Netherlands Food and Consumer
Product Safety Authority
Ministry of Agriculture,
Nature and Food Quality

Review of the registration process of macrobial biocontrol agents and products in Kenya

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Participants of the Seminar

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Contents

Preface

From 12-16 May 2019 a seminar was organised in Kenya as part of the PEAR-Kenya project to review the registration process for macrobials and macrobial products in Kenya and to identify options to strengthen and improve the registration process where necessary. The seminar was organised in collaboration with the Pest Control Product Board (PCPB) and Kenya Plant Health Inspectorate Service (KEPHIS). Antoon Loomans and Claudia Jilesen, both working at Netherlands Food and Consumer Product Safety Authority (NVWA), visited Nairobi, Kenya and convened the seminar.
The seminar was a sound approach to exchange opinions and experiences between people with different backgrounds and interests. It has brought people together that have never been at the same round table before. It was for many an eye-opener how the registration process is taking place, how the application process looks like and allowed an open-minded interaction and discussion between the various stakeholders and authorities. The seminar also gave the conveners the opportunity to experience how registration processes are organized in a country outside Europe, and allowed them to learn lessons and formulate these as take home messages as well.

Introduction

The use of natural enemies for the biological control of plant pests and invasive plants is of increasing importance. Biological control agents are explored, selected, mass-produced and transported across many countries throughout the world to be released in various programmes. Measures for the biological control of plants or plant pests using macrobials (see box 1) can include various programmes. Classical biological control, seasonal biological control, inundative biological control and conservation biological control (*sensu* Eilenberg et al., 2001) are the main categories. Only the first three categories are included for regulatory measures for the introduction and release of macrobials, as the latter focusses on the enhancement of macrobials, such as predators and parasitoids already present in the direct environment, and not a deliberate introduction and release.

Registration of macrobials and macrobial products generally consists of a highly formalized process, involving many procedures, people and actions, both for the applicant for registration as well as for the registration authority. It proceeds from the initial submission of the application by the applicant, the evaluation of the macrobial by the registration authority, to the final registration decision and the ultimate release of the macrobial. Each country, represented by their national competent authority, usually the National Plant Protection Organization (NPPO), has the legal obligation to facilitate the registration and documentation necessary for the import, export, transport and mass-production of biological control agents and other beneficial organisms (IPPC, 2017).

The National Authorities in Kenya have procedures in place for the registration of chemical substances as well as of microbials and macrobials. In collaboration with the Kenyan authorities, Wageningen University and Research has started a project in 2016 on sustainable pesticide management, i.e. the PEAR-Kenya project. The project aim is to contribute to sustainable agricultural production in Kenya. Specific aims are (i) to stimulate IPM and regulate pesticide use by farmers, taking into account the whole pesticide life cycle (from registration and procurement, import and/or local manufacture of pesticides to distribution and use, monitoring, including quality control, and waste management); (ii) to improve the structure, the clarity and the procedure of registration of plant protection products such that key products for Integrated Pest Management will be registered and on the market, without lowering (environmental) quality standards. Previously, visits and workshops have been organised for reviewing the procedures for chemical substances as well as microbials.

The objective of this seminar was to review the registration process, including risk evaluation, for macrobials and macrobial products in Kenya and to identify options to strengthen and improve the registration process if necessary. The seminar was organised in collaboration with the Pest Control Product Board (PCPB) and Kenya Plant Health Inspectorate Service (KEPHIS). Stakeholders (industry) and reviewers (university scientists) were also participating in the seminar. Basic documents, and

supporting information is given in the appendices: the programme of the seminar is provided in Annex 1, the participants list is provided in Annex 2, application forms for the registration of macrobials are given in Annex 3 (first introduction) and Annex 4 (product registration).

The Kenyan process was benchmarked against the approach for evaluation and registration of macrobial products used by other registration authorities, such as EPPO[1]/NAPPO[2] standards on Safe use of biological control (EPPO standard PM 6), individual countries such as the Netherlands and Canada, FAO/IPPC Guidelines for the registration of biological control agents (ISPM3) and general risk assessment procedures (EPPO PM6/2 (3)). Import and release of non-indigenous biological control agents).

Seminar structure

The seminar was set up in a three steps :

1. Review of the registration process currently in place in Kenya, involving the legal requirements, various related documents, and an analysis of the decision making process, including what different steps need to be taken, which actions and actors are involved, what time lines are followed and which data requirements are needed. Specific issues addressed were:
    a. How is the current process organized?
    b. How do forms for application for introduction / product release look like?
    c. Observations and remarks by the conveners on the process and documentation.
2. Review of the information currently requested: which information is needed to perform a proper risk assessment? And, do the questions asked lead to the proper information provided to perform a risk assessment?
3. Review of the information provided: once the application forms have been filled in by the applicant, is the information provided sufficient to perform a proper risk assessment? What are the criteria to evaluate respectively decide whether an agent can be introduced *c.q.* a product can be authorized? Do the answers given allow a proper risk assessment and decision making?

During the final day a field trip was organized to Real IPM Kenya in Thika, producer of biological control agents in Kenya, to visit the production facilities and mass rearing on site and to discuss the practical experiences from a producer's perspective.

Set up of the report

Chapter 1 describes the regulations currently in place for macrobial registration in Kenya, chapter 2 summarizes the results of the seminar and chapter 3 contains conclusions and recommendations to strengthen and improve the registration process for macro-biological organisms and their products.

[1] European and Mediterranean Plant Protection Organization (www.eppo.int)
[2] North American Plant Protection Organization (http://www.nappo.org/)

Box 1 Terminology

Regulation

Regulation of biological control agents applies to those measures that imply active import, transport and/or release of natural enemies for the control of plants or plant pest, e.g. classical, seasonal and inundative biological control programs where natural enemies are actively released. It does not apply to conservation or natural biological control, where natural enemies are already present in the environment and measures taken are directed to stimulate their presence and enhancement of their efficacy.

Macrobials

The term macro-biological control agents (abbreviated as macrobial) is used for natural enemies and beneficial organisms which are capable of self-replication, such as predators, parasitoids, parasites, phytophagous organisms, and nematodes. In this report we will further use the term "macrobial". It is restricted to living arthropods (such as insects, mites) and nematodes used for the control of plant pests and/ or invasive plants (Eilenberg et al., 2001) in different control programs.

From a regulatory perspective the term macrobial is used here when such agents, either as a living organism or a commercial product containing a living organism, are transported, imported, tested and /or released for the biological control of plant pests and invasive plants.

Pest control product

The term pest control product is used here as defined by PCPB as a product, device, organism, substance, or thing that is manufactured , represented , sold, or used as a means for directly or indirectly controlling, preventing, destroying, attracting, or repelling any pest. It may include conventional chemical pesticides, biopesticides, botanicals, biochemicals, micro-organisms and macro-organisms, or any compound or substance that enhances or modifies the physical or chemical characteristics of a pest control product to which it is added e.g. adjuvants and wetting agents.

1 Regulatory basis for registration of macrobials in Kenya

1.1 Regulatory authorities of Kenya

The Kenyan authorities currently have implemented the registration of macrobials and their products along two regulatory processes: first, the registration of macrobials upon import, second the registration of products containing macrobials. Two independent governmental organizations are responsible for each of these regulatory processes: The Kenya Standing Technical Committee for Import and Exports (KSTCIE) is responsible for the registration of macrobials upon import. The Kenya Plant Health Inspectorate Service (KEPHIS) serves as the secretariat. The Pest Control Products Board (PCPB) is responsible the registration of products containing macrobials. In Box 2 information on governmental organizations involved in the registration of macrobials is given.

Box 2 Governmental organisations involved in the registration of macrobials

Kenya Plant Health Inspectorate Service (KEPHIS) is the government parastatal whose responsibility is to assure the quality of agricultural inputs and produce to prevent adverse impact on the economy, the environment and human health. It is the official National Plant Protection Organisation for Kenya.

Kenya Plant Health Inspectorate Service

The Pest Control Products Board (PCPB) is a Statutory organisation of the Kenya Government to regulate the importation and exportation, manufacture, distribution and use of all pest control products.

Kenya Standing Technical Committee for Import and Exports (KSTCIE) is a Risk Analysis Committee. It is chaired by Ministry of Agriculture Livestock and Fisheries. KEPHIS serves as the secretariat. Members of KSTCIE include regulators and public institutions like PCPB, Kenya Agriculture and Livestock Research Organisation (KALRO), Directorate of Veterinary Services (DVS), Ministry of Public Health and Sanitation (MPHS), National Environmental Management Organisation (NEMA), National Museums of Kenya (NMK), private industry players (like IBMA) and scientific institutions like universities.

The role of the KSTCIE is to facilitate the safe import, shipment and release of biological control agents and other organisms through risk assessment, to provide recommendations for approval that address the safe handling, assessment and use of the organisms or products containing organisms while implementing appropriate sanitary and phytosanitary measures under existing regulations and to encourage responsible trade practices.

The scope of the KSTCIE includes biological control agents capable of self-replication like parasitoids, predators, parasites, nematodes, phytophagous organisms and pathogens such as fungi, bacteria and viruses, microorganisms (packaged or formulated as commercial products). It also includes regulate introductions intended for research (trials), commercialization and personal use.

2 Results of the seminar

2.1 Review of the registration process currently in place in Kenya

2.1.1 Seminar process followed

The first step was to establish the registration process currently in place in Kenya. Presentations from different perspectives were given:

1. KSTCIE (Ms. Kabole) on the process of macrobial biocontrol registration and an update of the regulation under development for macrobial products;
2. PCPB (Dr. Paul Ngaruiya) on product registration of macrobial biocontrol products;
3. Mr. Geoffrey Ongoya (IBMA) presented the industry perspective on the application process.
4. Mr. Loomans & Ms. Jilesen (NVWA) presented the international benchmarking (EPPO and The Netherlands and other countries).

The presentations were followed by a round table discussion, in which procedures for evaluation of risks and efficacy in Kenya were clarified step by step: the procedures for the introduction of beneficial organisms as an agent and/or product into Kenya (KSCTIE), and the procedures for registration and use of a macrobial as a pest control product (PCPB), how both relate to one another and what actors are involved and at which step decisions are made. Based on these discussions the process was analysed and finally summarized.

Presentations and discussions are summarized below, see Annex 5 for an overview.

2.1.2 First introduction of a macrobial in Kenya

When an institution, producer, company or other legal entity wants to import and introduce a macrobial as a species and/or as a product into Kenya for the first time, (s)he needs to seek clearance from the Kenya Standing Technical Committee on Imports and Exports on live organisms (KSTCIE), using an application form, specifying the requirements and supporting information, as shown in Annex 3. An applicant who is not a resident in Kenya must appoint an authorised local agent permanently resident in Kenya. The applicant is also required to submit a sample of the macrobial for the National Museums of Kenya or obtain a National Collection Number if already in collection. An additional sample should be sent to a National Agricultural Research Laboratory (NARL), the Biological Control Unit Muguga (KARI) and KEPHIS.

After receiving the application, the registration process proceeds in the following steps: KEPHIS, holding the secretariat for KSTCIE, checks the application and supporting documents for completeness, and subsequently distributes the application to its members (see Box 2) to review the dossier and conduct a risk assessment. Subsequently KEPHIS schedules and prepares the revised application for the next meeting of the KSTCIE committee. During the meeting of the KSTCIE committee, chaired by the Ministry

of Agriculture, members discuss and amend the dossier where necessary. Recommendations are drafted for the KSTCIE main committee meeting, where a decision is made on approval or rejection of the application. During the whole process the secretariat at KEPHIS coordinates and communicates to the committee members and applicants.

Once approved, the applicant can test or use the macrobial organism or the product containing the macrobial for research or for private use. When used in a classical biocontrol program, the research institution conducts host range tests under confined conditions and once considered safe, trials are conducted under semi-field conditions at verified institutions to assess its efficacy (see Figure 1, green fields).

2.1.3 Application of product containing a macrobial in Kenya

Once a macrobial has been approved for introduction into Kenya, and part of a product available for commercial use, it is mandatory by Kenyan law[3] to register all pest control products (see for definition Box 1) including those containing a macrobial (National Council for Law Reporting, 2012). In Kenya the Pest Control Product Board (PCPB) regulates the importation and exportation, manufacturing, distribution and use of Pest Control Products. A wide range of products are regulated, including macrobials used for pest control, to ensure its safety as well as its efficacy. An applicant who is not a resident in Kenya must appoint a single authorised local agent permanently resident in Kenya. After pre-consultation with the local agent an application for registration including the import licence and a full technical dossier must be prepared according to the guidelines available[4] and submitted at PCPB. After a check of completeness the application is evaluated, based on information provided in the technical dossier, including environmental safety, safety for human health, and proposed formulation and label. In case the application is approved, the product is granted experimental permit for local biological efficacy trials. These trials are conducted in institutions that are accredited by PCPB, currently 54, taking into account conditions set by KSTCIE and PCPB.

On completion of the biological efficacy trials, reports are sent to the registration department which makes recommendations to the PCPB board. Upon approval of the report and the commercial label by the Board, a full registration is granted for three years and a certificate of registration issued, one month after notification. Currently 1708 products are registered[5], of which 19 are based on a macrobial organism (14 different species in total). Ten products contain predatory mites (seven species), one product contains a predatory beetle, five products contain parasitic wasps (five species) and three products contain entomopathogenic nematodes (two species). In Table 1 an overview of the registered macrobials in Kenya is given.

[3] Pest Control Products Act. Chapter 346, Revised Edition 2012 [1985]. Section 4 Import, export, etc., of pest control products. (1) No person shall import into, or sell in, Kenya any pest control product unless that product has been registered, packaged and labelled in accordance with regulations made under this Act and conforms to the standards specified in those regulations.

[4] Available at http://pcpb.go.ke/application-forms/ "Form A2 Biopesticides Macrobials" and data requirements, gazetted in 2006 & 2015.

[5] http://pcpb.go.ke/crops/

Table 1: Overview of macrobials registrered in Kenya (May 2019)

PCPB Registration number	Type	Macrobial	Target pest	Crops
PCPB(CR)1595	Predatory mite	*Amblydromalus limonicus*	whiteflies	Roses (greenhouses)
PCPB(CR)1014		*Amblyseious cucumeris**	flower thrips, spider mites	Carnations
PCPB(CR)1104		*Amblyseious cucumeris**	flower thrips, spider mites	Carnations (greenhouses)
PCPB(CR)1344		*Amblyseius cucumeris*	thrips	Carnation
PCPB(CR)1769		*Amblyseius andersoni*	spider mites	Roses
PCPB(CR)0300		*Amblyseius californicus*	red spider mites (*T. urticae*); spider mites	Roses, vegetables
PCPB(CR)0726		*Amblyseius swirskii*	whiteflies	Roses
PCPB(CR)1417		*Hypoaspis miles*	thrips	Roses
PCPB(CR)0299		*Phytoseiulus persimilis*	spider mites (*T. urticae*)	Roses, vegetables
PCPB(CR)0727		*Phytoseiulus persimilis*	red spider mites	Roses, French beans
PCPB(CR)1636	Predatory beetle	*Cryptolaemus montrouzieri*	mealy bugs	Roses
PCPB(CR)0303	Parasitic wasp	*Aphidius transcaspinus*	aphids (*Acrosiphum* & *Aphis* spp.)	Vegetables
PCPB(CR)1067		*Coccidoxenoides perminutus*	mealybugs	Roses
PCPB(CR)0301		*Diglyphus isaea*	leafminer (*Liriomyza* spp.)	Flowers, vegetables
PCPB(CR)0302		*Encarsia formosa*	whiteflies (*Trialeurodes* spp.)	Flowers, vegetables
PCPB(CR)0748		*Eretmocerus eremicus*	whiteflies (*T. vaporariorum, B. tabaci*)	Greenhouses
PCPB(CR)1366	Nematode	*Steinernema carpocapsae*	caterpillars	Roses
PCPB(CR)0715		*Steinernema feltiae*	thrips, leaf miner, cutworms, sciarid flies	Carnations
PCPB(CR)1215		*Steinernema feltiae*	sciarid flies	Lisianthus

* incorrect spelling

2.1.4 Industry perspective on the application process

IBMA-Kenya (International Bio-control Manufacturers Association in Kenya) stressed the importance of having a good and well aligned registration procedure in place. To their opinion is the existing regulation – based on a general template of application for products - of macrobial organisms as biological control agents often is not appropriate for these agents and/or products and the registration process needs further harmonization. A few points IBMA addressed to improve the registration process were a need for a) harmonizing the risk assessment procedure to shorten the time taken for an application compared to the conventional products, b) adjusting the information requirement documents for macrobials (an microbials) in specific and c) consider efficacy testing per crop group instead of per crop. In addition, the use of waivers should be promoted and these 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.

2.1.5 International benchmarking

Worldwide there are two legislative standards that provide guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms (FAO, 1996; IPPC, 2017) and that protect native habitats and indigenous species from invading species (CBD, 1992). These standards are the basic frameworks worldwide for competent authorities in different regions – such as the European Union – and individual countries - such as the Netherlands and Kenya - to develop and implement national legislation and regulations. The European Union has no legislation in place that is tailor-made for macrobial biological control agents, and it is up to each country to draft its own regulation. Because regulation for macrobials is based on either plant health (IPPC, 2017) or environmental legislation (CBD), it may follow two different approaches. Registration procedures differ from one country to another depending on which legislation and regulations are nationally in place. There is a basic need, from a country perspective as well as from the perspective of an applicant, to harmonize procedures and the information requirements where possible. During the presentation examples were given how organizations such as EPPO and NAPPO harmonize this process and how individual countries such as the Netherlands and Canada have drafted and implemented the registration process (EPPO, 1999, 2014ab, 2016, 2018; NAPPO 2019abcd) (see Table 1). Examples presented e.g. by Mason et al (2017) were used as a benchmark for discussions, for comparison with the procedures and information requirements currently in place in Kenya and as suggestions for improvement of the Kenyan registration process (see Annex 6).

2.1.6 Time budget for registration

When applying for a first introduction of a macrobial into Kenya, it takes at least three months to review the dossier and to decide whether an application will be granted or not (KSTCIE committee) and an import permit of a macrobial can be licensed. For classical biological control purposes, efficacy testing takes place in contained conditions. Testing needs at least one generation to control contaminations if any, and host range assessment in the laboratory to verify the agents host specificity. This assessment can take months (in case of commercial products) to a number of years (in case of release of a classical biocontrol agent). Completion of efficacy testing includes a two or three fold life cycle in the laboratory, and three months greenhouse trials before the agent is ready for release into field trials.
When an application is made for registration as a plant protection product in Kenya it takes at least one to three years before a product is allowed on the market for a specific use, c.q. a crop. The relative long time is needed for planning and evaluating efficacy trials, which can depend on the season, availability of crops and number of repetitions to be made. Once approved the product is registered for an unlimited period of time.

2.1.7 Observations and remarks by the conveners

When the various national legislations for macrobials in Europe and Kenya are placed in perspective, it can be concluded that they all follow the international frameworks as drafted by IPPC (2017) and CBD (1992). Like most countries, Kenya implemented these requirements according to its own national legislation and regulations, having its national procedures, following its own processes for registration of macrobials and having its own application forms. Kenya has a clear structure that requires registration for introduction and release for research, classical biological control and for private use, and for releases as part of a commercial product. This has the advantage that it allows to separate both processes and allows a review on safety and efficacy and registration before a macrobial is introduced. This is unlike the European procedures where most countries do not require a registration at import (see Table 2), and where macrobials are reviewed when released commercially as a product, whether they contribute to pest and disease control or not. Figure 1 summarizes how the different regulatory processes, the interdisciplinary steps and processes for registration of macrobial organisms in Kenya are organized for first introduction and for commercial release.

