JUMUIYA YA AFRIKA MASHARIKI

THE EAST AFRICAN COMMUNITY

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EAC Harmonized Guidelines For The Registration Of Biopesticides And Biocontrol Agents For Plant Protection

Approved by the 39th Council of Ministers on 28th November, 2019

EAC SECRETARIAT, Arusha, Tanzania

Contents

FOREWORD

Transboundary crop pests and diseases are still a major threat to agricultural production and productivity in the East African Community and the rest of Sub-Saharan Africa causing tremendous damage to crops and threatening the livelihoods and food security of our farmers. In an effort to address this challenge, harmonization of pesticides management guidelines is an important priority in the EAC integration process. Article 108 of the Treaty for establishment of EAC provides the mandate for EAC Partner States to adopt common mechanisms for ensuring safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines. The ultimate aim of harmonization is to harness limited resources within the region, improve trade by reducing the time and cost associated with registration of pesticides and to provide better protection for the population and the environment from the toxic effects of pest control products.

The EAC Secretariat with support from USAID Kenya and East Africa and in collaboration with the Food and Agriculture Organization of the United Nations (FAO) through the European Commission programme on 'Capacity Building related to Multilateral Environmental Agreements (MEAs) in Africa, Caribbean and Pacific countries (ACP/MEAs' Phase 2) initiated a process of drafting EAC harmonized pesticides management guidelines in 2016. Subsequently, the 38th Extra-Ordinary Council of Ministers held on 30th January, 2019 adopted guidelines on efficacy trials, residue trials and registration requirements and directed Partner States to domesticate.

EAC embarked on this arduous journey in 2016 with a clear vision to produce world class-harmonised guidelines by 2018. The process of domestication and pilot testing of EAC harmonized guidelines on efficacy trials and registration requirements commenced in 2019. However, absence of harmonized guidelines for registration of biopesticides has been limiting efforts by the crop protection industry to test and register their products in the region. In this regard, the EAC Technical Working Group (TWG) on pesticides prioritized the development of additional guidelines for registration of biopesticides and biocontrol agents for plant protection in March 2019. The process culminated to adoption of the same by the 39th Council of Ministers in November 2019. The completion of the process of development of the guidelines is a realisation of the EAC vision and a fruition of the Community's efforts to capacitate policy institutions in the region and other sector relevant stakeholders to deliver on their mandates.

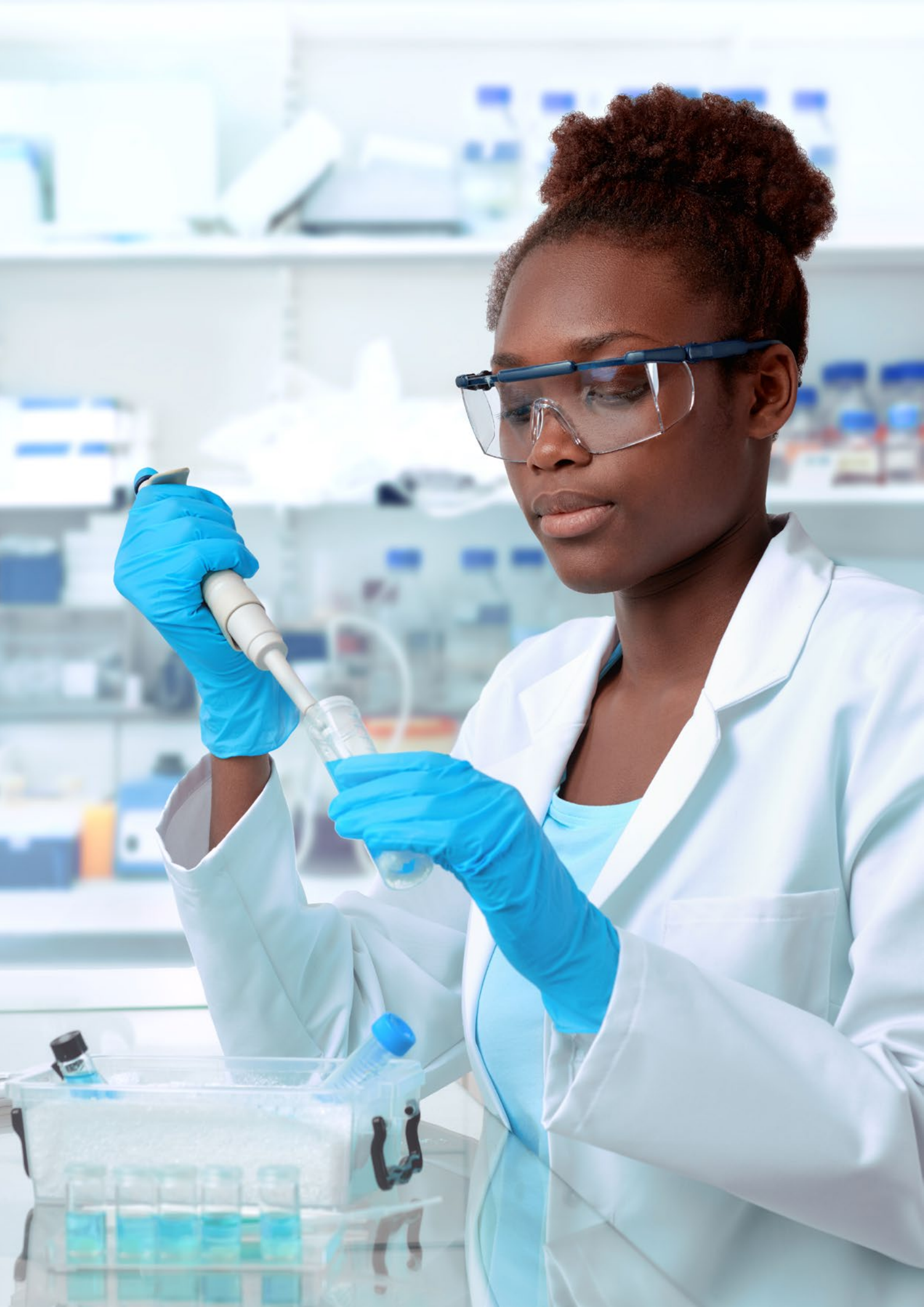
I wish to express my sincere gratitude to USAID Kenya and East Africa, the United States Department of Agriculture and the African Agricultural Technology Foundation for financial and technical support extended towards the development of these guidelines. Let me pay special tribute to the members of the EAC Technical Working Group (TWG) on pesticides for playing a very instrumental role in the drafting, validation and finalization process. The entire development process of the guidelines was carried out under the overall supervision and excellent leadership of the Directorate of Productive Sectors at the EAC Secretariat.

