxonomic identity, host range, impact on non-target organisms, distribution, biology, impact in an area of distribution, etc. This information will be determined after candidate biological control agents are studied under quarantine security.

The researcher, in conjunction with the quarantine facility to be used, should also provide the following information:

- the nature of the material proposed for importation
- the type of the research to be carried out
- detailed description of containment facilities (including security and the competency and qualifications of the staff)
- an emergency plan that will be implemented in the case of an escape from the facility.

This information may be required by the NPPO or other responsible authority prior to approval of the research to be conducted. The NPPO or other responsible authority may verify the accuracy of the documentation provided and examine the facilities, and may require modifications as necessary.

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4 Available expertise, instruments and work in international fora with competence in the area of risks to human health should be taken into account as appropriate.

5. Responsibilities of Exporter

The exporter of biological control agents or other beneficial organisms is encouraged to ensure that:

– all phytosanitary import requirements specified in the regulations of the importing country or on an import permit are complied with (see also section 3.2, which describes the related responsibilities of the NPPO)
– all appropriate documentation accompanies the consignment
– packaging is secure in order to prevent escape of the contents
– organisms for SIT have been treated to achieve the required sterility for SIT purposes (e.g. using irradiation with the required minimum absorbed dose). The treatment(s) used and an indication of the effectiveness of sterilization should also be provided.

5.1 Specific responsibilities regarding organisms intended for inundative release

Exporters of biological control agents or other beneficial organisms for inundative release should provide documentation on measures undertaken to ensure that levels of contamination acceptable to the importing NPPO or other responsible authority are not exceeded.

6. Responsibilities of the NPPO or other responsible authority of the importing contracting party upon import

6.1 Inspection

Where required (see section 3.1.5) after checking the documentation, inspection should take place at an officially nominated quarantine facility.

6.2 Quarantine

The NPPO should ensure that biological control agents or other beneficial organisms are cultured or reared in quarantine, if appropriate (see section 3.1.6), for as long as considered necessary.

6.3 Release

The NPPO or other responsible authority may allow biological control agents or other beneficial organisms to be passed directly for release, provided that all conditions have been complied with (particularly as described in section 3) and required documentary evidence is made available (see section 4).

7. Responsibilities of the NPPO or other responsible authority before, upon and following release

Prior to release, NPPOs or other responsible authorities are encouraged to communicate details of the intended release that may affect neighbouring countries. To facilitate information sharing in this manner, details of intended releases may also be communicated to relevant RPPOs prior to release.

If pest risk analysis was not undertaken prior to import in accordance with ISPM No. 2 (Guidelines for pest risk analysis) and/or ISPM No. 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004), it should be undertaken prior to release, taking into account uncertainties, as provided for in those standards. In addition to conducting pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

The NPPO or other responsible authority may verify the effectiveness of sterilization treatment(s) prior to release of sterile insects.

7.1 Release

The NPPO or other responsible authority should authorize and audit official requirements related to the release of biological control agents or other beneficial organisms, e.g. requirements related to release only in specific areas. This audit may be used to alter the requirements related to import or release of the organism.

7.2 Documentation

Documentation sufficient to allow trace-back of released biological control agents or other beneficial organisms should be maintained by the NPPO or other responsible authority.

7.3 Monitoring and evaluation

The NPPO or other responsible authority may monitor the release of biological control agents or other beneficial organisms in order to evaluate and, as necessary, respond to the impact on the target and non-target organisms. Where appropriate, it should include a marking system to facilitate recognition of the biological control agent (e.g. sterile insects) or other beneficial organism in comparison with the organism in its natural state and environment.

7.4 Emergency measures

The NPPO or other responsible authority of the importing contracting party is responsible for developing or adopting emergency plans or procedures, as appropriate, for use within the importing country.

Where problems are identified (i.e. unexpected harmful incidents), the NPPO or other responsible authority should consider possible measures or corrective actions and, where appropriate, ensure that they are implemented and that all relevant parties are informed.

7.5 Communication

It is recommended that the NPPO or other responsible authority ensures that local users and suppliers of biological control agents or other beneficial organisms, and farmers, farmer organizations and other stakeholders, are kept sufficiently informed and educated on the appropriate measures for their use.

7.6 Reporting

The contracting party should abide by any reporting obligations under the IPPC, e.g. where an organism used as a biological control agent or beneficial organism has shown pest characteristics.




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