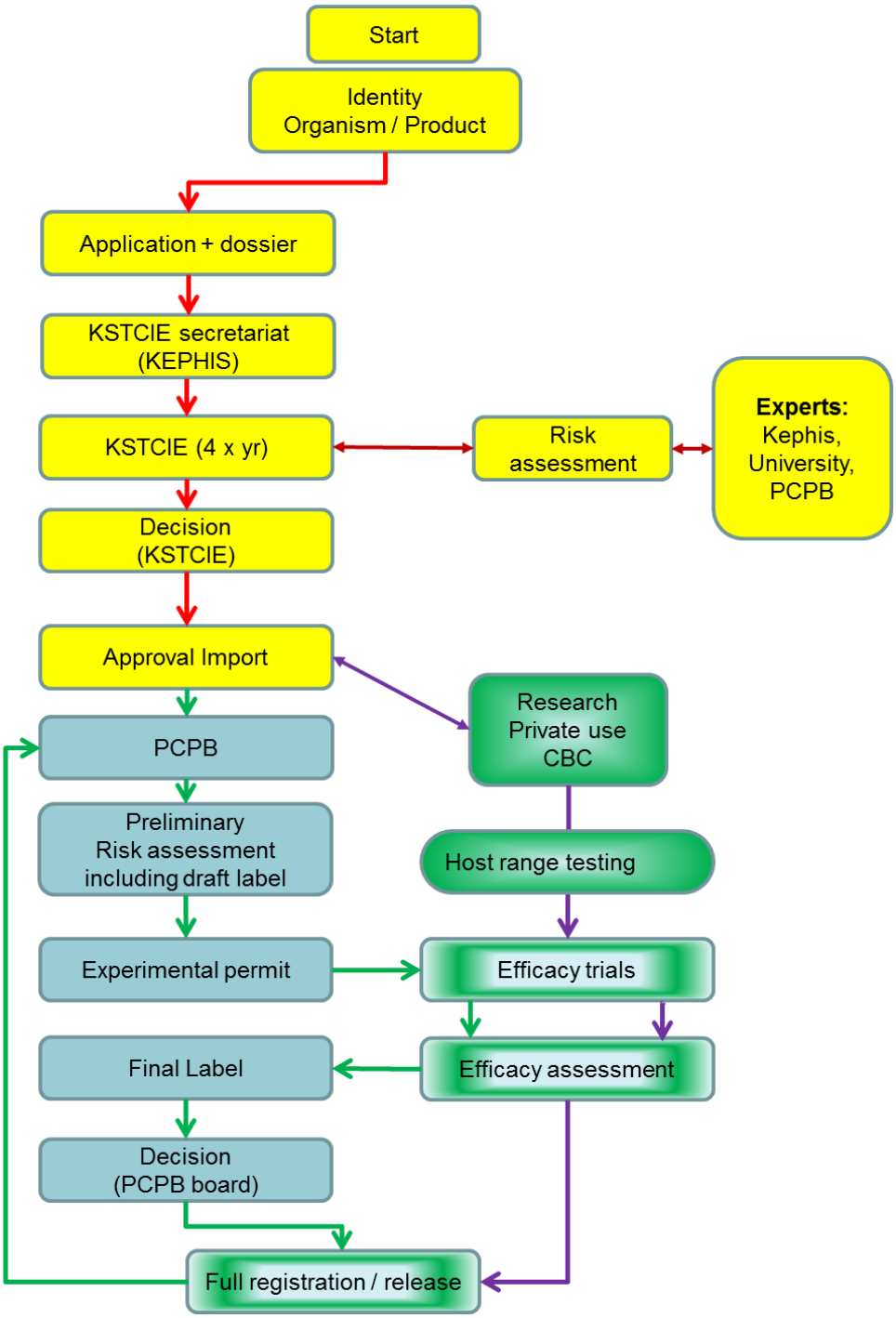

Figure 1 : Schematic overview of the interdisciplinary steps and processes for registration of macrobial organisms in Kenya. In yellow - procedures for the introduction of beneficial organisms as an agent and/or product into Kenya (KSCTIE), in blue - the procedures for registration and use of a macrobial as a pest control product (PCPB), in green experimental trials in lab and / or field on risk assessment and efficacy (for abbreviations Annex 4). The color of arrows indicates decision making process: first application for import (red), registration as a plant protection product (green), registration as a classical biocontrol agent (purple).

2.2 Review of the information currently requested

During the second day the application forms were discussed and assessed. Furthermore, information that is currently required, and whether the information given allows a proper assessment or safety and efficacy was evaluated.

2.2.1 Application forms main structure

Both for a first introduction of a macrobial into Kenya as well as for registration as a commercial product to be sold on the Kenyan market a registration is required (see Application forms in Annex 3 resp. Annex 4). Both registration procedures include data requirements related to efficacy (to assess whether it can control the target pest) as well as on safety (to assess risks to human, animal, plant and environmental health) of the macrobial organism as a species and/or product. This in contradiction to e.g. requirements for a number of European countries (such as the Netherlands) where no efficacy data are required for the release of a macrobial and no field trials are required in most countries (see Table 2).

Application forms used in Kenya (Annex 3 and 4) consist of different parts:

1. Part 1 - request for information data, such as names, addresses of applicants (the VISA application questions, no-choice);
2. Part 2 - Information on the identity of the macrobial organism, of the product, purposes of use, with multiple options as an answer, etc.;
3. Part 3 - Request for scientific data from research, literature or experience, which requires specific scientific knowledge and experience to interpret, analyse, evaluate and review these data to form an opinion on the safety and efficacy of the macrobial;
4. Part 4 - Supporting information, such as reports, copies of literature, identity and identification methods;
5. Part 5 - Declarations and signatures.

Most of these categories of information requirements are straightforward, except part 3 and sometimes part 2 where expertise and expert judgement of the reviewer is required.

2.2.2 Risk assessment, data requirements and international benchmarking

In all biocontrol programmes where macrobials are released, a risk assessment on environmental safety is required for non-native species, and on occasion even for non-native strains (e.g. France) of a native species as well. Many countries require a risk assessment for introduction of any macrobial species, whether native or non-native. Which information is required depends on whether the macrobial species is native to the country of release or not. The purpose of the biocontrol program, whether establishment of the agent is required, like in classical biological control (CBC), or not is also relevant.

An Environmental Risk Assessment (ERA) starts with the correct identification of the macrobial agent, either by an expert, experienced with the specific taxon, or by a validated molecular method, typing or test. Subsequently the following biological and ecological determinants are reviewed and evaluated to assess if and what impact introduction and release of the macrobial has on the environment (Mason et al., 2017):

- the ability to establish and spread in the country of release;
- the width of the host or prey range;
- the direct and indirect effects on human and animal health;
- the direct and indirect effects on non-target species and habitats.

The application forms used should be designed in a way that the desired information is brought forward, to allow an unambiguous, in unison assessment of the risks of introduction and use, to weigh the benefits of introduction and release, and how to mitigate risks once a permit has been licensed. EPPO, as well as NAPPO standards on safe use of biological control provide NPPOs with guidelines for import, containment, first release and /or certification when released commercially (EPPO 1999, 2014, 2016, 2018 PM 6; NAPPO 2018abcd).

The information required in Kenya for assessment of risks mentioned for first introduction (see Annex 3, part B) in general follow the international guidelines. During the seminar the different application forms (KEPHIS, PCPB) and the information that is required were compared and benchmarked against EPPO guidelines. EPPO guidelines are drafted to harmonize and structure the wide variety of requirements in Europe. In Annex 6 a summary of the findings is provided in a comprehensive table. It was observed that document structures are different and depend on the type of organism and purpose of application. The information requested is by and large similar, but differ in wording, description and paragraph where it is placed.

2.2.3 Efficacy assessment, data requirements and international benchmarking

Data on efficacy is in Kenya required for two specific cases: releases for classic biological control (CBC)[6] and for the authorisation of a macrobial product.

For releases for CBC purposes it is crucial that the released agent will establish and is able to control the target pest(s). When the macrobial is not effective (and not able to reproduce in nature) there is no added value of the release. Efficacy trials are conducted by accredited institutions after an approval for import given by KSTCIE. Depending on the risks trials are conducted under laboratory conditions and in greenhouses in containment. Before releasing in field trials a risk evaluation is done by KEPHIS.

[6] Classic biological control (CBC) is the intentional introduction of an exotic biological control agent for permanent establishment and long-term pest control to an area that the pest has invaded. The aim is to restore the balance between pest and natural enemy populations that was lost when the pest moved to the new geographical area without its enemies (Eilenberg et al., 2001).

After a positive evaluation, releases of macrobials are allowed in field trials. There is a follow up period of at least three years.

For the authorisation of a macrobial product in Kenya efficacy needs to be proven. An experimental permit for conducting local biological efficacy trials is needed. The PCPB performs a preliminary risk assessment and decides whether an experimental permit is granted. After the experimental permit is granted, efficacy trials are conducted by institutions that have been accredited by the PCPB. For living organisms, conditions set by KSTCIE need to be taken into account, e.g. the presents of a double door system. In total efficacy data of two to three seasons needs to be submitted. For example for roses, a period of seven weeks (= 1 flush) is regarded as one season. The applicant should write a summary dossier for efficacy. If efficacy is not, or not sufficiently proven, PCPB can suspend or revoke a certificate of registration.

Efficacy evaluation of macrobials is not required in most countries in the EU, including the Netherlands. The evaluation of macrobials is particularly based on **risks** to agricultural and natural ecosystems. If there are no risks for the environment, releasing of macrobials is often permitted without any efficacy evaluation. Efficacy requirements, if any, are nationally driven.

The aim of the EPPO standards on safe use of biological control (PM 6) is to provide NPPOs with guidelines for **assessing and reducing the risks** associated with various aspects of the introduction and use of biological control agents and, as appropriate, for **comparing** them with the **benefits in terms of efficacy**. However, limited guidance in given in these EPPO standards on how efficacy trials should be conducted and how benefits of macrobials can be evaluated.

For conventional, chemical products there is a legal EU requirement (EC Regulation 1107/2009) to prove that a product is efficacious. EPPO has developed (more than 300) standards which describe how to conduct of field and glasshouse trials to assess the efficacy of plant protection products against specific pests by comparison with reference product(s). In Box 3 efficacy is defined. Conventional, chemical products are less specific in the pests that they affect, and less dependent of environmental conditions to reach optimal efficacy as compared to e.g. plant protection products based on microbials or macrobials. The farmer has quite a big influence on the success of the application and the predictability of the result of the treatment is often quite high. Extrapolation from results in a limited number of small scaled efficacy trials to field situations is often reliable. For the efficacy of macrobials the influence on the success of the 'treatment' and the predictability of the 'treatment' is much lower. Efficacy is highly depending on the biological activity of the macrobial which can depend on environmental conditions, crop type etc. Extrapolation based on a limited number of small scaled efficacy trials to field situations is less reliable.

Box 3 Efficacy

Definition

Efficacy can be defined by an equation in which the positive effects of the treatment in performing the desired plant protection activity (e.g. controlling the target pest or modifying crop growth) and any other useful effect, such as controlling other non-target pests, are balanced against the negative effects, such as direct damage to the crop (phytotoxicity) or effects on pollinators and natural enemies, or development of resistance.

Efficacy of plant protection products can therefore be a balance between the following points:

- The positive effects of treatment in performing the desired plant protection activity to fulfil the claims made on the proposed label, in order to achieve improvement in the quantity and/or quality of the crop;
- Any negative effects, such as reduction of quality or quantity of yield, phytotoxicity, taint, transformation processes, damage to beneficial organisms, damage to succeeding or adjacent crops, development of resistance;
- Other aspects of efficacy which, depending on the product, can be either positive or negative; these include effects on non-target pests, the length of time for which the plant protection product continues to be active, its ease of use, and compatibility with cultural practices and other crop protection measures.

For efficacy a parallel can be drawn between the level of efficacy of low-risk plant protection products[7] and the level of efficacy of macrobials. When the risks of macrobials to the environment are low, the principles for efficacy and acceptable level of efficacy described in EPPO standard PP 1/296 (1) Principles of efficacy evaluation for low-risk plant protection products may also apply for macrobials. The primary criterion of acceptable efficacy is that the product should show an effect that is significantly superior to those recorded in the untreated control, i.e. that the use of the product is better than no use. Rather than looking at the efficacy of the individual macrobial, the contribution to sustainable agriculture including compatibility and function within an IPM program such as preventing or delaying the development of resistance against existing plant protection products should preferably be taken into account.

2.2.4 International benchmarking data requirements

In contrast to the procedures in place in Kenya in most of the European countries (such as the Netherlands) no efficacy data are required for the release of a macrobial and no field trials are required Table 2 provides an overview of the requirements used in 27 countries in Europe. There is a large variation in requirement on risk assessment and efficacy requirements. Only one country requires a permit for import. All countries make a risk assessment, 17 for organism of any (including native) origin, the other 10 only for non-native species or strains (France). For eight countries a risk assessment is made for each product, five of which need a registration per product, and three of

[7] products with low risk to human and animal health and the environment.

which require efficacy testing per crop group. Concerning the information data required seven countries have implemented the EPPO PM6/2 guidelines (Finland, France, Ireland, the Netherlands, Slovenia, Spain, UK), three countries (Greece, Latvia, Switzerland) follow these partly, whereas three countries have their own national requirements. For many (14) countries it is unclear what the data requirements are. The period between submission to official notification of approval or denial varies according to country and the consultation steps required, and may take three months (Latvia, Netherlands) to one year. Each country may have additional requirements that must be included in a submission. Those countries that require efficacy testing the procedure takes more time, from two (Austria, Switzerland) to five years (Spain).

Table 2 Overview of how 27 different European (24 EU, Switzerland, Norway, Iceland) countries have organized their registration procedure (based on preliminary questionnaire, EPPO 2018)

Country	Environmental assessment	Positive list	Origin	Data requirements	Import permit	Product registration	Organism or product	Length procedure	Efficacy data
Austria	yes	no	all origins	national	no	yes	product	1-2 years	crop group
Belgium	no	no	all origins	?	no	no	?	?	no
Bulgaria	yes	yes	all origins	?	no	no	organism	?	no
Croatia	yes	yes	all origins	?	?	?	?	?	no
Czech republic	yes	no	all origins	national	no	no	product	?	no
Denmark	yes	no	non-natives	?	no	no	organism	?	no
Estonia	no	no	all origins	?	no	no	?	?	no
Finland	yes	yes	non-natives	EPPO	no	no	organism	<6 months	no
France	yes	no	non-native strains	EPPO	no	no	organism	<1 year	no
Germany	no	no	all origins	?	no	no	?	?	no
Greece	yes	no	all origins	national (EPPO)	no	yes	product	?	no
Hungary	yes	no	non-natives	national	no	no	organism	?	no
Iceland	yes	no	non-natives	?	?	?	?	?	no
Ireland	yes	no	non-natives	EPPO	no	no	organism	<1 year	no
Italy	yes	no	non-natives	?	no	no	?	?	no
Latvia	yes	no	all origins	National (EPPO)	no	no	product	<3 months	no
Luxembourg	yes	no	non-natives	?	?	?	?	?	no
Netherlands	yes	yes	all origins	EPPO	no	no	organism	<3 months	no
Norway	yes	no	all origins	?	no	yes	product	<1 year	no
Poland	no	no	all origins	?	no	no	?	?	no
Portugal	no	no	all origins	?	no	no	?	?	no
Slovakia	no	no	all origins	?	yes	no	product	?	no
Slovenia	yes	no	non-natives	EPPO	no	no	organism	?	no

Country	Environmental assessment	Positive list	Origin	Data requirements	Import permit	Product registration	Organism or product	Length procedure	Efficacy data
Spain	yes	no	all origins	EPPO	no	yes	product	1-5 years	crop group
Sweden	yes	yes	all origins	?	no	no	organism	?	no
Switzerland	yes	no	all origins	National (EPPO)	no	yes	product	2 years	crop group
UK	yes	no	non-natives	EPPO	no	no	organism	<1 year	no

2.2.5 Observations and recommendations conveners

1. Both types of application, for first introduction and for product registration, are independently organized, and for both processes quite similar. However, not the exact same information is required, which causes confusion and an unnecessary delay in the registration process. We recommend to review the applications forms of KSTCIE and PCPB, compare wording and where possible consider the use of the same wording. The EPPO guidances can be used as reference (see Annex 5).
2. Whereas the application for the registration of a macrobial pest control product of PCPB (Annex 4) has extensive guidance on what information is required, the application form for introduction of biopesticides and beneficial organisms in Kenya (Annex 3) lacks guidance on when and what information is needed. We recommend to develop additional guidance.
3. The current application forms relate to all types of introductions in Kenya: microbials, macrobials, species and products. Separate application forms for each type of application will help to clarify which information is required for which type of introduction and prevents that information that is not relevant for a certain type of application is required.
4. As for the application form for first introduction (KSTCIE) it was noticed that:
    a. The paragraphs are clearly structured (general information, details organism, identity and information of product, safety information, project plan and declaration), and the relevant information is asked in the various parts. However, the order and organization of the different text boxes in each part can be improved. For example Part B, question 14 ('Information whether a macrobial is a GMO') is more relevant at the start, under Part A. Other parts may be placed in a different order, with a preference to cluster and highlight those parts that require data or scientific evidence (such as host range, specificity, effect on non-target species) for which expert knowledge and judgement is required.
    b. In part C the additional information requested for the organism in the product (e.g. C8-11), has already been requested in part B for the organism as a species (B11-20). This needs clarification or simplification.
5. As for the application form for the registration (PCPB) it is noticed that:

a. The information required for the active agent (Form A2, list MI)is in some parts identical to the information required for the formulated product (Form A2, list MII). For example, on identity ($1), biological properties, further information, biosafety , environmental safety and behavior in the environment. Try to avoid duplication of data requirements.
b. A number of sections in Form A2 MII specifically relate the formulated product and are not relevant for macrobials, such as sections 2 (physical and chemical properties), section 8 (intended uses), section 9 (minimal label requirements), section 10 (Evidence in other countries), section 11 (other specific requirements), section 12 (proposed packaging and section 13 (procedures of destruction and decontamination). A separate Form may be compiled for macrobials.
c. The provided guidance is detailed, but not always elucidates what is exactly requested. Some of the remarks specify what is required, some are general remarks ("provide any relevant information", "provide details") without specifying what is exactly required. More specific guidance will help the applicant to understand what information is requested.

Much clarity can be gained by evaluating the current application form A2, restructure the different paragraphs and fields, and avoid that the same information is requested twice. An update of the guidance, including adjustment on what information is required specifically for each question, and an indication when a question is optional or not, will allow a better understanding and a more straightforward application.

6. Regarding efficacy we suggest to take into consideration the following aspects:
a. Efficacy is evaluated for macrobials in Kenya as part of the registration process. In other parts of the world (e.g. North America and most European countries) efficacy of macrobials is rarely evaluated. It can be taken in consideration that when a macrobial has shown a low risk for the environment (as a result from the risk assessment), efficacy is not a requirement for the registration process. I may still be useful to gain information on efficacy for advisory purposes.
b. Rather than looking at the efficacy of the individual macrobial, the contribution to sustainable agriculture including compatibility and function within an IPM program such as preventing or delaying the development of resistance against existing plant protection products should be taken into account.
c. When a risk assessment has shown a low risk for the environment, the primary criterion of acceptable efficacy should be that the efficacy of the macrobial is significantly superior to those recorded in the untreated control, i.e. that the use of the macrobial is better than no use.