The design and printing of these guidelines was undertaken by CAB International (CABI) under its Action on Invasives programme, which is supported by the UK Foreign, Commonwealth & Development Office (FCDO) and the Netherlands' Directorate-General for International Cooperation (DGIS). Their support is gratefully acknowledged.

Hon. Christophe Bazivamo

Deputy Secretary General Productive and Social Sectors

EAC Secretariat



PREAMBLE

EAC Partner States are progressively intensifying their agriculture to meet the regional demands for food and exports. To sustainably achieve this, Partner States foresee a need for increased use of safer pesticide products. However, varied and inadequate regulatory regimes remain an impediment. Excessive use of conventional pesticides under the current regulatory regimes shall undoubtedly degrade the environment, reduce productivity and cause adverse effects on health of consumers accessing those commodities. Because of the above, there is need for development, at regional level, of efficient, competitive and sustainable agricultural sector that requires strict standards on the use of pesticides. Attention is now on the use of safer pest control alternatives especially Bio-pesticide and bio control agents.

Bio-pesticides are generally less toxic to humans and have less impact on the environment. Similarly, biocontrol agents are an important tool in Integrated Pest Management system. However, their registration system is still a challenge among Partner States. There is no specific legislation governing their registration. Where they exist, data requirement is insufficient. A meeting of the EAC Technical Working Group on pesticides held in Arusha in March 2019 prioritized development of regionally harmonized guidelines for registration of Biopesticides and bio control agents. The availability of the harmonized guidelines will facilitate trade by significantly simplifying data requirements among Partner States and ensure mutual recognition of work done within the region.

ABBREVIATIONS

BCF Bio Concentration Factor
CAS Chemical Abstracts Service
CFU Colony Forming Unit
CRISPR Clustered regularly interspaced short palindromic repeats
DNA Deoxyribonucleic acid
EAC East African Community
EC European Commission
FAO Food and Agriculture Organization of the United Nation
GMOs Genetically modified organisms
GV Granulosis virus
ICIPE International Centre of Insect Physiology and Ecology
IPM Integrated Pest Management
IPPC International Plant Protection Convention
ISO The International Organization for Standardization
ISPM International Standards for Phytosanitary Measures
IU International Unit: a standardised measure of dosage for Bt products
IUPAC The International Union of Pure and Applied Chemistry
NOEL No observable effect level' in testing toxicity and other undesired effects of a pesticide.
NPV Nuclear Polyhedrosis Virus
OECD Organisation for economic cooperation and development
POB Polyhedral Occlusion Body
RNA Ribonucleic Acid
SCLPs straight chain lepidopteran pheromones
TGAI Technical grade active ingredient.
WHO Word Health Organization

1. INTRODUCTION

The EAC Partner States need to intensify agricultural production to ensure achievement of food security and increased incomes through trade of agricultural produce that is necessary to support their economies. Currently, plant protection is heavily dependent on the use of conventional pesticides whose excessive use may adversely impact human health and environment. The development and use of alternative plant protection approaches such as Biopesticides is recommended to augment existing Integrated Pest Management (IPM) system. Biopesticides are a potential tool in integrated pest management as they generally pose minimal health or environment risk and can have good compatibility with many beneficial invertebrates used in IPM.

Biopesticides that include Microbials, macrobials, botanicals and semiochemicals are evaluated and registered following the same system as for conventional chemical pesticides in most Partner States. However, this approach poses an unnecessarily high and inappropriate regulatory burden. This is because many, if not most, of the data requirements and evaluation criteria are not relevant to biological pest control agents (e.g. the data requirements for chemical identity are not relevant for a microorganism but appropriate studies on taxonomy are critical). Further, the level of risk resulting from the use of biological pest control agents is often lower than for conventional chemical pesticides, so higher tier testing is usually unnecessary.

The registration of biopesticides and biocontrol agents should take into account the special biological properties of the natural agents and requires expertise in microbial ecology, bacteriology, virology and protozoology in order to understand the biology of the particular agents and evaluate key issues of safety and environmental impact. In dealing with biopesticides and biocontrol agents, it is important for regulatory authorities in the Partner States to co-opt scientists with established expertise in these areas in order to facilitate their registration.

1.1 OBJECTIVES

These guidelines aim at ensuring harmonized data requirements, evaluations and decision making with regard to registration of Biopesticides and biocontrol agents provide an acceptable level of protection for human and animal health and the environment.

1.1.1. Overall Objective

Provide farmers in the EAC region with a sustainable access to safer and effective biopesticides and Biocontrol agents for pest control.

1.1.2. Specific Objectives

i. Provide EAC Partner States with a harmonized framework for registration of biopesticides and Biocontrol agents.

ii. Facilitate mutual recognition and sharing of data for registration of biopesticides and biocontrol agents amongst the EAC Partner States.

iii. Facilitate best practices in the registration of Biopesticides and Biocontrol agents for plant protection.

1.2 GENERAL PROVISIONS

1.2.1 All EAC Partner States shall ensure that all new Biopesticides and biocontrol agents or new uses of existing products are subjected to a thorough efficacy evaluation before they are authorized for any use.

1.2.2 All efficacy trials involving Biopesticides and biocontrol agents shall be approved by the national pesticides regulatory authority of the Partner State.

1.2.3 Samples of the Biopesticides products shall be sent to the regulatory authority for forwarding to the testing institution.

1.2.4 Samples of the biocontrol agents shall be sent directly to the testing institution with approval of regulatory authority.

1.2.5 All dossiers shall be evaluated by expertise in microbial agents, macrobials agents and semiochemical agents in order to understand the biology of particular agents and evaluate key issues of safety and environmental impact.

1.2.6 All trials associated with biopesticides and biocontrol agents shall be conducted in accordance with the approved EAC harmonized Guidelines for efficacy trials.

1.2.7 In case there is no designated scientist or institution within a Partner State, the national authority may engage a technical expert in the subject area to conduct the trials.

1.2.8 The criteria for accreditation shall be clearly indicated to guarantee standards of the approved EAC harmonized Guidelines for efficacy trials.

1.2.9 Applicant intending to register Biopesticides or biocontrol agents in more than one Partner State shall ensure that a common crop/pest specific protocol is developed in line with the approved EAC harmonized Guidelines for efficacy trials. The applicant shall ensure the protocols are compiled with.

1.2.10 The efficacy trial report should be submitted in hard (duplicate) and soft copies to the respective regulatory authority in the Partner State, with a copy to the applicant.

1.2.11 The cost of conducting efficacy trials of biopesticides or biocontrol agents authorized by the regulatory authority will be incurred by the applicant.

1.2.12 New information on effectiveness of already registered biopesticide or biocontrol products will be relayed by the designated registration authority to the Partner States without delay for immediate follow up.

1.2.13 Where the provisions of the European and Mediterranean Plant Protection Organization (EPPO) guidelines conflict with these guidelines, the provision of these guidelines shall prevail.

1.2.14 All applicants intending to import/export live organisms into or out of the EAC Partner States should seek clearance from the National Plant Protection Organization.