2.3 Review of the information provided

During the meeting the information currently required by the Kenyan authorities (Annex 3 and 4) was discussed and compared with those required by EPPO (2014). Only general remarks are given as only limited time was available to discuss the review of the provided information.

Upon application, a check for completeness and a preliminary assessment of the information provided needs to be reviewed by trained specialists (see also Figure 1). It is crucial for a univocal review that the basic information supplied by the applicant is valid, science based and sufficient to allow an optimal quality of safety/risk as well as efficacy assessment. The information provided by the applicant should allow the individual reviewer, complemented with their specific knowledge of the macrobial and product, to assess whether the macrobial is safe, moderately safe or unsafe and or whether the product contributes to an effective control of the target organisms and to what level. During an Environmental Risk Assessment (ERA) the information made available should allow to assess whether the macrobial is able to establish and spread in the country of release, what is the width of the host or prey range, and whether there are any direct and indirect effect on non-target species and habitats expected in the areas of release.

2.3.1 Observations and recommendations by the conveners

During the final wrap-up of the seminar, participants addressed a number of topics which still needed attention, were beyond the scope of this seminar or had not been addressed during the workshop in particular.

1. Application and registration

- The Kenyan authorities can take advantage of the experience of other countries or organizations, such as EPPO and NAPPO, in developing an internationally harmonized approach and procedures for regulating macrobial biological control agents. For instance which species are already permitted for release, or registered elsewhere (e.g. The Netherlands) for classical and/or commercial releases, and consider a fast-track procedure for such organisms.
- An update of the current application forms for the registration of macrobials in Kenya would enhance a better understanding on how to interpret the questions, where information is needed and where scientific data are required. This will result in a better information supply and improve the current registration process. Furthermore, new specific guidance for introduction of macrobials (KSTCIE procedure) is recommended, the guidance for PCPB may be tweaked.
- Development of a specific form for release for research (not for commercialization), indicating what are the differences between research and commercial use, and clarifying how a positive control should look like.

- Domestication of the guidelines will allow optimal efficacy tests under local conditions, level of acceptance efficacy product (not to chemicals) and risks (no risk is not zero, compare to..)
- Harmonization of registration procedures and/or requirements between East African countries would allow an exchange of information and facilitate the registration process elsewhere.
- Determine criteria for a positive list, not well known what is native and what introduced
- For a good understanding and implementation of the application and registration procedures it would be good to formalize a meeting between authorities and stakeholders, to show what science is behind the whole registration process, efficacy testing and risk assessment,
- Including a training or curriculum for university students on biological control would contribute to a better support and acceptance of biocontrol as a significant contribution to IPM.

2. Diagnostics - There is a need for capacity building, on identification of pests and diseases (species as well as products) based on morphology as well as molecular analysis, tools to assess whether organisms are dead or alive (infectious), quality assurance measures for diagnostics such as methods of validation for specimen, establishment of a reference collection.
3. Capacity building - Database of experts on regulators, specialists, e.g. similar to the reference database of IOBC, exemption lists, based on clear criteria

2.4 Field trip

Thursday a field trip was organized to visit to the production facilities of Real IPM in Thika, north of Nairobi. Real IPM is a Kenya registered company, with 300 employees, and was founded in 2003, and since 2017 part of BioBest. Real IPM has two production sites, in Thika (20 ha) and in Embu (25 ha), mainly of *Phytoseiulus persimilis*, but in Thika it also produces other macrobials (*Neoseiulus cucumeris* and *Neoseiulus californicus*) as well as microbials. The products are largely sold on the African market, part of the production is exported to Europe. Within Kenya and Ethiopia products can be sold directly, for other countries (Uganda, Rwanda, South Africa, Tanzania and west-African countries) registration is required, but not to Europe. Real IPM is also accredited by PCPB as an official institution for local efficacy trials of chemical and biological products.

Quality control - To control purity and contamination each mass-rearing is started from a mother stock culture, every 3 months for microbials, for macrobials every year a new stock is coming in from CABI UK. People are trained in recognizing the organisms, samples are verified every 6 months by Real IPM, KEPHIS inspects products on a regular basis. When exported to the UK and Belgium a quality control check is carried out on the imported produce from Kenya before being sold on the European market.

3 Conclusions and recommendations

3.1 Recommendations by participants

- Registration process and application procedures for macrobials should be as simple and straightforward as possible.
- Pre-application meetings could help to assist applicants in the registration of macrobials. A follow-up meeting of stakeholders like this seminar will help in a common understanding of the use and implementation of macrobials in Kenya.
- Developing guidelines for application will have an additional value in the registration process of macrobials, preferably tailor-made for the domestic Kenyan situation, and east Africa respectively.

3.2 Main recommendations by the conveners

- Make the registration process and application procedures as simple as possible. Open direct communication lines, such as a webpage and a helpdesk, to assist applicants in the registration of macrobials. Creating a support line or pre-submission meetings with applicants will increase the understanding of the what and why of macrobial registration.
- Registration process: Interactions between the different authorities (KEPHIS, PCPB) will help to facilitate the application process. Creation of a positive list – macrobials of low risk, and high efficacy – based on sound criteria, will enhance and broaden the implementation of biocontrol.
- Applications: To better facilitate the application process, guidance is of great importance to inform the applicant what information is required, in which detail. The current forms used, take account of most relevant questions and required information. However, a restructuring of the organisation of information requested in related clusters could greatly increase the understanding of what type of data is needed, such as already known data on distribution, origin, hosts, etc. and data that need to be selected or generated and interpreted during the review. Applications for first introduction are still in need for such a guidance. Guidance for application forms for product registration are available already, but could be designed more tailor-made to the questions asked.
- Review: safety and efficacy assessments rely on the expert judgement and interpretation of science based data. To facilitate an adequate information supply, it will be helpful to indicate which fields are essential for weighing the safety and efficacy during the review and assessment process.
- Capacity building and education: creating a curriculum on biological control for university students to teach on the essentials of science based research on searching efficacious natural enemies for biological control. Education for advisors and farmers on when and how to apply macrobials, could build the capacity to integrate biocontrol in the IPM programme currently enrolled.

4 Acknowledgements

The conveners of the seminar would like to thank all participants for an open discussions, and a constructive participation. In specific Paul Ngaruiya (PCPB) and Mellon Kabole (KEPHIS) for presenting the current registration process for macrobials in Kenya and Geoffrey Ongoya (IBMA) for sharing the producers view on the process of registration process, and their patience for explaining what was not clear directly to us. Sam Ngugi (Real IPM) is greatly thanked for organizing the field trip at Real IPM, and showing the participants the various types of mass-production and greenhouses on the premises. Emily Osena (PEAR – Kenya) is greatly thanked for her everlasting energy to make the meeting work and Louise Wipfler (Wageningen University) for making us part of the PEAR project.

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6 **Annexes**

Annex 1 Programme of the seminar

Date	Time	Activity	Actor
Day 1 (14 May)			
Discussion on the macrobials registration administrative process and update of the regulation in Kenya			
	09:00 – 09:15	Opening of seminar, introductions of participants	CEO PCPB and CEO KEPHIS
	09:15 – 09:30	Objectives and programme of the seminar	NVWA
	09:30 – 10:30	Establishment of the present process for registering macrobials in Kenya: steps, actions, actors, time lines, information and data requirements, documents, legal requirements, decision making. Two presentations by: • KSTCIE (Ms Kabole) on the process on macrobial biocontrol registration by the KSTCIE and the regulation under development for macrobial products (update); • PCPB (Dr. Paul Ngaruiya) on product registration of macrobial biocontrol products. Sharing experiences of applications within the current system.	Presentations by KSTCIE and PCPB All for discussion NVWA facilitator
	10:30 – 11:00	Coffee/tea break	
	11:00 – 12:00	Establishment of the present administrative process – continued.	All (NVWA facilitator)
	12:00 – 12:30	Discussion and summary of the current administrative registration process.	All (NVWA facilitator)
	12:30 – 13:30	Lunch	
	13:30 – 14:30	Presentation international benchmarking (EPPO and The Netherlands	A. Loomans, C. Jilesen NVWA
	14:30 – 15:00	Presentation on application process in Kenya seen from the industry perspective	IBMA (to be identified)
	15:00 – 15:30	Discussion on possible improvements in the present administrative process.	All (NVWA facilitator)
	15:30 – 16:00	Tea/coffee break	
	16:00 – 16:30	Discussion on possible improvements in the present administrative process - continued	All (NVWA facilitator)
	16:30 – 17:00	Summary on findings of day 1 on the scope of legislation and regulation of macrobial biocontrol products for Kenya:	All (NVWA facilitator)
	17:00	Closure of day 1	
	Evening	NVWA to adjust and prepare the program for day 2 based on findings day 1 and suggestions by participants.	NVWA

Date	Time	Activity	Actor
Day 2 (15 May)			
Discussion on the requested information for an application of a macrobial registration			
	9:00 – 9:30	Lessons learned from day 1 (legal framework, overall goal, information required, criteria, analysis) and how to proceed.	NVWA
	09:30 –10:30	Which information is needed to perform a proper risk assessment? Assessment of application forms for introduction and product release. Do the questions lead to the proper information to perform a good evaluation.	All (NVWA facilitator)
	10:30 – 11:00	Coffee/tea break	
	11:00 – 12:00	Continued	All (NVWA facilitator)
	12:00 – 12:30	Discussion and summary	
	12:30 – 13:30	Lunch	
	13:30 – 15:30	Is the requested information sufficient to perform a proper risk assessment? What are the criteria to evaluate respectively decide whether an agent can be introduced c.q. a product can be authorised?	All (NVWA facilitator)
	15:30 – 16:00	Tea/coffee break	
	16:00 – 17:00	Lessons learned and follow up steps	All (NVWA facilitator)
	17:00	Closure of the seminar.	
	17:30 – 21:30	Social diner	All

Date	Time	Activity	Actor
Day 3 (16 May)			
Technical visit Biocontrol producers / industry			
	9:00 – 13.00	Technical visit Real IPM Thika	All

Annex 2 Participants list

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Annex 3 KEPHIS Application form for introduction of biopesticides and beneficial organisms in Kenya

Information for applicants

1. The applicant is responsible for the content of the information submitted;
2. An applicant who is not a resident in Kenya must appoint an authorised local agent permanently resident in Kenya. A confirmation letter of the same should accompany this application;
3. The application dossier comprises the application form and attached supporting information
4. All parts should be filled by summarising the required information in the spaces provided and references/supporting information provided as clearly labelled annexes;
5. A cover letter should accompany this application form;
6. The application dossier should be submitted in 4 hard copies, separately bound;
7. In case of more than one product, the applicant must fill a separate form for each product;
8. Additional information relating to the application may be required.
9. The hard copy dossiers shall be submitted to:

Managing Director

KEPHIS Headquarters

P.O. Box 49592-00100, Nairobi

PART A: GENERAL INFORMATION	
1. Name of applicant/ Company	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
5. Name of Manufacturer	

6. Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided	
7. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other)	
8. Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc	
9. Quantity/ Amount proposed for importation	

PART B:DETAILS OF THE ORGANISM	
1. The scientific name(s) of the organism (Genus, species, strain/variety) *All must be provided*	
2. Common Name	
3. The type of organism/ micro-organism (Bacteria, virus, fungus, nematode, insect, mite etc)	
4. Category (Macrobial, Microbial etc)	
5. Methods of identification	
6. Are the organisms live or dead? If killed describe the process used *(Attach evidence)*	
7. Biology of the organism (*attach annexes and acceptable and peer reviewed publications)*	
8. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism *(Detailed descriptions).*	
9. Relationship to known plant and animal parasites	
10. Mode of dispersal/ spread of the organism, Invasiveness, and colonization ability	
11. Mode of action of the organism	

12. Natural occurrence (Ecosystem where it is found naturally)	
13. Origin of organism and world distribution and uses	
14. Is the organism genetically modified? *If genetically modified,* *a)Approval from the Kenya Biosafety Authority* *b) Describe.*	
15. Host range	
16. Specificity to target	
17. Description of benefit	
18. Effect to non-target organisms	
19. Stability of the organism in the environment.	
20. Environmental requirements	
21. Effect on availability of soil nutrients and water.	
22. Impact in its area of distribution	
23. List of countries where the organism/product is introduced. (*attach evidence)*	

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		
2. Origin of Product (*country and state/district)*		
3. Product Type/ function (e.g. insecticide, fungicide, etc.)		
4. Target pest and host		
5. **Formulation Details**		
5.1. Type of formulation: (e.g. EC, WP, etc.)		
5.2. Declare full composition of the product (Active agent (s) and inert ingreadients) (Detailed information on formulation may be provided separately in a sealed envelope)		
Active agent(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %

5.3. Details of Formulator (Names, Postal address, Physical address)	
5.4. Details of trademark owner (Names, Postal address, Physical address)	
5.5. Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)	Yes ☐ No ☐ If no give reasons
5.6. Is the product registered in other countries	Yes ☐ No ☐ State the countries
5.7. Certificate of analysis from the Country of origin.	Available ☐ Not available ☐ Give reasons
5.8. Specify other Physical characteristics of the product such as grade, matrix etc.	
6. Production	
7.1 Describe production method	
7.2 Quality control -method	
7.3 Shelf life	
7.4 Market label for the country of manufacture (Attach as annex)	
7.5 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex*	
7. **Information for product use**	
7.1. Mode of application	
7.2. Area of application (Greenhouse/ open field)	
7.3. Stage of the crop	
7.4. Dosage rates and frequency of application	
8. Mode of action.	

(Attach all supporting scientific publications)	
9. Description of benefits *(Attach all supporting scientific publications)*	
10. Effect on availability of soil nutrients and water.	
11. Environmental requirements. *(Attach all supporting scientific publications)*	
12. Information on Combined use/Compatibility with other crop protection measures	
13. Efficacy of the product in trials done elsewhere and results. *(Attach all supporting scientific publications)*	
14. Packaging	
14.1. Type of Packaging material / container:	
14.2. Pack size(s):	
14.3. Disposal of empty container(s):	
15. The proposed point of entry into the country	
16. The proposed final disposition of the organism such as destruction, treatment or destined for general release	

PART D. SAFETY INFORMATION

1. TOXICOLOGY (Formulated product) For microbial products only

1.1. Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated

1.2. Rabbit	Skin irritation	Eye irritation
None		
Mild		
Moderate		
Severe		

1.3. Skin Sensitization in guinea pig:(tick)	None ☐	Mild ☐	Moderate ☐	Severe ☐
1.4. WHO classification:	Ia	Ib	II	III
1.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets				
Material Safety data (summarise material safety data sheet information here) (Attach MSDS)				
1.6. Summary of environmental effects				

1.6.1. Toxicity to bees	
1.6.2. Toxicity to fish and other aquatic organisms	
1.6.3. Toxicity to birds	
1.6.4. Toxicity to earthworms and soil micro-organisms	
1.6.5. Toxicity to other non-target organisms	
1.6.6. Toxicity to other non-target plants	
1.6.7. Persistence in environment	
1.6.8. Metabolites	
1.6.9. Other effects: Specify	

PART E: PROJECT PLAN	
1. Nature and objectives of the activities proposed	
2. Project participants; roles and responsibilities	
3. Documents procedures and record keeping	
4. Duration,; contingency plans; manner of transport; containment; storage; destruction and decontamination (*attach additional sheet if necessary)*	
5. The name, address and physical location of the specific site or sites where the activities will be conducted. The site may include for	

example, an entire facility, a laboratory, a growth chamber or a field	

Any necessary additional information that will be useful to support the evaluation process will be accepted.	
PART E: DECLARATION	
For and on behalf of..... I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…… Name in full (Printed)	……. Signature
……..…… Official Title	…….. Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……..... ..... Signed : Date:

Annex 4 PCPB Application for the registration of a macrobial pest control product

FORM A2

PEST CONTROL PRODUCTS ACT, CAP 346, 1982, KENYA

APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT

Introduction

1. These guidelines are for any proposed use of naturally occurring predators, parasitoids and entomopathogenic nematodes for the control of weeds, invertebrate pests, or pathogens of crops and pests of livestock and public health.
2. Information in support of a request for registration, both published and unpublished (fully cited) should be supplied in the form of a summary data sheet laid out according to the format given in Form A2
3. A pre-registration consultation between the applicant and the registration authority is strongly recommended.

Information for Applicants

1. The application form must be completed by a person duly authorized by the applicant/company
2. The application must be submitted in triplicate to:
   2 Pest Control Products Board (PCPB)
   3 P.O. Box 13794 - 00800 Loresho, Nairobi.
   4 E-mail address: info@pcpb.or.ke/md@pcpb.or.ke
   5 Tel: 254- 020 – 8021846/7/8
   6 Website: www.pcpb.or.ke

3. Every application must be accompanied by:-
   a. registration fee as prescribed.
   b. 3 copies of the draft label as per PCPB requirements.
4. The applicant shall be required to submit:-
   a. a sample of the pest control product; with National Museums of Kenya or National Collection Number obtained if already in collection.
   b. a sample of the technical grade of its active agent;
   c. additional sample should be sent to NARL (KARI) and Biological Control Unit Muguga (KARI) and KEPHIS
   d. any other sample as may be required by PCPB.
5. All applicants intending to import/export live organisms into or out of the country should seek clearance from the Kenya Standing Technical Committee on Imports and Exports on live organisms (KSTCIE).
6. The use of genetically modified organisms (GMOs) and living modified organisms (LMOs) for use as macrobial pest control products should be cleared by the National Biosafety Committee on GMOs before an application is made. Genetically modified crops are handled by the National Biosafety Committee.

7. List MI and MII are supplied as check lists and indices to ensure that the applicant has provided all relevant data and all cited material.
8. The application must be accompanied by a technical dossier as per PCPB data requirements i.e. Lists MI and MII
9. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya.