1.3 SCOPE

These Guidelines cover:

i. Microorganisms (bacteria, fungi, viruses, protozoa)
ii. Macroorganisms (predators and parasitoids, insects and mites)
iii. Biochemical pesticides (botanicals and semiochemicals).

These guidelines shall not cover biochemical pesticides and any other products that may pose adverse effects on human, non-target organisms and environment. Therefore, in this case, such products shall not be considered as biopesticides and shall be evaluated as conventional pesticides. In some cases waivers will be granted where there is sufficient evidence that there are no safety concerns.

Microbial, macrobial, botanical and semiochemical biopesticides derived from or based on genetically modified organisms (GMOs) and pest control agents based on "RNA interference" technology or on "clustered regularly interspaced short palindromic repeats (CRISPR)" or other gene editing techniques and microbial agents for control of vertebrate pests e.g rodents are not covered.

1.4 REGULATORY AUTHORITY

These guidelines have been developed on the premise of article 108 of EAC Treaty which requires EAC Partner States to adopt common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines.

2. DEFINITIONS

Active agent: A living component in a biopesticide to which pest control activity is attributed.

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

Acute dermal LD50: A statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute inhalation LC50: A statistically derived estimate of the inhaled concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD50: A statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Antagonism: refers to the action of any organisms that suppress or interfere the normal growth and activity of a plant pathogen, such as the main parts of bacteria or fungi.

Baculoviruses: a member of a family of DNA viruses infecting only invertebrate animals. Some have a very specific insect host, and may be used in biological pest control.

Bioassay: Procedure or method of testing potency of a substance by its effect on living cells or tissues.

Biocontrol: A pest control strategy that uses living natural enemies, antagonists or competitors of the organism being protected and other self-replicating biotic entities.

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

Biopesticide: A generic term generally applied to a substance derived from nature, such as a microorganism or botanical or semiochemical that may be formulated and applied in a manner similar to a conventional chemical pesticide and that is normally used for short-term pest control.

Botanical: Natural (unmodified) plant extracts.

Botanical pesticides: Formulations of pesticides that originate from plants as phytochemicals and eliciting toxic effects on insects and mites.

Colony Forming Unit: An estimate of viable bacterial or fungal cells.

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

Endotoxin: a toxin present inside a bacterial cell that is released when it disintegrates.

Entomopathogenic: is the ability to act as a parasite of insects and kills or seriously disables them.

Entomotoxic: Any substance that is toxic to insects

Environmental Fate: The destiny of pesticides after release into the environment.

Formulated product: The pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.

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

Human health exposure: Degree of likelihood that one or more exposures to a biopesticides may have damaged or will damage the health of the exposed person(s).

Immunology assay: biochemical test that measures the presence of concentration or a macromolecule or a small molecule in a solution through the use of an antibody (usually) or an antigen (sometimes).

Inert ingredient: means any substance (or group of structurally similar substances if designated by Generalist.

Infectivity: The ability of a microorganism to invade and persist in a viable state or to multiply within or on an organism, with or without disease manifestation.

Integrated Pest Management (IPM): The careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep biopesticides and other interventions to levels that are economically justified and reduce or minimize risks to human and animal health and/or the environment.

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

Macrobials: An invertebrate natural enemy used for pest management.

Macroorganisms: Are organisms large enough to be seen by the normal unaided human eye.

Metabolites: are breakdown products that form when a biopesticide is used in the environment and mixes with air, water, soil or living organisms.

Microbial: relating to or characteristic of a microorganism, especially a bacterium causing disease or fermentation.

Microorganism: Living organism (such as a bacteria, fungi, viruses) too small to be seen with naked eye but visible under a microscope.

Mode of action: it describes a functional or anatomical change, at the cellular level, resulting from the exposure of a living organism to a substance.

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

Non-target organism: Living organisms other than the one against which the biopesticide is applied.

Oligophagous: An organism that attacks a limited group of related hosts.

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

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

Pathogenicity: The ability of a microorganism to inflict injury and damaging the host after infection.

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

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

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

Regulatory authority: The government agency or agencies responsible for the registration and management of pesticides/biopesticides for manufacturing, distribution, stock and sale within the country.

Residue: means any specified substances in or on food, agricultural commodities or animal feed resulting from the use of a pesticide.

Semiochemicals: Substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioural or physiological response in other individuals of the same or other species.

Shelf life: the length of time in the approved label for which a formulated biopesticide remains stable and fit for use.

Technical grade: The technical material used to manufacture the biopesticide product.