PURPOSE OF APPLICATION (tick as appropriate)

a. Pest control products containing a new active agent	☐
b. Pest control products where source of active and/or formulation is not identical to that of a registered product	☐
c. Registration transfer	☐
d. Amendments to existing registration	☐
e. Other (Explain)	
Will the product be marketed under own label? Yes ☐ No ☐ If No, specify ……	

1. APPLICANT

1.1 Name of applicant		
1.2 Corporate name of company		
1.3 Reg No. of the company		
1.4 Name of registration holder		
1.5 Name of local agent in country: (if different from registration holder)		
1.6 Status: (Importer / formulator / distributor etc.)		
1.7 Physical Address	1	2
1.8 Postal Address:	1	2
1.9 Telephone (and area code):	1	2
Fax (and area code):	1	2
E-Mail:	1	2

2. PRODUCT

2.1 Identity and stage(s) of active agent and culture collection code			
2.2 Concentration of active agent in technical material.			
2.3 Description of product	Trade name:		
	Trade mark:		
	Trade mark holder:		
	Internal code:		
2.4 Function of the product: (eg. predator, parasitoid, entomopathogenic nematode)			
2.5 Intended use: (veterinary, horticultural, public health, industrial, agriculture, forestry, etc).			
2.6 Target pest(s) and host(s)			
2.7 Method, dosage rates and frequency of application: a. Production b. Formulation: (if any)	Yes ☐ ☐ If no, specify ……. Yes ☐ ☐ If no, specify …….		
2.8 Type of formulation: (if any)			
2.9 Is the product registered in country of : a) origin b) manufacture: c) formulation:	Yes ☐ ☐ If no, specify ……. Yes ☐ ☐ If no, specify ……. Yes ☐ ☐ If no, specify …….		
2.10 Registration in SEARCH country/ies: (country names, product name and registration number)			
2.11 Registration in other country/ies, particularly OECD countries: (country names, product name and registration number)			
2.12 Customs Tariff Code: (Brussels Tariff Nomenclature)			

3. IDENTIFICATION

Identification of Macrobial agent	Life stage (egg/adult larva etc)		
3.1 Identification Scientific name Common name(s)	Genus	Species	Sub species
3.2 Contents (number per Unit)			

4. SOURCE

Source (original isolation)	

5. FORMULATION

5.1 Formulator: (Name)	Postal Address: Physical address:
5.2 Internal code:	

5.3 Composition (information on composition may be attached in sealed envelop)		
Ingredients and Function:	Units	Range

6. SUMMARY OF ENVIRONMENTAL EFFECTS (BIOSAFETY)

6.1 Risk assessment for replacement of indigenous or endangered species in same niche (exotic macrobials only)	
6.2 Risk to bees:	
6.3 Risk to fish and other aquatic organisms:	
6.4 Risk to birds:	
6.5 Risk to earthworms and soil micro-organisms:	
6.6 Risk to other non-target organisms	
6.7 Other effects:specify (human health problems)	

7. PACKAGING

7.1 Packaging material/container:	

7.2 Pack size(s)	

8. OTHER SPECIFIC REQUIREMENTS

8.1 Operator exposure	
8.2 Likely operator exposure under field conditions	
8.3Sanitary and phytosanitary measures	
8.4 Has the product been cleared by the phytosanitary authorities?	Yes ☐ ☐

9. DECLARATION

For and on behalf of …… I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete	
…… Name in full (printed)	…… Signature
…… Official Title	…… Date
Official Stamp Of Applicant / Company	FOR OFFICIAL USE Remarks …….. …… …… …… …… …….. Signed: Date

NOTE: The format of this application form is recognized by all SEARCH countries.

7 FORM A2, LIST MI

8

ACTIVE AGENT: DOSSIER INDEX FOR MACROBIAL PEST CONTROL AGENTS

The dossier accompanying the application must provide full details (as applicable) of the information requested in this list. Methods of identification should be provided. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active agent, compile a separate dossier for each active agent.

1. DESIGNATION / IDENTITY OF ACTIVE AGENT (PURE)

	Annex No. in dossier if study included	**Official use only**
1.1 Common name		
1.2. Full taxonomic name including isolate, strain or subspecies (where appropriate)		
1.3 Full taxonomic classification		
1.4 Methods of identification, enumeration, etc.		
1.5 Manufacturer or Development Code		
1.6 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.7 Methods of production and quality control.		
1.8 Collection and culture reference number where culture is deposited.		
1.9 Patent status of production process		
Is the product under patent?		
Who is patent holder?		
When was product patented?		
Expiry date of patent		

2. BIOLOGICAL PROPERTIES OF THE MACROBIAL AGENTS

	Annex No. in dossier if study included	**Official use only**
2.1 History of the macro-organism and its uses. Natural occurrence and geographical distribution	9.	10.

2.2 Description of the target organism(s) and mode of action	11.	12.
2.3 Host specificity range and effects on species other than the target harmful organism	13.	14.
2.4 Development stages/life cycle of the macro-organism	15.	16.
2.5 Invasiveness, dispersal and colonisation ability	17.	18.
2.6 Effect of environmental parameters on stability and survival (UV, temperature, soil pH, humidity, etc.) of macrobial agents	19.	20.
2.7 Relationships to known plant, animal or human parasites	21.	22.
2 8 Genetic stability of macrobial agent and target crops	23.	24.
2.9 Information on the production of metabolites (relevant to entomopathogenic nematodes)	25.	26.

3. FURTHER INFORMATION ON THE MACRO-ORGANISM

	Annex No. in dossier if study included	**Official use only**
3.1 Biological function (control of insects, mites, ticks, nematodes, weeds, molluscs, etc)	27.	28.
3.2 Information on the occurrence or potential development of resistance of the target organism(s) and resistance management strategy.	29.	30.
3.3 Methods to prevent loss of predation or parasitic properties of the seed stock of the macro-organism	31.	32.
3.4 Recommended methods and precautions concerning handling, storage, or transport	33.	34.
3.5 Procedures for destruction or decontamination	35.	36.
3.6 Measures in case of an accident	37.	38.

4. BIOSAFETY

Hazard data may be waived where there is sufficient evidence that the product is safe. This would be based on results of medical surveillance, published data, as well as actual studies on the product.

(Active agent and/or technical grade)	**Annex No. in dossier if study included**	**Official use only**
4.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)		

4.2 Discussion of the effects of repeated human exposure		
4.3 Other studies		

5. ENVIRONMENTAL SAFETY

Waivers 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.

	Annex No. in dossier if study included	**Official use only**
5.1 Aquatic organisms (2 species)		
5.2 Aquatic invertebrate		
5.3 Bees		
5.4 Representative natural enemies		
5.5 Representative non-target plant		

6. BEHAVIOUR IN ENVIRONMENT (Active agent)

	Annex No. in dossier if study included	**Official use only**
6.1 Persistence of active agent (days)		
6.2 Mobility of active agent		

9 FORM A2,
LIST MII

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11 FORMULATED PRODUCT: DOSSIER INDEX FOR MACROBIAL PEST CONTROL PRODUCT

The dossier accompanying the application must provide full details (as applicable) of the information requested in this list. Methods of identification and formulation of the macrobial pest control product should be provided. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active agent, compile a separate dossier for each active agent.

1. DESIGNATION / IDENTITY OF ACTIVE AGENT (FORMULATED)

	Annex No. in dossier if study included	**Official use only**
1.1 Formulation type and Code		
1.2 Source and specifications for components included in the formulation		
1.3 Full taxonomic classification		
1.4 Method of identification enumeration and quantification		
1.5 Development Code		
1.6 Source, Name and Address of formulator and address and location of processing plants.		
1.7 Collection and culture reference number where culture is deposited.		
1.8 Methods of production and quality control.		
1.9 Patent status of production process		
a) Is the product under patent?		
b) Who is patent holder?		
c) When was product patented?		
d) Expiry date of patent		

2. PHYSICAL AND CHEMICAL PROPERTIES

	Annex No. in dossier if study included	**Official use only**
2.1 Physical state (solid, liquid etc)		
2.2 Colour		

2.3 Odour		
2.4 Effects of light, air, temperature, water on technical characteristics of the formulation		
2.5 Storage stability in proposed packaging		
2.6 Shelf life		
2.7 Compatibility with other pesticides		
2.8 Water content (Humidity)		

3. BIOLOGICAL PROPERTIES OF THE FORMULATED MACROBIAL AGENTS

	Annex No. in dossier if study included	**Official use only**
3.1 History of the formulated product and its uses	39.	40.
3.2 Description of the target organism(s) and mode of action of the macrobial agent	41.	42.
3.3 Host specificity range and effects on species other than the target harmful organism	43.	44.
3.4 Life cycle stage at which the macrobial agent is applied	45.	46.
3.5 Invasiveness, dispersal and colonisation ability	47.	48.
3.6 Effect of environmental parameters (UV, temperature, soil pH, humidity, etc.) on stability and survival of macrobial agents	49.	50.
3.7 Relationships to known plant, animal or human parasites	51.	52.
3 8 Genetic stability of the formulated macrobial agent	53.	54.
3.9 Information on the production of metabolites (relevant to entomopathogenic nematodes)	55.	56.

4. FURTHER INFORMATION ON THE FORMULATED MACROBIAL AGENT

	Annex No. in dossier if study included	**Official use only**
4.1 Biological function (control of insects, mites, ticks, nematodes, weeds, molluscs, etc)	57.	58.
4.2 Information on the occurrence or potential development of resistance of the target organism(s).	59.	60.

4.3 Methods to prevent loss of predation or parasitic properties of the seed stock of the macro-organism	61.	62.
4.4 Recommended methods and precautions concerning handling, storage, or transport	63.	64.
4.5 Procedures for destruction	65.	66.
4.6 Measures in case of an accident	67.	68.

5. BIOSAFETY

Hazard data may be waived where there is sufficient evidence that the product is safe. This would be based on results of medical surveillance, published data, as well as actual studies on the product.

Formulated agent	**Annex No. in dossier if study included**	**Official use only**
5.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)		
5.2 Discussion of the effects of repeated human exposure		
5.3 Other studies		

6. ENVIRONMENTAL SAFETY

Waivers 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.

	Annex No. in dossier if study included	**Official use only**
6.1 Aquatic organisms (2 species) Fish		
Daphnia		
6.2 Aquatic invertebrate		
6.3 Bee		
6.4 Representative natural enemies		
6.5 Representative non-target plant		

7. BEHAVIOUR IN ENVIRONMENT

	Annex No. in dossier if study included	Official use only
7.1 Persistence of active agent (days)		
7.2 Mobility of active agent		

8. INTENDED USES

	Annex No. in dossier if study included	Official use only
8.1 Function (control of insects, mites, ticks, nematodes, weed, molluscs, etc)		
8.2 Target pest(s)		
8.3 Area of use		
8.4 Application rate (appropriate units)		
8.5 Method of application		
8.6 Recommended number and timing of applications		
8.7 Stage of treatment of host crop		
8.8 Directions for use		
8.9 Pre-harvest interval		
8.10 Contraindications		
8.11 Local efficacy data (guidelines provided separately)		

9. MINIMUM LABEL REQUIREMENTS

Specify the warnings, use restrictions and safety precautions, which must be present on the label in all countries. The proposed label must be included in the dossier, should contain the specified warnings, use restrictions and safety precautions as well as meet PCPB label requirements.
PCPB label requirements will be provided separately.

10. EVIDENCE OF REGISTRATION IN OTHER COUNTRIES

11. OTHER SPECIFIC REQUIREMENTS

	Annex No. in dossier if study included	Official use only
11.1 Medical surveillance, on manufacturing plant personnel		
11.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry, fisheries.		

12. PROPOSED PACKAGING

	Annex No. in dossier if study included	Official use only
12.1 Type of packaging in which the product is imported		
12.2 Type of packaging for distribution in Kenya		
12.3 Packaging material		
12.4 Sizes of individual packaging		

13. PROCEDURES OF DESTRUCTION AND DECONTAMINATION

	Annex No. in dossier if study included	Official use only
13.1 Controlled incineration		
13.2 Procedures of cleaning application equipment (nematodes)		
13.3 Recommended methods and precautions concerning handling, storage, display or transport.		

GUIDELINE: DOSSIER FOR MACROBIAL PEST CONTROL AGENT

The dossier accompanying this form should provide details of the information requested. Methods used in the identification of the agent (based on international standards on the nomenclature for arthropods), detailed biological properties and efficacy studies etc. must be given. Numbering used in the dossier must correspond with that used in the application form.

1 IDENTITY OF ACTIVE AGENT (TECHNICAL GRADE)

REQUIREMENTS:	**REMARKS:**
1.1 Common name	Indicate where applicable
1.2. Full taxonomic name including isolate, strain or subspecies (where appropriate)	Full scientific name including any relevant information
1.3 Full taxonomic classification	Indicate full systemic classification including any relevant information
1.4 Methods of identification	Indicate procedure used to identify the active agent: Morphology, histology, molecular biology, etc
1.6 Development code 1.7	Specify Source/Developer
1.6 Source, Name and Address of developer and address and location of processing plants.	Indicate company and country of origin. Name, address, location of processing plant.
1.7 Methods of production and quality control.	Developer to outline how the agent is isolated, purified, bulked, and maintained. Quality assurance should include methods of counting the number of macrobials per unit volume / weight.
1.8 Collection and culture reference number where culture is deposited.	Agent is to be deposited in a recognized culture collection institute (e.g. National Museums of Kenya), the name of the collection and the culture reference number is to be given.
1.9 Patent status	Give status as indicated below:
Is the production process of agent under patent?	
Who is the patent holder?	
When was the process patented?	
Expiry date of patent	

2. BIOLOGICAL PROPERTIES OF THE MACROBIAL AGENT

REQUIREMENTS:	**REMARKS:**

2.1 History of the macrobial, its uses, natural occurrence and geographical distribution	69. The geographical region and the place in the ecosystem (e.g. host plant, host animal, or soil from which the macro-organism was isolated) must be stated. The natural occurrence of the macro-organism in the relevant environment shall be given if possible to strain level. Indicate whether the macro-organism has been GRAS (Generally Regarded As Safe) listed
2.2 Description of the target organism(s) and mode of action	The principal mode of action should be indicated and if the macro-organism produces a toxin with a residual effect on the target organism. In that case, the mode of action of this toxin should be described. If relevant, information on the site of infection and mode of entry into the target organism and its susceptible stages should be given. The results of any experimental studies must be reported. Transmissibility (possibility of spread of the macro-organism from one target population to another, but also from one target species to another (target) species after release under the proposed condition of use) shall be indicated.
2.3 Host specificity range and effects on species other than the target harmful organism	Any available information on the effects of macrobial on non-target organisms within the area of spread shall be given. The occurrence of non-target organisms closely related to the target species in the area of release shall be indicated.
2.4 Developmental stages/life cycle of the macrobial agent	Information on the life cycle, symbiosis, parasitism, competition, predation, host organisms, etc. of the macrobial agent must be presented. The generation time and the type of reproduction of the macro-organism must be stated. Information on the occurrence of resting stages and their survival time, their virulence and infection potential must be provided.
2.5 Invasiveness, dispersal and colonization ability	Information is to be provided on the behaviour of the macro-organism under typical environmental conditions of use.
2.6 Effect of environmental parameters (UV, temperature, soil pH, humidity, etc.) on stability and survival on stability and survival of macrobial agent	The persistence of the macro-organism under the typical environmental conditions of use must be indicated. Any particular sensitivity to certain components of the environment (e.g. UV light, soil, water) must be stated. The environmental requirements (temperature range, pH, humidity, nutrition requirements, etc.) for survival, reproduction, and effectiveness of the macro-organism must be stated.

2.7 Relationships to known plant or animal or human pests or vectors of disease	The possible existence of one or more species of the genus of the agent known to be pests or vectors of diseases of humans, animals, crops or other non-target species shall be indicated. It shall be stated whether it is possible, and by which means, to clearly distinguish the active macro-organism from the pest or vectors of disease
2.8 Genetic stability of the macrobial agent and the target crop	Where appropriate, information on genetic stability (e.g. mutation rate of traits related to the mode of action or uptake of exogenous genetic material) under the environmental conditions of proposed use must be provided. The ability of the macrobial agent to control pests on Genetically Modified Crops must be indicated.
2.9 Information on the production of metabolites (especially toxins) (relevant to entomopathogenic nematodes).	The conditions under which the macro-organism produces the metabolite(s) (especially toxin(s)) must be described.

3. FURTHER INFORMATION ON THE MACROBIAL PEST CONTROL PRODUCT

REQUIREMENTS:	**REMARKS:**
3.1 Biological function (control of insects, mites, nematodes, weed, molluscs, etc)	70. The biological function must be specified
3.2 Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and resistance management strategy.	71. Available information on the possible occurrence of the development of resistance or cross-resistance of the target organism(s) must be provided. Where possible, appropriate management strategies should be described
3.3 Methods to prevent loss of predation properties or parasitism of seed stock of the macro-organism	Methods to prevent loss of activity of starting cultures are to be provided. In addition, any method, if available, that could prevent the macro-organism from losing its effects on the target species must be described, particularly on macrobial agents produced on artificial diets.
3.4 Recommended methods and precautions concerning handling, storage, and transport	Indicate any specific precautions
3.5 Procedures for destruction	Methods for safe disposal of macrobial agents that are no longer needed should be provided.
3.6 Measures in case of an accident	Information on procedures for rendering the macro-organism harmless in the environment (e.g. water or soil) in case of an accident must be provided.

4. BIO-SAFETY

Include an executive summary discussing **ALL ISSUES** named under section 3 of the form or provide the individual summaries from each study relating to issues mentioned under section 3 of the form. Information on the methods of testing used must be provided

REQUIREMENTS:	**REMARKS:**
4.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)	Available reports of occupational health surveillance programmes, must be submitted. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the macro-organism (e.g. in efficacy trials).
4.2 Discussion of the effects of repeated human exposure	Provide any available information
4.3 Other studies	Provide any available information

5. ENVIRONMENTAL SAFETY

Provide either an executive summary or individual summaries of studies on the behaviour in the environment providing information requested in the form.

REQUIREMENTS	REMARKS
5.1 Aquatic organisms (2 species) Fish Daphnia	Provide any relevant information
5.2 Aquatic invertebrate	Specify and provide details on other organisms according to the information requested on the form.
5.3 Bees	
5.4 Representative natural enemies	
5.5 Representative non-target plant	Provide any relevant information.

6. BEHAVIOUR IN ENVIRONMENT

REQUIREMENTS	REMARKS
6.1 Persistence of active agent (days)	Provide any relevant information with special reference to rates of re-seeding
6.2 Mobility of active agent	Indicate the rate of spread of the macrobial agent in the environment after application.

GUIDELINE: DOSSIER FOR FORMULATED MACROBIAL PEST CONTROL PRODUCT

The dossier accompanying this form should provide details of the information requested. Methods used in the identification of the agent (based on international standards on the nomenclature for arthropods), detailed biological properties and efficacy studies etc. must be given. Numbering used in the dossier must correspond with that used in the application form.

1 IDENTITY (FORMULATED PRODUCT)

REQUIREMENTS	REMARKS
1.1 Formulation type and Code	Provide information on the formulation type
1.2. Source and specifications for components included in the formulation	Give geographical origin, company, reference laboratory, etc.,
1.3 Full taxonomic classification	Indicate full systemic classification including any relevant information
1.4 Methods of identification, enumeration and quantification	Morphology, histology, molecular biology, numbers of infective material per unit volume/weight, etc
1.5 Development Code	Specify Source/Developer
1.6 Source, Name and Address of formulator and address and location of processing plants.	Indicate company and country of origin. Name, address, location of processing plant.
1.7 Collection and culture reference number where culture is deposited.	Agent is to be deposited in a recognized culture collection institute (e.g. National Museums of Kenya), the name of the collection and the culture reference number is to be given.
1.8 Methods of production and quality control.	Developer to outline how the agent is isolated, purified, bulked, and maintained. Quality assurance should include methods of counting the number of macrobials per unit volume / weight.
1.9 Patent status	Provide information as indicated below
a) Is the production process of agent under patent?	
b) Who is the patent holder?	
c) When was the process patented?	
d) Expiry date of patent	

2. PHYSICAL AND CHEMICAL PROPERTIES

REQUIREMENTS	REMARKS
2.1 Physical state (solid, liquid etc)	
2.2 Colour	
2.3 Odour	

2.4 Effects of light, air, temperature, water on technical characteristics of the formulation	Provide information with evidence
2.5 Storage stability in proposed packaging	Specify conditions for storage with evidence
2.6 Shelf life	Indicate production date and expiration date. Provide data to support shelf life.
2.7 Compatibility with other pesticides	Indicate type of pest control products with which the product is or is not compatible. Give evidence
2.8 Water content (Humidity)	Indicate level of moisture/humidity under which the product remains viable

3. BIOLOGICAL PROPERTIES OF THE FORMULATED MACROBIAL AGENT

REQUIREMENTS:	**REMARKS:**
3.1 History of the formulated product and its uses	72. The geographical region and the place in the ecosystem (e.g. host plant, host animal, or soil from which the macro-organism was isolated) must be stated. The natural occurrence of the macro-organism in the relevant environment shall be given if possible to strain level. Indicate whether the macro-organism has been GRAS (Generally Regarded As Safe) listed
3.2 Description of the target organism(s) and mode of action of macrobial	The principal mode of action should be indicated and if the macro-organism produces a toxin with a residual effect on the target organism, then the mode of action of this toxin should be described. If relevant (e.g. nematodes), information on the site of infection and mode of entry into the target organism and its susceptible stages should be given. The results of any experimental studies must be reported. Transmissibility (possibility of spread of the macro-organism from one target population to another, but also from one target species to another after release under the proposed condition of use) shall be indicated.
3.3 Host specificity range and effects on species other than the target harmful organism	Any available information on the effects of macrobial on non-target organisms within the area of spread shall be given. The occurrence of non-target organisms closely related to the target species in the area of release shall also be indicated.