3. CATEGORIES OF BIOPESTICIDES

For the purpose of these guidelines, biopesticides fall into three categories:

i. Microbial pesticides (Bacteria, fungi, viruses)
ii. Biochemical pesticides (Botanicals and Semiochemicals)
iii. Macroorganisms (Predators and Parasitoids)

3.1 Major registration categories of Biopesticides and biocontrol agents

In the following sections the data requirements for each category of Biopesticides and biocontrol agents are described. The data requirements will apply equally whether the application is for:

3.1.1 Experimental use permit: means status granted (bearing experimental Permit number) allowing experimental use prior to submitting application for full registration.

3.1.2 Full registration: Granted when all registration requirements have been met and the registration authority has granted approval for Biopesticides and biocontrol agents according to the conditions laid down in the certificate of registration.

3.1.3 Temporary/Emergency registration: means registration status granted to a microbial biopesticide (with temporary registration number) after pre-submission consultation and approval has been given for full submission, but not allowing the Biopesticides and biocontrol agents to be used.

3.1.4 Provisional registration: means registration status granted to Biopesticides and biocontrol agents (bearing provisional registration number) pending supply of further data required by the registration authority(Black, 2013).

3.2 MICROBIAL PESTICIDES

Microbial pesticides are microorganisms that produce a pesticidal effect. They have pesticidal modes of action that often include competition or inhibition, toxicity and even use of the target pest as a growth substrate. Microbial pesticides can control many different kinds of pests, although each separate active agent is relatively specific for its target pest (s).

3.2.1. Data requirements for microbial pesticides registration

3.2.2. Biological and Chemical Characteristics

Microbial biopesticide products covered under this guideline shall meet the criteria summarized in Table 1.

3.2.2.1. Systematic name

The systematic names, consisting of genus and species names, of microbial shall be given. (example: *Bacillus thuringiensis, Trichoderma harzianum*).

3.2.2.2. Strain or isolate of microbials

The strain or isolate of microbial shall be stated clearly. (Example: *Bacillus thuringiensis* subsp. *kurstaki*, strain ABTS-351; *Metarhizium anisopliae ICIPE 69 strain*)

3.2.2.3. Source or origin, host range, and mode of action

The source or origin of microbial shall be indicated including country, where its isolated from, ecological habitat. The host range of microbial should be clearly indicated. Reports from any reliable and reputable publication journal are accepted. The mode of action of microbial should be indicated clearly (example:, infection of target, competitive or antagonistic behaviour, etc).

3.2.2.4. Biological properties

- History and geographical distribution of active agent
- Life cycle
- Mode of action
- Relationship to known plant animal or human pathogens
- Host range
- Dispersal
- Colonizing ability
- Information on production of metabolites
- Genetic stability

3.2.2.5. Specification of active agent (Technical grade) and Composition of the product

Specification of the active agent shall include names, and amount of the active agent, concentration and contaminants. Microbial active agent needs to be specified in relevant unit of activity. The example unit of activity for each microbial are as follows:

a. Entomotoxic bacteria in endotoxin content (IU/mg or ml),
b. Baculoviruses (Nuclear Polyhedrosis Virus (NPV) and Granulosis virus (GV) in viral unit (Polyhedral Occlusion Body (POB)/capsul count/ml or mg),
c. Entomopathogenic fungi and antagonistic bacteria (Colony Forming Unit (cfu)/g or ml) product.

The Composition of active and inert ingredients in % w/w and purpose in formulation shall be stated.

3.2.2.6. Impurities and contaminants

The technical grade and formulation product shall be free from biological contaminants especially plant, human and animal pathogenic contaminants such as *Salmonella typhi*, *Salmonella paratyphi* A, B, and C, *Salmonella sendai*, *Salmonella cholera-suis*, *Shigella dysenteriae*, *Escherichia coli* and *Vibrio cholerae*. The technical grade shall be free from the contaminants. (Other microbial contaminants should not exceed 1 x 10^4 count/ml or g of formulation (FAO, 2012, 2018). The microbial contaminants shall be determined throughout the process of production. The method used shall be mentioned and the result attached in product specification sheet.

3.2.2.7. Physical chemical properties of formulated product

Physical chemical properties specification of the product include appearance, physical state, colour, pH, persistent foaming, solubility or suspendability, particle size, viscosity (liquids) and density. Type and test method used shall be indicated clearly.