3.4 Life cycle stage at which the macrobial agent is applied	Information on the life cycle stage of the macrobial agent for field release must be presented. The life cycle stage at which the target organism is susceptible to the macrobial attack must also be given.
3.5 Invasiveness, dispersal and colonisation ability	Information on the behaviour of the macro-organism under typical environmental conditions of use must be provided.
3.6 Effect of environmental parameters (UV, temperature, soil pH, humidity, etc.) on stability and survival on stability and survival of macrobial agent	The persistence of the macro-organism under the typical environmental conditions of use must be indicated. Any particular sensitivity to certain components of the environment (e.g. UV light, soil, water) must be stated. The environmental requirements (temperature range, pH, humidity, nutrition requirements, etc.) for survival, reproduction, and effectiveness of the macro-organism must also be stated.
3.7 Relationships to known plant or animal or human pests or vectors of disease	The possible existence of one or more species of the genus of the agent known to be pests or vectors of diseases of humans, animals, crops or other non-target species shall be indicated. It shall be stated whether it is possible, and by which means, to clearly distinguish the active macro-organism from the pest or vectors of disease
3.8 Genetic stability of the formulated macrobial agent and the target crop	Where appropriate, information on genetic stability (e.g. mutation rate of traits related to the mode of action or uptake of exogenous genetic material) under the environmental conditions of proposed use must be provided. The ability of the macrobial agent to control pests on Genetically Modified Crops must be indicated.
3.9 Information on the production of metabolites (especially toxins) (relevant to entomopathogenic nematodes).	The conditions under which the macro-organism produces the metabolite(s) (especially toxin(s)) must be described.

4. FURTHER INFORMATION ON THE FORMULATED MACROBIAL AGENT

REQUIREMENTS:	**REMARKS:**
4.1 Biological function (control of insects, mites, ticks, nematodes, weeds, molluscs, etc)	73. The biological function must be specified

4.2 Information on the occurrence or possible occurrence of the development of resistance of the target organism(s).	74. Available information on the possible occurrence of the development of resistance or cross-resistance of the target organism(s) must be provided. Where possible, appropriate management strategies should be described
4.3 Methods to prevent loss of predation properties or parasitism of seed stock of the macro-organism	Methods to prevent loss of activity of starting cultures are to be provided. In addition, any method, if available, that could prevent the macro-organism from losing its effects on the target species must be described, particularly on macrobial agents produced on artificial diets.
4.4 Recommended methods and precautions concerning handling, storage, and transport	Indicate any specific precautions
4.5 Procedures for destruction	Methods to dispose safely of the macrobial agent which are no longer needed should be provided.
4.6 Measures in case of an accident	Information on procedures for rendering the macro-organism harmless in the environment in case of an accident must be provided.

5. BIO-SAFETY

Include an executive summary discussing **ALL ISSUES** named under section 3 of the form or provide the individual summaries from each study relating to issues mentioned under section 3 of the form. Information on the methods of testing used must be provided

REQUIREMENTS:	**REMARKS:**
5.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)	Available reports of occupational health surveillance programmes, must be submitted. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the macro-organism (e.g. in efficacy trials).
5.2 Discussion of the effects of repeated human exposure	Provide any available information
5.3 Other studies	Provide any available information

6 ENVIRONMENTAL SAFETY

Provide either an executive summary or individual summaries of studies on the behaviour in the environment providing information requested in the form.

REQUIREMENTS	**REMARKS**
6.1 Aquatic organisms (2 species) Fish and Daphnia	Provide any relevant information
6.2 Aquatic invertebrate	

6.3 Bees	Specify and provide details on other organisms according to the information requested on the form.
6.4 Representative natural enemies	
6.5 Representative non-target plant	Provide any relevant information.

7. BEHAVIOUR IN ENVIRONMENT

REQUIREMENTS	REMARKS
7.1 Persistence of formulation (days)	Provide any relevant information with special reference to rates of re-seeding
7.2 Mobility of active agent	Indicate the rate of spread of the macrobial agent in the environment after application.

8. INTENDED USES

REQUIREMENTS	REMARKS
8.1 Function (control of insects, fungi, mites, ticks, bacteria, viruses, nematodes, weed, molluscs, etc)	State whether it will be used as a fungicide, insecticide etc.
8.2 Target pest(s)	Name of target pest(s)
8.3 Area of use	Specify (crops, livestock, public health, or environment)
8.4 Application rate (appropriate units)	Specify rate
8.5 Method of application	Specify
8.6 Recommended number and timing of applications	Specify timing and frequency
8.7 Stage of treatment of host crop	Specify growth stage of host crop
8.8 Directions for use	Specify on label and / or leaflet
8.9 Pre-harvest interval	Specify on label and / or leaflet
8.10 Contraindications	Specify on label and / or leaflet
8.11 Efficacy data (guidelines provided separately)	Provide efficacy data from country of origin and other countries of similar climatic conditions. In addition efficacy data from local trials must be provided.

9. MINIMUM LABEL REQUIREMENTS

Specify the warnings, use restrictions and safety precautions which must be present on the label in all countries. The proposed label must be included in the dossier, should contain the specified warnings, use restrictions and safety precautions as well as meet PCPB label requirements.
PCPB label requirements will be provided separately.

10. EVIDENCE OF REGISTRATION IN OTHER COUNTRIES

11. OTHER SPECIFIC REQUIREMENTS

	Remarks
11.1 Medical surveillance, on manufacturing plant personnel	Provide details
11.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry, fisheries.	Provide details

12. PROPOSED PACKAGING

12.1 Type of packaging in which the product is imported	Provide details
12.2 Type of packaging for distribution in Kenya	Provide details
12.3 Packaging material	Provide details
12.4 Sizes of individual packaging	Provide details

13. PROCEDURES OF DESTRUCTION AND DECONTAMINATION

13.1 Controlled incineration	Provide details
13.2 Procedures of cleaning application equipment	Provide details
13.3 Recommended methods and precautions concerning handling, storage, display or transport.	Provide details

List of abbreviations

μg	Microgram
a.a.	Active Agent
BCF	Bio Concentration Factor
CFU	Colony Forming Units
CIPAC	Collaborative International Pesticides Analytical Council
EC	Emulsifiable Concentrate
EC_{50}	Median Effective Concentrate
FAO	Food and Agriculture Organization of the United Nations
g/kg	Grams per Kilogram
g/l	Grams per litre
GLP	Good Laboratory Practice
GRAS	Generally Regarded as Safe
ISO	International Standards Organisation
LC_{50}	Median Lethal concentrate
LD_{50}	Median Lethal Dose
mg/l	Milligrams per litre
MSDS	Material Safety Data Sheet
NOEL	Non Observable Effective Level
^{o}C	Degrees centigrade
OECD	Organisation for Economic Co-operation and Development
PCPB	Pest Control Products Board
PHI	Pre Harvest Interval
SEARCH	Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration
WHO	World Health Organization
WP	Wettable Powder

Annex 5 Presentations

5.1 Presentation KEPHIS

17-9-2019

KENYA PLANT HEALTH INSPECTORATE SERVICE

VISION

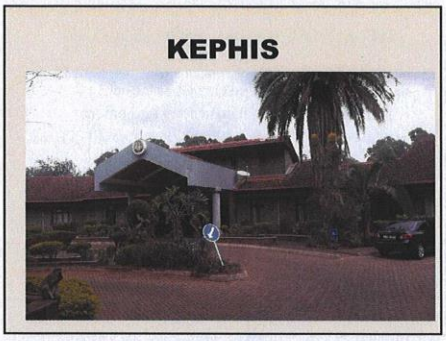
Healthy plants, safe trade and sustainable agro environment for a prosperous Kenya

MISSION

To Provide a Science based regulatory services by assuring plant health quality of agricultural inputs and produce for food security, globally competitive agriculture and sustainable development

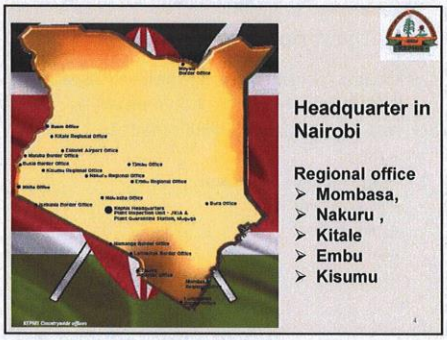
SEMINAR ON REGISTRATION OF MACROBIALS 2019

MELLON KABOLE



KEPHIS

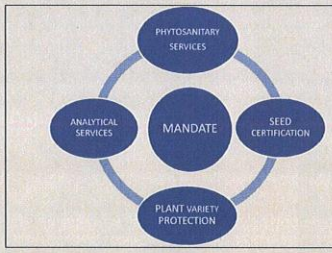
- KEPHIS is a state corporation offer regulatory services in agricultural sector. It is the official NPPO Kenya.
- National Plant Protection Organisation for Kenya



Headquarter in Nairobi

Regional office
- Mombasa,
- Nakuru ,
- Kitale
- Embu
- Kisumu

SUMMARY OF KEPHIS MANDATE



KEPHIS LEGAL FRAMEWORK

The National legislations that provide the authority for KEPHIS operations includes :

1. KEPHIS Act No. 54 2012,
2. Cap 324- The Plant Protection Act,
3. Cap 326- The Seeds and Plant Varieties Act
4. Cap 319- The Agriculture Produce (Export) Act
5. Legal notices 305, 108, 48
6. Bio safety Act, 2009 (KEPHIS is represented in the NBA Board).

1

INTERNATIONAL FRAMEWORK

- International treaties/ conventions to which Kenya is a signatory that guide KEPHIS activities include:
  - WTO - Sanitary and Phytosanitary Agreement
  - International Plant Protection Convention (IPPC) (ISMPs)
  - FAO / WHO- Codex Alimentarius Commission
  - The Union for the Protection of New Plant Varieties of Plants (UPOV)
  - The International Seed Testing Association (ISTA)
  - Organization for Economic Cooperation and Development (OECD) Seed Schemes.
  - CBD- Cartegena Protocol on Biosafety (CPD)

KEPHIS SERVICES

Phytosanitary service

- **Import inspections and regulation** prevention of the introduction of harmful foreign pests, diseases, weeds.
- **Export certification** to ensure we meet our international market requirements (facilitate trade

PEST DIAGNOSTIC SERVICES

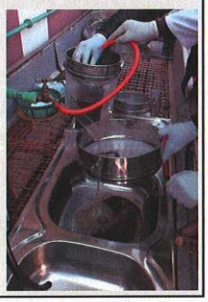
- Facilities for identification of pest and disease in phytosanitary and certification systems.
- We have facilities for identification of :
  - **Fungal,**
  - **bacterial and phytoplasma,**
  - **virus and viroid,**
  - **nematodes,**
  - **insects,**
  - **weeds**

Plant health Laboratory at PQBS, Muguga

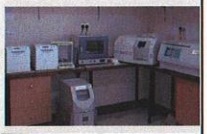
We have 7 fully functional and equipped laboratories

- Bacteriology
- Entomology
- Nematology
- Mycology
- Virology
- Molecular biology and
- Tissue culture

Nematology laboratory



Molecular biology laboratory



Modern equipments
- Realtime PCR
- LAMP
- DNA barcoding

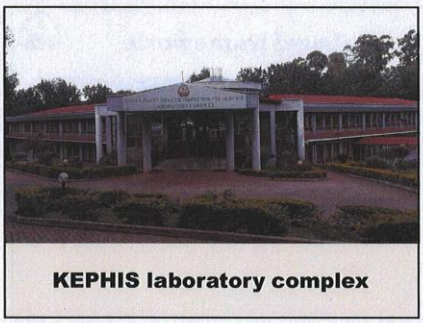
17-9-2019

Treatment

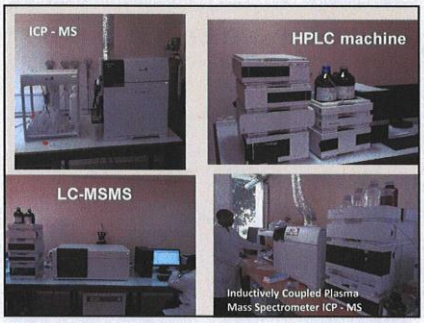
- Approve and supervise treatment facilities of grains, wood, flower, fruits etc
- This include devitalization, treatment of wood packaging material

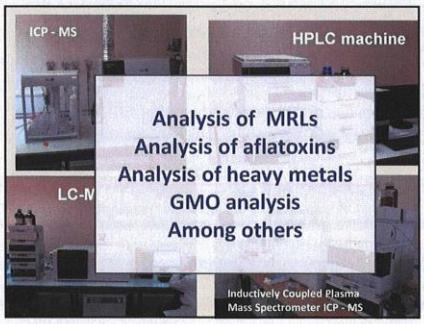
Analytical services

- **Pesticide residue analysis** - KEPHIS undetake national pesticide residue monitoring program export **Maximum Residue Limits (MRLs)**.
- Allow meet and continue accessing the EU market for beans and peas
- **Water analysis** for irrigation suitability
- **Soil analysis**
- **Analysis for heavy metals** in food products.
- **Aflatoxin analysis**



KEPHIS laboratory complex





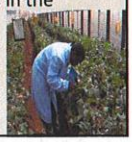
KEPHIS SERVICES Cont.

- **Seed certification** ensures that farmers have access to the most suitable and superior varieties for maximum productivity.
- Certification involves seed merchant and grower registration, Field inspection, Seed testing and labeling, post control and post certification.
- **Plant variety protection** - KEPHIS performs rigorous testing of new varieties for their **value for cultivation and use** (VCU) thus encouraging breeders to develop and protect their new varieties.

3

Other services

- Trade negotiations for Market Access (e.g. US, South Africa, South Korea)
- Standard setting and Harmonization of standards regionally and internationally.
- Surveillance for pests and diseases in the country.
- Pest risk analysis



KSTCIE

Kenya Standing Technical Committee for Import and Exports (KSTCIE)

- ❑ A Risk Analysis Committee
- ❑ Started in 1998
- ❑ Chaired by Ministry of Agriculture Livestock and Fisheries
- ❑ KEPHIS is the secretariat
- ❑ Members
  - Regulators and public institutions; PCPB, KALRO, DVS, MPHS,NEMA, NMK
  - Private industry players
  - Scientific institutions

Scope include

- Biological control agents capable of self-replication
  - Parasitoids, predators, parasites, nematodes, phytophagous organisms
  - Pathogens such as fungi, bacteria and viruses
- Insects, sterile insects
- Beneficial organisms: e.g.- mycorrhizae and pollinators
- Microoganisms: packaged or formulated as commercial products
- Biofertilizers

Regulate introductions intended for;

- Research (trials)
- Commercialization
- Personal use

Legal framework

Protection of human, plants, animals and the environment

- Laws of Kenya guide operation of each member institution
- International laws e.g. ISPM No.3 *`Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms* (2005)`-IPPC,
- Draft regulation for KSTCIE operations forwarded for approval

Role of KSTCIE Committee

- ❑ To facilitate the safe import, shipment and release of biological control agents and other organisms through risk assessment
- To provide recommendations for approval that address the safe handling, assessment and use of the organisms or products containing organisms while implementing appropriate sanitary and phytosanitary measures under existing regulations
- ❑ To encourage responsible trade practices

Role of Secretariat

`Guidelines For Introduction And Use Of Bio-products, Biological Control Agents And Related Products` provided as a guide

- ❑ Receive applications on behalf of KSTCIE
  - ❑ Application through the Import Certification System *(Yet to be launched)*
    - ❑ Fill in form, specific form based on the product type
    - ❑ Attach filled form to application and submit
    - ❑ Application accepted (applications screened for completeness to ensure all requirements for risk assessment are provided)
    - ❑ Separately provide four hard copy of the application form + supporting documents(dossiers)

17-9-2019

Role of Secretariat

- Review and distribute submitted applications (dossiers) to relevant member institutions and technical experts for risk evaluation
- Maintain communication between applicant and reviewers until all concerns are addressed
- Receive comments and recommendations from reviewers and summarize them to constitute the for discussion in KSTCIE sub-committee meeting
- Applicant may be called upon to clarify on any issues of concern

Role of Secretariat

- After KSTCIE sub-committee,
  - Satisfactory applications are recommended for discussion in main KSTCIE meeting and the applicant invited for the meeting
  - If unsatisfactory, applicant is informed on what information to provide
- KSTCIE main committee meeting
  - Approval/rejection of application by KSTCIE
  - Feedback to applicant on KSTCIE sub committee decision e of import permit through ICS system.

Role of committee members

- Receive and recommendations of the summary agenda for discussion in KSTCIE sub-committee meeting
- Attend and discuss the applications in committee meetings
- Review the recommendations as directed by committee deliberations to determine the decisions
- Review committee procedures as requested
- Conduct inspections/ monitoring as requested

Role of scientific community

- Conduct risk assessment
- Attend committee meetings as requested
- Register as experts in KEPHIS website to expand database and opinions
- Conduct quality, safety and efficacy trials

Timelines

- Meetings every three months
- Allowance of one and half months for risk assessment process and preparation for meeting

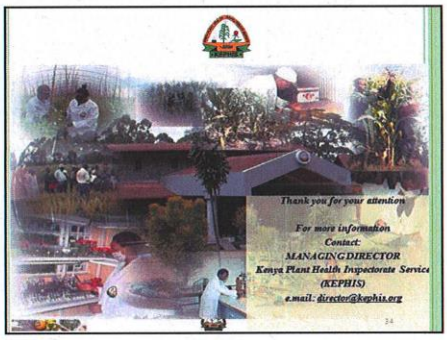
Data requirements

- Four application forms ;
  - –Bio-stimulants and Plant growth regulators
  - –Soil and water conditioners, wood ash and Organic fertilizers
  - –Biofertilisers
  - –Bio-pesticides and beneficial organisms

5

Data Requirements cont.,

- PART A: General Information
- PART B:details of the Organism
- PART C: Identity and Information of Product
- PART D. Safety Information
- PART E: Project Plan



5.2 Presentation PCPB

REGISTRATION OF MACROBIAL PEST CONTROL PRODUCTS IN KENYA;

Macrobial seminar SEMINAR, Nairobi

14th May, 2019

Paul N. Ngaruiya (Dr).

Pest Control Products Board, Kenya

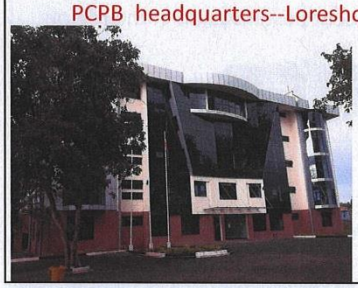
Presentation outline

1. Introduction
2. Range products regulated
3. Overview Registration procedure, macrobials
4. Quality assurance

Introduction

- PCPs regulated in Kenya by PCPB, Industrial chemicals by NEMA
- PCPB is a Statutory organization of Kenya Government established under an Act of parliament, the Pest Control Products Act, Cap 346, Laws of Kenya of 1983,
- amended in 2009
- to regulate the importation and exportation, manufacture, distribution and use of pest control products.
- 6 main subsidiary legislations– registration, licensing, import/export, labeling—1984, Disposal regulation, fees and other charges– 2006
- amended in 2006, 2014 and 2015
- Awaiting gazettement of revision

PCPB headquarters--Loresho

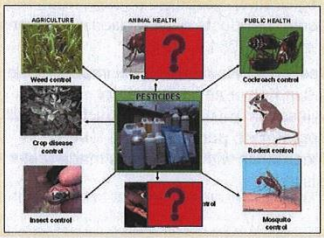


Mandate

- Assessing safety, efficacy, quality, & economic value of pest control products.
- Assessing suitability of premises used for manufacture / formulation, re-packing, storage & distribution of PCP
- Processing and issuing import/export permits
- Creating awareness of the general public
- Monitoring and ensuring adherence of quality
- Investigating, prosecuting contravention of PCP Act.
- Supervising the disposal of obsolete or undesired PCPs
- Advising the Cabinet Secretary on all matters relating to the Provisions of the PCP Act and Regulations

Range of products regulated

Conventionals; Technical grades; adjuvants; Biopesticides;



Range of products regulated

Sec 2-- "A pest control product is a product, device, **organism**, substance, or thing that is manufactured , represented , sold, or used as a means for directly or indirectly controlling, preventing, destroying, attracting, or repelling any pest...."

May include;

- Conventional chemical pesticides
- Biopesticides; Botanicals, biochemicals, microorganisms, macrobials such as natural enemies, preditors—Classified through stakeholder engagements and benchmarking and legislation--2003-2006
- Any compound or substance that enhances or modifies the physical or chemical characteristics of a pest control product to which it is added e.g adjuvants and wetting agents
- Technical grade active ingredients

Why regulate

- Regulation of PCP is an important legal requirement All over the world
  - Netherlands –CTGB, China-ICAMA, US-EPA, UK-CRD, Canada- PMRA
- Every government has an obligation to ensure the safety of its citizens, animals, plants and the environment.
- The primary purpose of using pesticides is to control pests in crops and animals in order to reduce yield losses
- PCPs are potentially hazardous to human, animals, and the environment.

❖ Physical hazards

❖ Health hazards

❖ Environmental hazards

❖ Possibility of **ineffective** products eg counterfeits

❖ Some invasive

❖ This calls for strict risk assessment, management and mitigation to ensure human & environmental protection.

Recent Pest invasion in the region

LGB

Quelea quelea birds

Recent Pest invasion in the region cont'd

MLND

Fruit fly

Tuta absoluta

Fall army worm

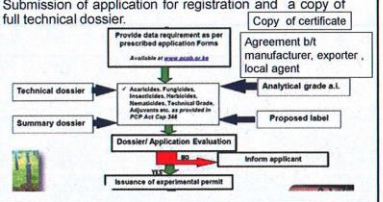
How regulated through Registration

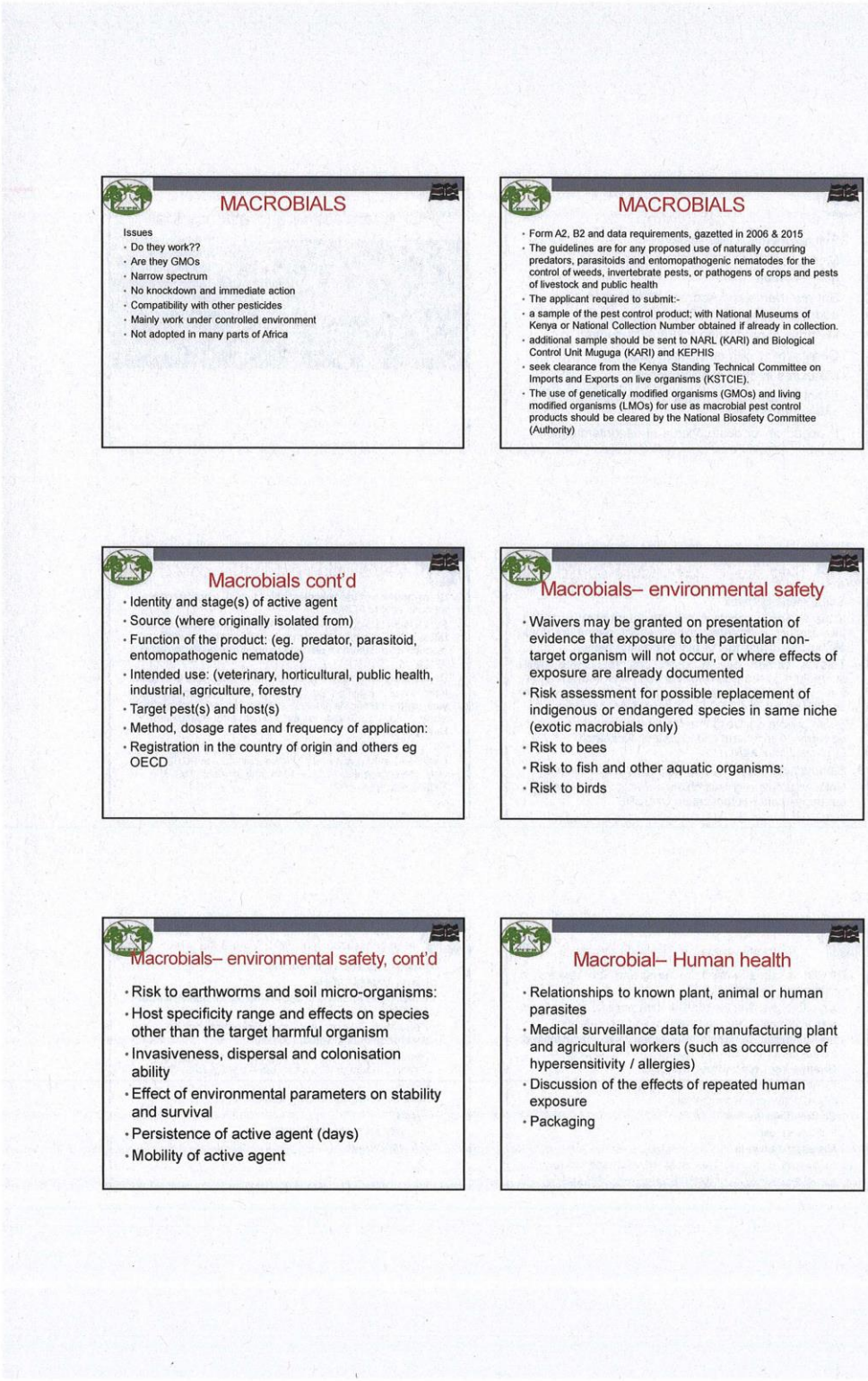
- Registration -governed through Pest Control Products Registration regulations gazette in 1984 & 2006
- Section 4: "No person shall import into, or sell in Kenya any pest control product unless that pest control product has been **Registered, packaged and labeled** in accordance with regulations made under this act..."

Registration cont'd

Appointment of local agent/representative & Pre-consultation—**One agent**

Submission of application for registration and a copy of full technical dossier.





MACROBIALS

Issues

- Do they work??
- Are they GMOs
- Narrow spectrum
- No knockdown and immediate action
- Compatibility with other pesticides
- Mainly work under controlled environment
- Not adopted in many parts of Africa

MACROBIALS

- Form A2, B2 and data requirements, gazetted in 2006 & 2015
- The guidelines are for any proposed use of naturally occurring predators, parasitoids and entomopathogenic nematodes for the control of weeds, invertebrate pests, or pathogens of crops and pests of livestock and public health
- The applicant required to submit:-
- a sample of the pest control product; with National Museums of Kenya or National Collection Number obtained if already in collection.
- additional sample should be sent to NARL (KARI) and Biological Control Unit Muguga (KARI) and KEPHIS
- seek clearance from the Kenya Standing Technical Committee on Imports and Exports on live organisms (KSTCIE).
- The use of genetically modified organisms (GMOs) and living modified organisms (LMOs) for use as macrobial pest control products should be cleared by the National Biosafety Committee (Authority)

Macrobials cont'd

- Identity and stage(s) of active agent
- Source (where originally isolated from)
- Function of the product: (eg. predator, parasitoid, entomopathogenic nematode)
- Intended use: (veterinary, horticultural, public health, industrial, agriculture, forestry
- Target pest(s) and host(s)
- Method, dosage rates and frequency of application:
- Registration in the country of origin and others eg OECD

Macrobials– environmental safety

- Waivers 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
- Risk assessment for possible replacement of indigenous or endangered species in same niche (exotic macrobials only)
- Risk to bees
- Risk to fish and other aquatic organisms:
- Risk to birds

Macrobials– environmental safety, cont'd

- Risk to earthworms and soil micro-organisms:
- Host specificity range and effects on species other than the target harmful organism
- Invasiveness, dispersal and colonisation ability
- Effect of environmental parameters on stability and survival
- Persistence of active agent (days)
- Mobility of active agent

Macrobial– Human health

- Relationships to known plant, animal or human parasites
- Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)
- Discussion of the effects of repeated human exposure
- Packaging

Formulation

- Full taxonomic, classification
- Method of identification, enumeration and quantification
- Source, Name and Address of formulator and address and location of processing plants.
- Methods of production and quality control.
- Compatibility with other pesticides
- Measures in case of an accident
- Label: to specify warnings, use restrictions and safety precautions
- Procedures for destruction and decontamination

PCPB lab testing and efficacy trials

Registration procedure cont'd

- Completeness check
- If the PCPB is satisfied with the information provided, the product is granted experimental permit for local biological efficacy trial or other bridging trials.
- This is carried out in institutions that have been accredited by the Board for various trials—currently 54– For living organisms, also to take into account conditions set by KSTCIE, eg double door system
- Some private eg. Delmonte for pineapples, some public eg Kenya Agricultural and Livestock Research Organization(KALRO)
- Sample delivered to PCPB—import license required
- Unique samples eg macrobials delivered to the testing centre with prior authorization by PCPB

Registration procedure cont'd

- On completion of the biological efficacy trial, a confidential report is sent to PCPB.
- Submission of a commercial label reflecting the application rates, timing of application as recommended by the local researcher, mitigation measures to non targets, among other things.
- Registration committee makes recommendations to the Board
- If the board is satisfied, Board may grant **full registration** for 3 years and a certificate of registration issued. renewable after every 2 years. Certificate issued 1 month after notification– **Being reviewed**.
- Currently 1708 products registered, 19 based on macrobials
- Listed on List of registered products available on PCPB website– segregated– crops--1448, public health-158, & Technical grades--102

Suspension or deregistration

- PCPB is empowered to suspend or revoke a certificate of registration if:
  - it realized later that the content of the application was false,
  - new information indicates that the product is unsafe,
  - the premises in which the product is manufactured, formulated or stored are unsuitable for the purpose.
  - **Changed source without authority**
  - **Principal withdraws technical support**
  - Not effective or uneconomical
  - Contravened the law
  - Public interest
  - Misleading adverts
- Can appeal to the Minister, who may amend or vary the decision as he thinks fit and whose decision shall be final

Communication to pesticide users & the public

- Workshops, shows, media etc
- Mainly through labels
- Labelling regulations in Legal Notice No. 89/1984 and 127/2006
- Regulation 3(1): No pest control product shall be distributed or sold without a label.
- Regulation 3(2): No label shall be used on a pest control product unless it has been approved by the Board
- Must be in English and Kiswahili
- Types
  - ***Experimental /provisional***
  - ***Commercial***

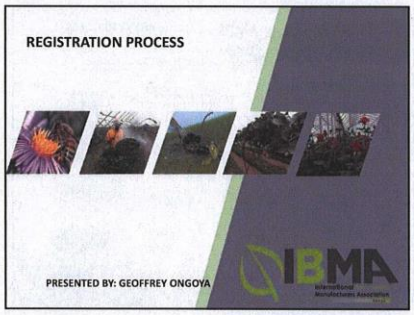
Quality assurance

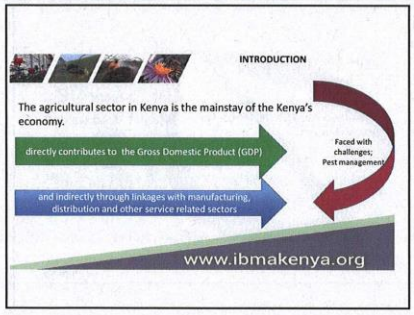
- PCPB is equipped with an analytical laboratory
- Provides of analytical support services and quality assurance of pest control products during & after registration focusing on formulation analysis.
- Over 250 new applications received annually requiring quality checks
- In 2017/18, 340 samples were analysed and results used to correct products that were not complying.
- Increasing scope of analysis—new also lab to cover biopesticides
- Considering accreditation of labs for identification and quantification

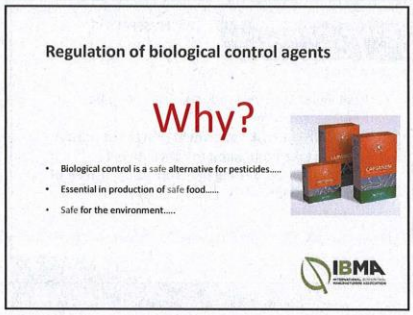
General observations

- Need to have accredited labs for identification
- Need for capacity building in identification, quantification and culture collection centre
- Quality control for active agent and contaminants
- How do importing counties for horticultural produce treat macrobials found on imported consignments?
- Acceptable level of control??
- Lack of certificates of registration in some countries of origin

5.3 Presentation IBMA Kenya







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Regulation of biological control agents

Why?

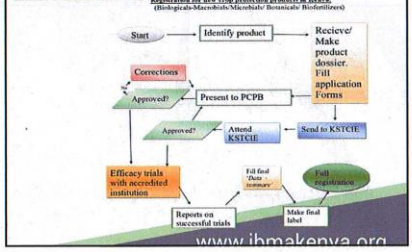
- Increased concern about the environment
- Increased concern about Biodiversity
- *Can it be justified to introduce exotic species?*

➢ Existing regulation often not appropriate for IBCA's
  - Specific regulation required, to avoid overregulation

➢ Increases credibility of biocontrol industry

IBMA

CURRENT PROCESS



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PERSPECTIVES

- Positive lists (GRAS) products- Consider data requirement waivers
- Harmonize the risk assessment process to shorten the time taken compared to conventional
- Consider efficacy testing per crop group instead of per crop (PCPB)

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Conclusions:

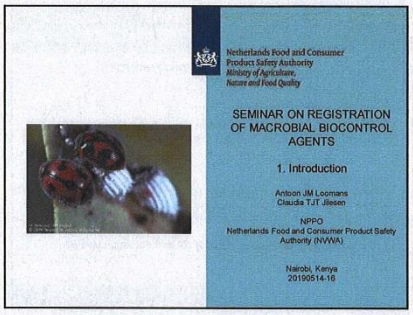
- A smooth and clear procedure is vital
- Take risks proportionate; balanced to risks of pesticides
  Safe unless otherwise proven

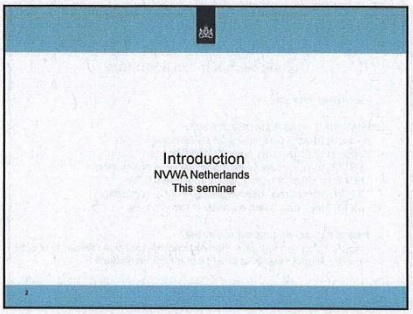
➢ *Keep supporting the use of biocontrol agents*

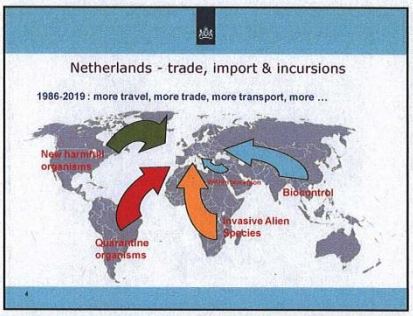
IBMA

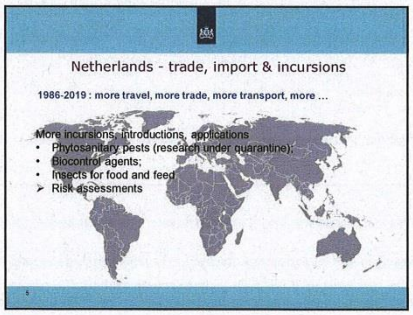
2

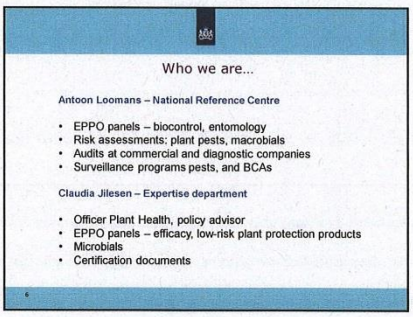
5.4 Presentations NVWA











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Outline Seminar - programme

1. Registration process –

Establishment present process in Kenya
- steps, actions, actors, time lines, data requirements
- documents, legal requirements, decision making

✓ KSTCIE on the process on macrobial BCA registration
✓ PCPB on product registration of macrobial BCA
✓ NVWA international benchmarking on BCA registration
✓ IBMA Kenya on current application experiences

➢ How is the current process organized?
➢ How do forms for application for introduction / product release look like?
➢ Possible improvements of process and documentation?

7

Outline Seminar - programme

2. Information requested -

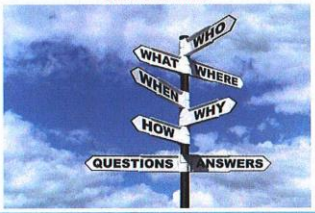
Which information is needed to perform a proper risk assessment?
➢ Do the questions asked lead to the proper information to perform a RA?

3. Information provided -
Is the provided information sufficient to perform a proper risk assessment?
What are the criteria to evaluate respectively decide whether an agent can be introduced c.q. a product can be authorized?

➢ Do the answers given allow a proper RA and decision making?

8

Outline Seminar



9

2

Netherlands Food and Consumer Product Safety Authority
Ministry of Agriculture, Nature and Food Quality

SEMINAR ON REGISTRATION OF MACROBIAL BIOCONTROL AGENTS

2. International and national benchmarking

Antoon JM Loomans
Claudia TJT Jiesen

NPPO
Netherlands Food and Consumer Product Safety Authority (NVWA)

Nairobi, Kenya
20190514-16

Overview

1. Regulatory Landscapes
2. Background, history
3. Globally
4. Europe - EPPO
5. Examples – e.g. Netherlands
6. Objectives of the Workshop

2

Regulatory Landscapes International

3

Regulation Biocontrol (1)

IPPC (1951) Addresses exotic phytosanitary (quarantine) pests
ISPM 3 (2005): 'Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms'

CBD (1992) Addresses environmental impact of exotic species (habitat)
Art 8 (h) *"Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species"*

FAO (1996) Code of conduct for the import and release of exotic biological control agents

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Regulation Biocontrol (2)

Plant Protection Product Acts - pesticides, microorganisms (macro organisms)

Harmonization on regulation biocontrol
EPPO (1999, 2001, 2003), OECD (2004), IOBC (2005), REBECA (2007)

REBECA

OECD

International Organisation for Biological and Integrated Control (IOBC)
West Palearctic Regional Section (WPRS)
IOBC-WPRS

5

International Plant Protection Convention (IPPC)

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: ...