3.2.2.8. Production process and quality control

The production process shall be stated clearly;

a. The name and address of the production plant shall be provided
b. Flowchart of the production process shall be submitted with the application. All raw materials used shall be stated.
c. The quality control procedure shall be described

3.2.2.9. Test procedure and criteria for identification

Test procedure and criteria for identification for each microbial shall be stated clearly. The robust methods of bioassays and identification shall be used:

a. Entomotoxic bacteria; immunology assays: Elisa/Dot Blot assay test or potency of product by bioassay method (LC50) on target larvae (*Trichoplusia ni*/*Helocoverpa armigera*) and potency against a reference using artificial diet or leaf disc method or in the water for mosquito larvae.
b. Baculoviruses; biological assay for determining the LC50/LD50 of the formulation. Bioassay for Nuclear Polyhedrosis Virus (NPV) by the diet surface contamination method and Granulosis virus (GV) using bioassay against *Chilo infuscatellus*, *Plutella xylostella* or *Acheae janata*.
c. Entomopathogenic fungi; pathogenicity test on a relevant insect and bioassay procedure shall be provided

Test procedure other than the above may also be used for consideration. The identification and bioassay shall be carried out in a laboratory accredited and/or recognized by the regulatory authority

3.2.2.10. Shelf life claim

Applicants shall provide storage stability studies and shelf life in the proposed packaging to support specific shelf life claim

3.2.2.11. Quality verification report

The verification report from a laboratory accredited and/or recognized by the regulatory authority shall be provided to confirm that the content of active agent is the same as the composition declared.

3.2.2.12. Bioefficacy

The recommended product use on crops shall be obtained from local bioefficacy trials. Efficacy trials shall be carried out in accordance with the approved EAC harmonized guidelines evaluating & reporting the efficacy of pest control products for plants.

3.2.2.13. Laboratory studies

Additional laboratory study reports may be submitted depending on proposed uses.

3.2.2.14. Packaging and labelling

3.2.2.14.1. Packaging material

The type of packing material used shall be stated. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.

3.2.2.14.2. Labels and leaflets

A draft label and or leaflet as required by the respective partner states labelling regulations shall be submitted to the regulatory authority for evaluation.

3.2.2.14.3. Infectivity and pathogenicity or toxicity to test animals

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

studies or published data. Where no evidence is provided or where there is insufficient evidence, toxicological studies have to be conducted as indicated under TIER 1 in the first instance. TIER 2 is applied when, in the absence of evidence of pathogenicity, either toxicity of infectivity is observed in TIER 1.

TIER 3 is applied when there are issues of known or suspected subchronic toxicity and human pathogenicity and tests for effects following long-term exposure and particular adverse effects of intra-cellular parasites of mammalian cells. Report on infectivity and pathogenicity or toxicity on test animals for the technical material of the microbial shall be submitted to the regulatory authority of the Partner States. Acute studies (six pack for formulated product shall be submitted to the regulatory authority of the Partner States.

3.2.2.15. Human health hazard/assessment, environmental fate and effects

3.2.2.15.1. Human health hazard

Data on animal tests are required to facilitate risk assessment. Specific studies on the active agent and formulated product as indicated in the summary of data requirements for microbial registration shall be submitted. Peer reviewed reports from scientific journals on human health based on the active agent may be submitted where there is sufficient evidence that the active agent is safe and has been in use for many years.

3.2.2.15.2. Ecotoxicological and Environmental fate

Waivers may be granted on presentation of evidence that exposure to the particular non target organisms will not occur, or where effects of exposure are already documented. TIER 1 studies should report any observed pathogenicity/infectivity to the test species. TIER 2 studies are required on representative non target species if acute studies indicate that adverse effects will occur during routine application. Data on the effect on birds, aquatic organisms, algae and bees shall be submitted for evaluation. Data on the fate and behavior of the microbials in the environment shall be provided.

3.2.2.15.3. Residues

Data shall be submitted if microbes are suspected to produce any residue of concern on food or feed items. Inert ingredients used in formulated products must not produce residues of concern on food or feed items. Where applicable, residue data shall be provided as per the EAC harmonized guidelines for the conduct of supervised residue field trials.

Table 1: Summary of data requirements for the registration of microbial

No.	Status of data requirements	Active agent (A.A.)	Formulation Formulated product
A. Biological and Chemical Characteristics			
1	Systematic name	R	
2	Strain or isolate of microbials	R	
3	Common name (if available)	R	
4	Source or origin (country, where its isolated from, ecological habitat)	R	
5	Physical chemical properties of the product • Physical • Colour • PH • Persistent foaming • Suspendability • Particle size • Viscosity • Density • Test method		R
6	Biological properties • History and geographical distribution of active agent • Life cycle • Mode of action • Relationship to known plant animal or human pathogens • Host range • Dispersal • Colonizing ability • Information on production of metabolites • Genetic stability	R	
7	Composition of the product	R	R
8	Production process and quality control • Name and address of manufacturer • Name and address of Formulator • Flowchart of production process	R	R
9	Test Procedure and criteria for identification	R	
10	Impurities and contaminants	R	
11	Shelf life claim		R
12	Quality verification report		R