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

International Plant Protection Convention

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SCOPE ISPM 3

- The standard provides guidelines for risk management related to the export, shipment, import and release of biological control agents and other beneficial organisms.
- The standard addresses biological control agents capable of self-replication as well as sterile insects and other beneficial organisms and includes those packaged or formulated as commercial products.
- 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.

ISPM 3 NPPOs or other 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 ...;
- ensure [they] 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** ... in order to assess impact on target and non target organisms.
- Prior to release, NPPOs or other responsible authorities are encouraged to communicate details of the intended release that may affect neighbouring countries.... details ... may also be communicated to relevant RPPOs."

Regulatory Landscapes Europe

1. EU Regulation on invasive alien species (1143/2014)

Article 2:

This Regulation does not apply to:

- (d) harmful organisms listed in the Plant Health Directive 2000/29 and harmful organisms for which measures have been adopted in accordance with Article 16(3) of that Directive;
- (f) micro-organisms manufactured or imported for use in plant protection products already authorised or for which an assessment is ongoing under the Plant Protection Products Regulation 1107/2009

Biological control not implicitly referred to

2. EU Regulation on Plant Health Law (2016/2031)

A pest shall be referred to as a 'quarantine pest', with respect to a defined territory, if it fulfils all of the following conditions:

- (a) its identity is established ...;
- (b) it is not present in that territory ... or, if present, only distributed to a limited extent within that territory ...;
- (c) it is capable of entering into that territory, of perpetuating its presence ... for the foreseeable future ...(hereinafter: 'to establish') and of spreading within that territory, or, if present, those parts of it where it is distributed to a limited extent ...;
- (d) its entry, establishment and spread would ... have an unacceptable ... impact for that territory, or, if present, those parts of it where it is distributed to a limited extent; and
- (e) feasible and effective measures are available to prevent the entry into, establishment or spread of that pest within that territory, and mitigate its phytosanitary risks and impacts.

Biological control not referred to, unless Quarantine pest

3. EU Regulation on the placing of plant protection products on the market (1107/2009 EC)

A PPP shall not be placed on the market or used unless it has been authorised in the MS concerned in accordance with this Regulation."

- "... lays down rules for the authorisation of plant protection products (PPP) in commercial form and for their placing on the market, use and control within the Community.
- "...lays down both rules for the approval of active substances, safeners and synergists, which PPP contain or consist of, and rules for adjuvants and co-formulants.
- ... shall apply to substances (or preparations), including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'

2

Data requirements PPP (Regulation EC 284/2013)

Information shall be sufficient to evaluate efficacy and risks (= safety)

- *A summary and evaluation of all data relevant to the environmental impact shall be carried out ... It shall include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the database.*

NOT a Pest Risk Analysis (PRA) under plant health rules!

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Data requirements PPP – Efficacy (1)

EPPO PP 1/214 (4) Principles of acceptable efficacy

The efficacy of a PPP can be defined as a measure of the overall effect of its application on the agricultural system in which it is used.

The net result of the positive and negative effects should be a sufficient overall agricultural benefit to justify the use of the plant protection product.

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Data requirements PPP – Efficacy (2)

EPPO Standard PP 1/296(1) Principles of efficacy evaluation for low-risk plant protection products

Contribution to sustainable agriculture including compatibility and function within an IPM programme (such as preventing or delaying the development of resistance against existing plant protection products).

The primary criterion of acceptable efficacy is that the product should show results that are significantly superior to those recorded in the untreated control, i.e. that the use of the product is better than no use (not compared to chemical control !)

Could this apply to macrobials as well ?

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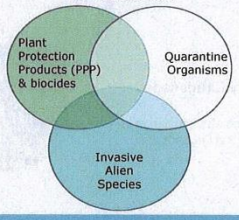
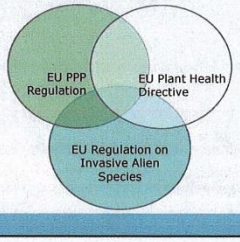
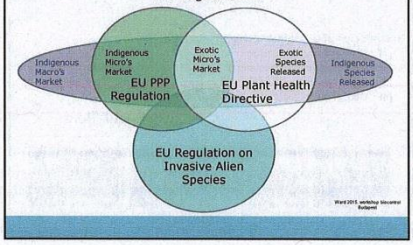
EU Regulations



EU Regulations



EU Regulations



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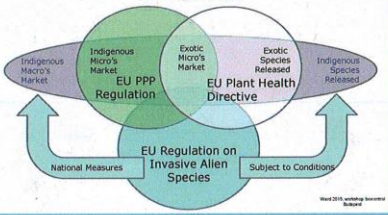
EU Regulations



Summary of EU situation

- Three EU regulations address - different risks of introduction
- Some countries BCAs under Plant Health, Environment, PPP
- But not, explicitly, biological control agents
- New separate legislation is unlikely for the EU
- Use of biological control may be unnecessarily restricted
- Therefore we need agreed guidance to ensure harmonisation of interpretation and implementation
  - Agreed between whom?
  - What guidance, addressed to whom?
  - How harmonised?
  - In what direction to harmonise?
  - How to build on what has already been achieved?

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Regulatory Landscapes EPPO

European and Mediterranean Plant Protection Organization

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Legislation & regulation biological control

1. **Biological control:**
   - conservation, classical; inoculative, inundative control
   - natural; urban en greenhouse ecosystems
2. **Biocontrol agents (BCAs):**
   - macrobials: arthropods (insects, mites), nematodes
3. **Environmental risks (plant health risks):**
   - non-target effects, displacement
   > legislation and regulation

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Regulation Biocontrol

Strategies of biological control [Eilenberg et al., 2001]

(1) Classical biological control
(2) Inoculative biological control
(3) Inundative biological control
(4) Conservation / natural biological control

} release BCAs native / exotic agents

⇩ Regulation

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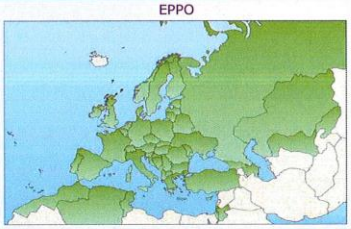
EPPO



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4

EPPO / IOBC

52 countries:
North Africa, Near East Asia, Russia + republics

EPPO / IOBC standards Safe Use Biological Control

Workshop EPPO – CABI -1996 **Safety & Efficacy BCA**

PM 6/1(1) – 1999 **First import of exotic biological control agents for research under contained conditions**

PM 6/2(2) – 2014 **Import and release of non-indigenous biological control agents**

PM 6/3(4) – 2016 **List of biological control agents widely used in the EPPO region, 94 species.**

PM 6/4(1) – 2018 **Decision-support scheme for import and release of biological control agents of plant pests**

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Open ends in EPPO

EPPO member states:
- variety of existing legislative acts and measures
- a sovereign right to make its own decision whether or not to release a BCA

Improvements (Hunt et al., 2006; Mason et al., 2017)
- Harmonization data requirements, application procedures and dossier formats between MS
- Widespread use EPPO standard PM 6/2 as a standardized application form (similar to NAPPO RSPMs 7 & 12).
- Pan-European expert panel be created to evaluate dossiers using a well-defined set of risk analysis criteria. NAPPO experts all countries are consulted and recommendations are exchanged among national regulatory authorities.
  - EPPO / IOBC joint panel
  - EPPO standard PM6/4 - decision support scheme for the release of IBCAs as an alternative to an independent advisory group.

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Open ends in EPPO

EPPO member states:
- variety of existing legislative acts and measures
- a sovereign right to make its own decision whether or not to release a BCA

Instigate **global harmonisation**
- Facilitate / biocontrol companies that sell agents around the world.
- Allowing companies access to the horticultural sector must be balanced against the risk of spreading unsafe IBCAs between countries.

➢ Harmonisation of requirements between EPPO and other regional plant protection organizations could help to resolve such hurdles.

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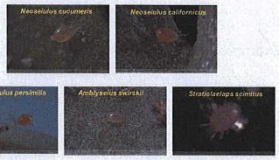
EPPO PM 6/3(4) "Positive List"

Predatory mites



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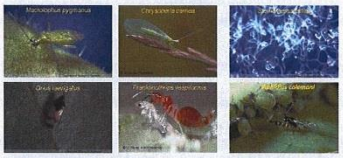
EPPO PM 6/3(4) "Positive List"

Predatory bugs, parasites, EPN



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EPPO PM 6/3(4) "Positive List"

Parasitoids

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EPPO PM 6/3(4) "Positive List" - excluded

Invertebrate BCAs not exempted:

Harmonia axyridis, Hippodamia convergens, Podisus maculiventris, Orius insidiosus, Dicyphus hesperus, Cotesia marginiventris, Amblyseius californicus, Encarsia pergandiella, Phasmarhabditis hermaphrodita, etc.

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EPPO PM 6/3(4) "Positive List" - future

How to use the positive list!?
- Pre-evaluation on non-significant risks
- Aid for quick regulation procedures

Points of attention:
- Proper identification is crucial:
  - list is a species list, correct ID species necessary
  - confirmation (by expert)
  - vouchering of specimens
  - check for contamination
- Include BCAs "and other beneficial organisms"?
- Grouping of species possible?

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Examples countries …

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Examples: Canada

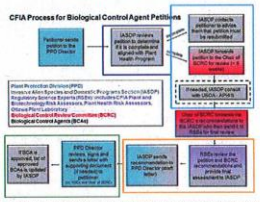

Figure 5. Review process for petitions to release a classical biological control agent in Canada.

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Examples EPPO member states - UK

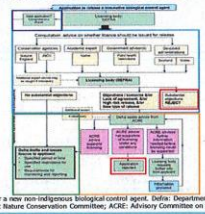

Figure 2. Review process for a new non-indigenous biological control agent. Defra: Department for the Environment, Food and Rural Affairs; JNCC: Joint Nature Conservation Committee; ACRE: Advisory Committee on Releases to the Environment.

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Examples EPPO member states - Switzerland

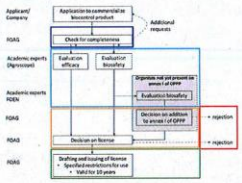

Figure 4. Review process for a biocontrol product used in an agricultural context in Switzerland. FOAG: Federal Office for Agriculture; FOEN: Federal Office for the Environment; OPPP: Ordinance on Plant Protection Products

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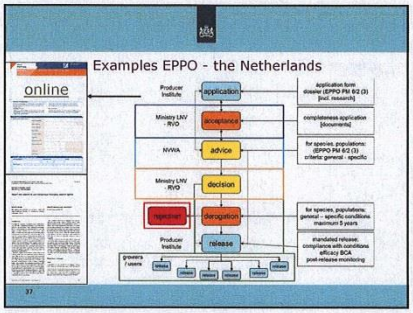
Examples EPPO - the Netherlands



Examples other states

What is different, what is in common?

- Legislation, regulations differ per country region
- Harmonisation efforts NAPPO, EPPO on process
  - Administration: application (forms): new, renewals, exemption
  - Completeness (data, info requirements)
  - Consultation (assessment of data, evaluation)
  - Conclusion (import, release; conditions)
  - Administration: licence / permit (for import, release)
  - Guidance for applications
- Role - Interafrican Phytosanitary Council (IAPSC)?

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The Netherlands ...

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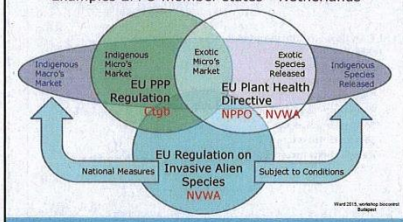
Examples EPPO member states - Netherlands



Regulation the Netherlands

Micro-organisms (fungi, bacteria, viruses, etc.) : legislation PPP

- are considered substances, products
- applications and risk assessments for products performed by Ctgb (https://www.ctgb.nl/)

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Regulation the Netherlands

Macro-organisms (animals): Nature Protection Act (Plant Protection Act)

Release of **macro-organisms (insects, mites, nematodes, etc.)** in the Netherlands conform Nature Protection Act (protection of species, habitat, biodiversity):
article 3.34 § 1: *"release of animals or eggs of animals into nature is forbidden"*

Applies for macro-organisms as a species such as :

- Natural enemies release as biological control agents of pests and invasive plants,
- Beneficials (prey, hosts) as supporting (food) organisms.

The prohibition to release not only into nature, but also if they can end up in nature via (greenhouse) crops, storage, buildings, etc..

Applicatations by RVO and Assessements by NVWA (https://www.nvwa.nl/)

Plant Protection Act: in case of phytophagous feeding (herbivores, omnivores)

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Regulation the Netherlands

Macro-organisms (animals): Nature Protection (Plant Protection) Act

Two options Criteria for Environmental Risk Assessment

1) Exemptions – BCAs & prey already in use 1967 - 2004 (1) – 2015 (2):

- 200 already (widely) used BCAs, exotic / native
- Quickscan based on available information: safe for native flora and fauna
- Based on arguments NOT to (continue) release
- 169 exempted - 134 species 2004, 35 species added in 2015
- Exotic / native 79 + 55 / 15 + 20 (94 + 75)

2) Licensed – species not exempted or not yet used

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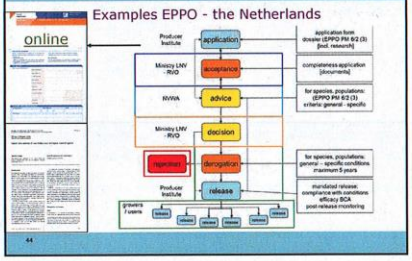
Examples EPPO - the Netherlands



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New applications the Netherlands - derogations

BCAs new or not exempted
Applications 2005 – 2017
Applicant responsible

- Evaluation of individual dossier
- Derogation - individual license
- Permit to release a single species
- 38 species licensed
- 80 permits [10 renewals]
- 2 applications not permitted

New applications the Netherlands – derogated species

Applications 2005 – 2017

- 14 parasitoids
- 7 predatory mites
- 7 other beneficials (mites, shrimp eggs)
- 2 polyphagous predatory bug
- 5 coccinellid
- 1 lace wing
- 1 nematode
- 1 herbivore (IAS)

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Post-release surveys: general conclusions

- Coccinellids, aphid parasitoids, predatory mites, predatory bugs
- Released exotics escape from the protected environment
- Survival & Establishment exotics outdoors: some local, most not. widespread *Harmonia axyridis* exception to a rule (?)
- Dispersal – spread limited
- Specificity – in hosts /prey, availability plant substrate
- Ecology (predatory mites, predatory bugs) poorly understood!
  - Occurrence on spiderinfested evergreen *Buxus*, Bambusoidaea (subtropicals e.g. *Neoseiulus californicus*)

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Considerations Benefits and Risks

Release

- ERA greenhouse BCAs is a "light" form of assessment,
- Step-based approach: "yes, unless" in stead of "no, provided that"
- White (positive/exemption) lists as assessment prior to application.

Import

- Over 5 billion specimens / year imported from outside EU
- Veterinary checks (GVD), sometimes product; phytosanitary permits (PP)

Export

- Annual audits on process, skills, identity and purity commercially BCAs
- Issuing of phytosanitary and veterinary certificates

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6. Objectives – this seminar

- Common understanding of which rules apply to which scenarios
- Knowledge of how rules are currently applied in different countries
- Analysis of resulting problems and of knowledge gaps
- Recommendations to regulators
- Recommendations to industry
- Recommendations to researchers
- Recommendations to this project
  - Input to strategy in relation to application on Biological Control Agents
  - Input to terms of reference for the assessment on Biological Control Agents
  - Input to decision-support for evaluation of Biological Control Agents

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9/17/2019

Netherlands Food and Consumer Product Safety Authority
Ministry of Economic Affairs

SEMINAR ON REGISTRATION OF MACROBIAL BIOCONTROL AGENTS

4. Evaluation of Risk and Efficacy

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Nairobi, Kenya
20190514-16

Overview

1. Information obtained
2. How to ... evaluate information?
   - Key information for decision making (need to know) / additional information (nice to know)
   - Criteria
   - Step wise approach

2

Regulatory Landscapes

International
Regional Europe
National Netherlands

3

How to evaluate biological control ?

5. **Invasive pests:**

- **Pest Risk Analysis (PRA)**
  plant protection
  phytosanitary risks, pathway: accidental introductions
- **Environmental Risk Analysis (ERA)**
  environmental protection
  ecological risks, no pathway: intentional introductions

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How to evaluate biological control ?

5. **Invasive pests:**

- **Pest Risk Analysis (PRA)**
  plant protection
  phytosanitary risks, pathway: accidental introductions
  - **IPPC - ISPMs, EPPO PRA for pests)**
  - **EPPO – Guidelines for Import and Release**
  - **EPPO - DSS PM 6/4(1) 2018 : Decision-support scheme**
- **Environmental Risk Analysis (ERA)**
  environmental protection
  ecological risks, no pathway: intentional introductions
  - **Van Lenteren et al., 2003, 2006)**

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PM 6/2(3) = guidance required info, not a form

Part 1. Application information
- Information on the applicant
- Purpose of the application and use

Part 2. Information for indigenous and non-native BCAs
- Taxonomy and origin
- Product information

Part 3. Information requirements for release of a non-native BCA
- 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

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PM 6/2(3) Evaluation

Evaluation of the dossier: National Authority

1. Subject to **pest risk analysis (PRA)** before release?
   1. Not e.g. exempted species
   2. Yes as appropriate
      1. ISPM No. 2 (Framework for pest risk analysis)
      2. ISPM No. 11 (Pest risk analysis for quarantine pests),
      3. EPPO Standard PM 5/3(5) (Guidelines on Pest-Risk Analysis) detailed instructions to conducting pest risk assessment.
2. Should also consider **possible impacts on the environment**, such as non-target invertebrates.
3. Respect all relevant national and international regulations (for example on the **safeguard of natural resources, the movement of rare/endangered organisms**).
4. After examination dossier make a **decision** within a previously agreed period of time to grant a permit (licence).
5. May propose **precautions or restrictions** in the manner of release, recommend that the organism should **not be imported or released**.
6. The permit to import and/or release will be valid for a fixed period of time, after which a renewal may be sought.