No.	Status of data requirements	Active agent (A.A.)	Formulation Formulated product
B. Bioefficacy			
13	Field efficacy studies on proposed use		R
14	Laboratory studies for Bioassays	CR	
C. Packaging and Labelling			
15	Packaging material		R
16	Labels and leaflets		R
D. Human Health, Infectivity and Pathogenicity or Toxicity to test animals			
17	Infectivity and pathogenicity **TIER 1 Studies** • Medical surveillance data for manufacturing plants and agricultural workers (Such as occurrence of hypersensitivity/ allergies) • Acute oral LD_{50} mg/kg LC_{50} (rat/rabbit) • Acute dermal • Inhalation LC_{50} mg/4 hours (rat/rabbit) • Dermal irritation • Eye irritation • Skin sensitazition • Intra-peritoneal (fungi and protozoa)/Intravenous (others) injection for infectivity **TIER 2 Studies** • Subchronic toxicity 28 day NOEL mg/kg/day **TIER 3 Studies** • Chronic toxicity/Carcinogenicity NOEL mg/kg/day (mouse/rat) • Neurotoxicity NOEL mg/kg/day • Teratogenicity NOEL mg/kg/day • Reproduction (rat/rabbit) • Mutagenicity	R	
	Acute Toxicity studies • Acute oral LD50 mg/kg LC50 (rat/rabbit) • Acute dermal • Inhalation LC50 mg/4 hours (rat/rabbit) • Dermal irritation • Eye irritation • Skin sensitization		R

No.	Status of data requirements	Active agent (A.A.)	Formulation Formulated product
E. Ecotoxicology and Environmental Fate			
18	Ecotoxicology fate **TIER 1 (Acute studies)** • Birds (2 species) • Aquatic organisms (2 species) • Aquatic invertebrates • Algae • Bees • Representative natural enemies • Earthworms • Soil micro organisms • Representative non target plant **TIER 2** • Birds (1 specie) reproduction and NOEL • Aquatic organisms (2 species) reproduction, BCF & NOEL	R	
	Environmental fate – Behaviour in the soil, surface & ground water Persistence of active agent, Mobility of active agent, Major metabolites where appropriate		
F. Residue			
19	Residue data	CR	
20.	Clearence from National Plant Protection Organization (NPPO) authorizing import or export.	R	R
21.	Procedure for destruction and decontamination		R

Abbreviations: R = Required CR = Conditionally Required

3.3 BIOCHEMICAL PESTICIDES

Biochemical pesticides means a pest control product whose active ingredient derived from naturally occurring plants, animals, or other organisms intended to control plant pests. For the purpose of these guidelines, Biochemical pesticides include Botanicals and Semiochemicals.

3.3.1. BOTANICAL/PLANT EXTRACTS

Botanical active substance: It consists of one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/or other methods of extractions. Botanical products covered under this guideline shall meet the criteria summarized in Table 2.

3.3.2. Data requirements for registration of botanical/plant extract

3.3.2.1. Nomenclature

The systematic and common names the plant shall be provided. The active ingredient (s) of the plant extracts shall be provided if available.

3.3.2.2. Source or origin

The source or origin of botanical/plant extract shall be indicated including country, where its extracted from, plant part, and ecological habitat. The applicant shall provide information on registration status of the product in the country of origin.

3.3.2.3. Physical chemical properties of active ingredient and formulated product.

Information of color, physical state, odour, storage stability, corrosion characteristics, UV-light absorption, water solubility and vapor pressure for the plant extracts and formulated products shall be submitted. The specification of the technical grade and the formulated product shall conform to FAO specifications whenever such specifications are available.

3.3.2.4. Composition of the product

Composition of active and inert in % w/w or w/v and purpose in formulation shall be provided. If available, the following information shall be submitted: IUPAC and CAS chemical names and numbers, and structural formula.

3.3.2.5. Manufacturing process

The extraction process shall be stated clearly and the following information shall be provided;

a. The name and address of the manufacturing plant.
b. A description of the quality control procedures and equipment shall be provided to assure consistency of the composition of substance produced.
c. Information on substances used in the manufacturing process (example: identity of any extraction solvent, enzymes, stabilizers such as antioxidants), and any special precautions such as control of light, humidity and temperature.
d. Flowchart of the process of extraction of active ingredient and the manufacture of formulated product shall be submitted.

3.3.2.6. Test procedures and criteria for identification

The applicant shall provide test procedures for the plant extracts and or a validated analytical method for the active ingredients.