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PM 6/2(3) Evaluation

Evaluation of the dossier: National Authority

- Based on information made available (from PM6/2(2) by applicant
- Weighed against information available by evaluator

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Biocontrol Risk Assessment: forms and guidance

EPPO, PM6/4(1) 2018 DSS

- **Based on PM6/2(3)**

PM 6/04 (1) Decision-support scheme for import and release of biological control agents of plant pests

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Biocontrol Risk Assessment: steps

DSS EPPO, PM6/4(1) 2018

1. **Express PRA**
   1. **Step 1: initiation (reason, earlier)**
   2. **Step 2: BCA categorization**
   3. **Step 3: Impact assessment**
   4. **Step 4: Decision taking**
2. **Full PRA**

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Biocontrol Risk Assessment: criteria

DSS EPPO, PM6/4(1) 2018

1. **Express PRA**
   1. **Step 1: initiation (reason, earlier)**
      1.1. Provide the reason for performing the EIA
      1.2. Existence of an earlier EIA
   2. **Step 2: BCA categorization**
      2.1. Specify the BCA
      2.2. Identification of the assessment area
      2.3. Distribution of the BCA within the IAA (present, widely; indigenous)
   3. **Step 3: Impact assessment**
   4. **Step 4: Decision taking**
2. **Full PRA**

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Biocontrol Risk Assessment: criteria

DSS EPPO, PM6/4(1) 2018

1. **Express PRA**
   1. **Step 1: initiation (reason, earlier)**
   2. **Step 2: BCA categorization**
   3. **Step 3: Impact assessment**
      3.1. What is the intended use of the BCA?
      3.2. Likelihood of BCA establishment (i.e. perpetuation, foreseeable) in the IAA after release
      3.3. Likelihood of dispersal of the BCA within the IAA
      3.4. Likelihood of occurrence of non-target effects of the BCA within the IAA
   4. **Step 4: Decision taking**
2. **Full PRA**

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Biocontrol Risk Assessment: criteria

DSS EPPO, PM6/4(1) 2018

1. **Express PRA**
   - **4. Step 4: Decision taking**
     - 4.1 Is the BCA likely to make a positive environmental impact in the IAA by reducing target pest populations and/or by preventing/reducing plant protection product treatments / procedures?
     - 4.2 Is the BCA's positive environmental impact in the IAA likely to significantly exceed the negative environmental impact identified in Question 3.4?
     - 4.3 The BCA is not likely to present a risk for the IAA or the risk is likely to be compensated by a positive environmental impact from the introduction of the BCA. The assessment can stop, and import and releases can be recommended (**summarize the main reasons for stopping the assessment**).
     - 4.4 The BCA is likely to present a risk for the IAA and this risk is not likely to be compensated by a positive environmental impact from the introduction of the BCA. The assessment can stop, and import and releases should not be recommended (**summarize the main reasons for stopping the assessment**).
2. **Full PRA**

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Biocontrol Risk Assessment: criteria

DSS EPPO, PM6/4(1) 2018

1. **Full PRA, step 1**
   - 1.01-1.04. as in express PRA;
   - 1.05 Existing EIA valid? Entirely = STOP, partly, not
   - 1.06-1.12 Specify all hosts, distribution; valid taxonomic entity, identifiable*; native, present
   - 1.12. Release impacts distribution,
   - 1.13. Non-targets present = step 2 - detailed info more analysed
   - 1.14. Current distribution = IAA?, NO = stop, release allowed 1.17
   - 1.15. Evironmental impacts unwanted? NO = stop, release allowed 1.17
   - 1.16. Potential environmental impact! = step 2 detailed info more analysed
   - 1.17. Release considered safe; release allowed
   - 1.18. Assessment not possible *, inappropriate

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Biocontrol Risk Assessment: criteria

DSS EPPO, PM6/4(1) 2018

1. **Full PRA, step 1**
2. **Full PRA, step 2, establishment + uncertainty**
3. **Full PRA, step 3, spread + uncertainty**
4. **Full PRA, step 4, impact + uncertainty**
5. **Full PRA, step 5, summarize uncertainties**
6. **Full PRA, step 6, conclusion**

Assessment & Evaluation

- Based on information made available (from PM6/2(2) by applicant
- Based on information available by evaluator

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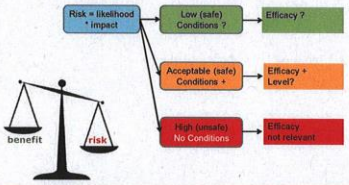
Balance risk / efficiency



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Efficacy Assessment

EPPO Standard PP 1/296(1) -
... Contribution to sustainable agriculture including compatibility and function within an IPM programme (such as preventing or delaying the development of resistance against existing plant protection products).

➢The primary criterion of acceptable efficacy is that the product should show results that are significantly superior to those recorded in the untreated control, i.e. that the use of the product is better than no use (not compared to chemical control !)

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Efficacy Assessment

When efficacy of low risk is expected (assessed?) low

- Based on experience, information provided
- What data are required / necessary ?
  - When it adds some part of control?
  - Role in an IPM system?

➢ What to apply for macrobials ?

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Annex 6 benchmarking Kenyan information requirements and EPPO Pm 6/2(2)

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
PART A: GENERAL INFORMATION PART B: DETAILS OF THE ORGANISM PART C: IDENTITY AND INFORMATION OF PRODUCT PART D: SAFETY INFORMATION PART E: PROJECT PLAN PART F: DECLARATION	**Application form page 1-5** PURPOSE OF APPLICATION 1. APPLICANT 2. PRODUCT 3. IDENTIFICATION 4. SOURCE 5. FORMULATION 6. SUMMARY OF ENVIRONMENTAL EFFECTS (BIOSAFETY) 7. PACKAGING 8. OTHER SPECIFIC REQUIREMENTS 9 DECLARATION	**FORM A2, LIST MI** 1. DESIGNATION / IDENTITY OF ACTIVE AGENT (PURE) 2. BIOLOGICAL PROPERTIES OF THE MACROBIAL AGENTS 3. FURTHER INFORMATION ON THE MACRO-ORGANISM 4. BIOSAFETY 5. ENVIRONMENTAL SAFETY 6. BEHAVIOUR IN ENVIRONMENT (Active agent)	**FORM A2, LIST MII** 1 DESIGNATION / IDENTITY OF ACTIVE AGENT (FORMULATED) 2 PHYSICAL AND CHEMICAL PROPERTIES 3 BIOLOGICAL PROPERTIES OF THE FORMULATED MACROBIAL AGENTS 4 FURTHER INFORMATION ON THE FORMULATED MACROBIAL AGENT 5 BIOSAFETY 6 ENVIRONMENTAL SAFETY 7 BEHAVIOUR IN ENVIRONMENT 8 INTENDED USES 9 MINIMUM LABEL REQUIREMENTS 10 EVIDENCE OF REGISTRATION IN OTHER COUNTRIES 11 OTHER SPECIFIC REQUIREMENTS 12 PROPOSED PACKAGING 13 PROCEDURES OF DESTRUCTION AND DECONTAMINATION	Part 1. Application information (A) Information on the applicant (B) Purpose of the application and use Part 2. Information for indigenous and non-indigenous BCAs (A) Taxonomy and origin (B) Product information Part 3. Information requirements for intentional release of an non-indigenous BCA with reference to: (A) Biology and ecology (B) Assessment of risks and benefits (a) Establishment (b) Host specificity (c) Dispersal (d) Non-target effects Part 4. Submission of forms and signature(A) Submission details(B) Agreement: safeguards and signature Part 5. Appendices, if appropriate

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
PART A: GENERAL INFORMATION				
1. Name of applicant/ Company	1.1 Name of applicant 1.2 Corporate name of company 1.3 Reg No. of the company			1.1 Name of organization Name of applicant (only a legally authorized person is allowed to apply) Affiliation of applicant
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided	1.7 Physical Address 1.8 Postal Address 1.9 Telephone (and area code) Fax (and area code) E-Mail			1.1 Address, Post code, City, Phone, Fax, E-mail, Chamber of Commerce number
3. Name of Local agent (if different from applicant)	1.5 Name of local agent in country: (if different from registration holder)			1.2 Name of contact person (research manager and / or quarantine officer) Affiliation of contact person
4. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided	1.7 Physical Address 1.8 Postal Address 1.9 Telephone (and area code) Fax (and area code) E-Mail			1.2 Visiting address, Post code, City, Phone, Fax, E-mail
5. Name of Manufacturer				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
6. Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided				1.5 Facilities and procedures Describe how the risks, in particular probability of escape and possible extent into the wild for import / rearing of non-indigenous organisms will be managed. Address, Post code, location, Facility, Contingency plan, Standard Operating Procedures, Quality control management, Accreditation
7. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other)				1.4 Purpose of use: - Import: Research, (Mass) rearing - Release: Trials, Commercial - Type of biocontrol programme - Type of area where BCA will be released
8. Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc	2.5 Intended use: (veterinary, horticultural, public health, industrial, agriculture, forestry, etc).			
9. Quantity/ Amount proposed for importation				
	1.4 Name of registration holder			
	1.6 Status: (Importer / formulator / distributor etc.)			

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
				1.3 Information about the application: - Application type: Renewal/ First Application - Listed on EPPO PM 6/3? - Relation with previous/ other applications - Application or registration elsewhere in EPPO region - License period requested
PART B: DETAILS OF THE ORGANISM				
24. The scientific name(s) of the organism (Genus, species, strain/variety) *All must be provided*	2.1 Identity and stage(s) of active agent and culture collection code 3.1 Identification Scientific name Common name(s)			2.1 Identity For what species/ organism is the application made? Indicate which species is involved (a single species per application) and full scientific name and taxonomy. (Class, Order, Family, Genus, Species, Sub-species, Common names, Alternative names, Associated organisms Indicate means, methods of ID confirmation and reference(voucher) specimen (Authority, Methodology, Reference (voucher) specimen deposits
25. Common Name	3.1 Identification Scientific name Common name(s)			
26. The type of organism/ micro-organism (Bacteria, virus, fungus, nematode, insect, mite etc)				
27. Category (Macrobial, Microbial etc)				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
28. Methods of identification			1.4 Method of identification enumeration and quantification	
29. Are the organisms live or dead? If killed describe the process used *(Attach evidence)*				
30. Biology of the organism (*attach annexes and acceptable and peer reviewed publications)*		2.4 Development stages/life cycle of the macro-organism	1.3 Full taxonomic classification 3.4 Life cycle stage at which the macrobial agent is applied	2.2 Characterization of BCA Specify life-stages, strains or taxonomic constraints. Diagnostic descriptions, Specific characteristics, Taxonomic characteristics 3.1 Information regarding biology and ecology Give a description of the biology and ecology of the BCA - Life cycle – generations / year - Developmental biology - Mechanisms of survival - Mechanisms of dispersal - Climatic conditions - Habitat range - Host range - Natural enemies
31. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism *(Detailed descriptions).*				2.5 Product composition Entomopathogens, hyperparasitoids Co-formulants Contaminants (host, pest)
32. Relationship to known plant and animal parasites		2.7 Relationships to known plant, animal or human parasites	3.7 Relationships to known plant, animal or human parasites	

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
33. Mode of dispersal/ spread of the organism, Invasiveness, and colonization ability	6.1 Risk assessment for replacement of indigenous or endangered species in same niche (exotic macrobials only)	2.5 Invasiveness, dispersal and colonization ability	3.5 Invasiveness, dispersal and colonisation ability	3.3.3 Dispersal Dispersal test results are not required for releases in protected structures which restrict escape (e.g. glasshouse), but should be provided when BCAs are released into open fields or structures that do not restrain escape (e.g. polytunnels). In fields and polytunnels large numbers of organisms are released augmentively and have the potential to disperse into the wider environment before populations decline and die out. - Ability to disperse
34. Mode of action of the organism		2.2 Description of the target organism(s) and mode of action		
35. Natural occurrence (Ecosystem where it is found naturally)		2.1 History of the macro-organism and its uses. Natural occurrence and geographical distribution		2.3 What is the immediate source of the organism? Include details of the origin and distribution of the BCA (species or lower taxon). Field collected Laboratory culture Producer / supplier Original area and distribution Areas where introduced before
36. Origin of organism and world distribution and uses	4. Source (original isolation)			

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
37. Is the organism genetically modified? *If genetically modified,* *a)Approval from the Kenya Biosafety Authority* *b) Describe.*				
38. Host range		2.3 Host specificity range and effects on species other than the target harmful organism	3.3 Host specificity range and effects on species other than the target harmful organism	3.3.2 Host range assessment When outdoor establishment of the BCA is necessary or likely to occur, host range information is essential for the risk assessment - Known hosts - Organisms tested - Procedures used for host range testing - Effects on plants used by target and non-target hosts
39. Specificity to target		2.3 Host specificity range and effects on species other than the target harmful organism	3.3 Host specificity range and effects on species other than the target harmful organism	
40. Description of benefit				
41. Effect to non-target organisms				3.3.4 Direct and / or indirect non-target effects A summary of known direct and indirect non-target effects should always be given, irrespective of whether host range and / or dispersal have been assessed. - Summary of available information and conclusions on risks

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
42. Stability of the organism in the environment.				3.3.1 Potential for establishment When outdoor establishment of the BCA is very unlikely and is predicted to die out rapidly (as indicated by the data provided), the subsequent fields need not be completed, and no further risk assessments are necessary - Physical constraints - Resource constraints - Survival data and methods used - Evidence of establishment
43. Environmental requirements		2.6 Effect of environmental parameters on stability and survival (UV, temperature, soil pH, humidity, etc.) of macrobial agents	3.6 Effect of environmental parameters (UV, temperature, soil pH, humidity, etc.) on stability and survival of macrobial agents	
44. Effect on availability of soil nutrients and water.				
45. Impact in its area of distribution				
46. List of countries where the organism/product is introduced. (*attach evidence)*				
PART C: IDENTITY AND INFORMATION OF PRODUCT				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
17. Trade/commercial name	2.3 Trade name, trade mark		1.5 Development Code	2.4 Product information Product / trade name Producer / supplier Method of supply Life stages Label information Storage Method of use
18. Origin of Product (*country and state/district)*				
19. Product Type/ function (e.g. insecticide, fungicide, etc.)	2.4 Function of the product (eg predator, parasitoid, entomopathogenic nematode)	3.1 Biological function (control of insects, mites, ticks, nematodes, weeds, molluscs, etc)	4.1 Biological function (control of insects, mites, ticks, nematodes, weeds, molluscs, etc) 8.1 Function (control of insects, mites, ticks, nematodes, weed, molluscs, etc)	
20. Target pest and host	2.6 Target pest(s) and host(s)		8.2 Target pest(s)	1.6 Information about the target organism(s) Give a description of the biology and ecology of the target pest(s), including weeds. - Target host taxon - Names of target pests - Original area of distribution of the pests - Biology of pests - Target crops hosting the pest
5. Formulation Details				
5.1. Type of formulation: (e.g. EC, WP, etc.)	2.8 Type of formulation: (if any)		1.1 Formulation type and Code 2.1 Physical state (solid, liquid etc)	

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
5.2. Declare full composition of the product (Active agent (s) and inert ingredients) (Detailed information on formulation may be provided separately in a sealed envelope) Active agent(s) (Common name/s), Minimum a.i.% purity, a.i. Range %	2.2 Concentration of active agent in technical material. 3.2 Contents (number per Unit) 5.3 Composition (information on composition may be attached in sealed envelop)		1.2 Source and specifications for components included in the formulation	2.5 Product composition Co-formulants Contaminants (?)
5.3 Details of Formulator (Names, Postal address, Physical address)	5.1 Formulator: (Name and postal address)		1.6 Source, Name and Address of formulator and address and location of processing plants.	
5.4 Details of trademark owner (Names, Postal address, Physical address)	2.3 Trade mark holder			
5.5 Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)	2.9 Is the product registered in country of: a) origin b) manufacture c) formulation		3.1 History of the formulated product and its uses	
5.6 Is the product registered in other countries	2.11 Registration in other country/ies, particularly OECD countries: (country names, product name and registration number)		3.1 History of the formulated product and its uses	
5.7 Certificate of analysis from the Country of origin.				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
5.8 Specify other Physical characteristics of the product such as grade, matrix etc.				
6. Production				
6.1 Describe production method			1.8 Methods of production and quality control	
6.2 Quality control -method			1.8 Methods of production and quality control	
6.3 Shelf life			2.6 Shelf life	
6.4 Market label for the country of manufacture (Attach as annex)				
6.5 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex*				
7 Information for product use				
7.1 Mode of application	2.7 Method, dosage rates and frequency of application: a. Production b. Formulation: (if any)		8.5 Method of application	
7.2 Area of application (Greenhouse/ open field)				
7.3 Stage of the crop			8.7 Stage of treatment of host crop	

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
7.4 Dosage rates and frequency of application	2.7 Method, dosage rates and frequency of application: a. Production b. Formulation: (if any)		8.4 Application rate (appropriate units) 8.6 Recommended number and timing of applications	
8 Mode of action. *(Attach all supporting scientific publications)*			3.2 Description of the target organism(s) and mode of action of the macrobial agent	
9 Description of benefits *(Attach all supporting scientific publications)*				3.4 Efficacy and benefits of the BCA Assessment of efficacy, economic and environmental benefits - Method(s) to determine efficacy - Results of efficacy trials - Economic benefits - Environmental benefits
10 Effect on availability of soil nutrients and water.				
11 Environmental requirements. *(Attach all supporting scientific publications)*				
12 Information on Combined use/Compatibility with other crop protection measures			2.7 Compatibility with other pesticides	
13 Efficacy of the product in trials done elsewhere and results. *(Attach all supporting scientific publications)*			8.11 Local efficacy data (guidelines provided separately)	
14. Packaging				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
14.1 Type of Packaging material / container:	7.1 Packaging material/container		12.1 Type of packaging in which the product is imported 12.2 Type of packaging for distribution in Kenya 12.3 Packaging material	
14.2 Pack size(s):	7.2 Pack size(s)		12.4 Sizes of individual packaging	
14.3 Disposal of empty container(s):				
15 The proposed point of entry into the country				
16 The proposed final disposition of the organism such as destruction, treatment or destined for general release				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
				2.6 Particular situations In the case of: - A renewal of a previously successful application (section 1.3) OR - The species or population being indigenous to the country or ecoregion OR - The BCA being imported for research or rearing only OR - The BCA's mention on the EPPO list of biological control agents widely used in the EPPO region (PM 6 / 3, Appendix 1 or 2) in the intended area of release, no further information is required and only the submission details in 4(A) and (B) and Appendices (Part 5) need to be completed. For other applications, such as the release of a non-indigenous species, the information requirements in Part 3 must be supplied.
PART D. SAFETY INFORMATION				
1. TOXICOLOGY (Formulated product) For microbial products only				
1.1 Rat				
1.2 rabbit				

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
1.3 Skin	8.1 Operator exposure 8.2 Likely operator exposure under field conditions	4.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)	5.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies) 11.1 Medical surveillance, on manufacturing plant personnel	
1.4 WHO classification				
1.5 summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets				
Material Safety data (summarise material safety data sheet information here) (Attach MSDS)				
1.6 Summary of environmental effects				Potential hazards of BCA, product or any co-formulants, and measures taken to limit operator exposure, with emphasis on - Human health - Animal health - Measures of prevention
1.6.1 Toxicity to bees	6.2 Risk to bees	5.3 Bees	6.3 Bee	
1.6.2 Toxicity to fish and other aquatic organisms	6.3 Risk to fish and other aquatic organisms	5.1 Aquatic organisms (2 species) 5.2 Aquatic invertebrate	6.1 Aquatic organisms (2 species) Fish, Daphnia 6.2 Aquatic invertebrate	
1.6.3 Toxicity to birds	6.4 Risk to birds			

KEPHIS INTRODUCTION OF BIOPESTICIDES AND BENEFICIAL ORGANISMS IN KENYA	PCPB APPLICATION FOR THE REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT			EPPO PM 6/2 (3) Import and release of non-indigenous biological control agents
1.6.4 Toxicity to earthworms and soil micro-organisms	6.5 Risk to earthworms and soil micro-organisms			
1.6.5 Toxicity to other non-target organisms	6.6 Risk to other non-target organisms	5.4 Representative natural enemies	6.4 Representative natural enemies	
1.6.6 Toxicity to other non-target plants		5.5 Representative non-target plant	6.5 Representative non-target plant	
1.6.7 Persistence in environment		6.1 Persistence of active agent (days)	7.1 Persistence of active agent (days)	
1.6.8 Metabolites		2.9 Information on the production of metabolites (relevant to entomopathogenic nematodes)	3.9 Information on the production of metabolites (relevant to entomopathogenic nematodes)	
1.6.9 Other effects: Specify	6.7 Other effects: specify (human health problems)			