3.3.2.7. Impurities

The applicant shall provide information on the identity and quantity of the impurities in the plant extracts.

3.3.2.8. Storage stability

The applicant shall specify the shelf life of the products based on test conducted under the following conditions:

a. FAO Accelerated Storage Test Procedures is performed at 54 ± 2 °C for 14 days or at 45 ± 2 °C for 6 weeks or at 40 ± 2 °C for 8 weeks or at 35 ± 2 °C for 12 weeks or at 30 ± 2 °C for 18 weeks when applicable.
b. Two-Year Storage Stability (Ambient testing) to demonstrate the storage stability of a formulation under true storage conditions usually over a period of 2 years. The test shall be conducted at ambient temperature or, 20 °C, 25 °C or 30 °C dependent on the final area of use.
c. The packaging used in the study shall be based upon that in which the product is sold.

3.3.2.9. Verification report

The applicant shall provide a verification report base on a five batch analysis of the plant extracts and formulated products to ensure that content of active ingredient is the same as in composition declared. A report from own or third party independent laboratory is accepted.

3.3.2.10. Packaging and labelling

3.3.2.10.1. Packaging material

The type of packing material used shall be stated. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.

3.3.2.10.2. Labels and leaflets

A draft label and or leaflet as required by the respective partner states labelling regulations shall be submitted to the regulatory authority for evaluation.

3.3.2.11. Human health hazard/assessment, environmental fate and effects

3.3.2.11.1. Human health hazard

Data on animal tests are required to facilitate risk assessment. Specific studies on the active ingredient and formulated product for registration of botanical products shall be submitted. Peer reviewed reports from scientific journals on human health based on the plant extract or active ingredient may be submitted where there is sufficient evidence that the plant extract or active ingredient is safe and has been in use for many years.

3.3.2.11.2. Ecotoxicological and Environmental fate

Waivers may be granted on presentation of sufficient evidence that exposure to the particular non target organisms will not occur, or where effects of exposure are already documented. TIER 1 studies should report any acute effects on non-target species. TIER 2 studies are required on non-target species if acute studies indicate that adverse effects will occur during routine application.

Data on the effect on birds, aquatic organisms, algae and bees shall be submitted for evaluation. Data on the fate and behavior of the plant extracts and the active ingredient in the environment shall be provided.

3.3.2.11.3. Efficacy and laboratory studies

Efficacy data requirements for botanical/plant extract are similar to those for conventional agriculture products. Required field and laboratory studies will depend on purpose of uses.

3.3.2.11.4. Residues

Data shall be submitted if plant extracts are suspected to produce any residue of concern on food or feed items. Inert ingredients used in formulated products must not produce residues of concern on food or feed items. Where applicable, residue data shall be provided as per the EAC harmonized guidelines for the conduct of supervised residue field trials.

Table 2: Summary of data requirements for registration of botanicals

No.	Status of data requirements	Active agent (A.I.)	Formulation
A. Physical and Chemical Characteristics			
1	Systematic name	R	
2	Common name (if available)	R	
3	Source or origin	R	
4	Specification of the product • Physical state • Colour • Odour • Storage stability • Corrosion characteristics • UV-light absorption • Water pressure • Vapor pressure	R	R
5	Composition of the product	R	R
6	Manufacturing process and quality control • Manufacturer name and address • Flowchart of manufacturing process	R	R
7	Test procedure and criteria for identification	R	R
8	Impurities	R	
9	Verification report	R	R
10	Packaging and labelling		R
B. Toxicology Evaluation			
11	**TIER 1 Studies** • Acute oral LD_{50} mg/kg LC_{50} (rat/rabbit) • Acute dermal • Inhalation LC_{50} mg/4 hours (rat/rabbit) • Dermal irritation • Eye irritation • Skin sensitazition **TIER 2 Studies** • Subchronic toxicity 28 day NOEL mg/kg/day **TIER 3 Studies** • Chronic toxicity/Carcinogenicity NOEL mg/kg/day (mouse/rat) • Neurotoxicity NOEL mg/kg/day • Teratogenicity NOEL mg/kg/day • Reproduction (rat/rabbit) • Mutagenicity	R	

No.	Status of data requirements	Active agent (A.I.)	Formulation
12	Acute toxicity studies • Acute oral LD50 mg/kg LC50 (rat/rabbit) • Acute dermal • Inhalation LC50 mg/4 hours (rat/rabbit) • Dermal irritation • Eye irritation • Skin sensitization		R
13	Ecotoxicology and Environmental Fate	R	
	Ecotoxicology fate **TIER 1 (Acute studies)** • Birds (2 species) • Aquatic organisms (2 species) • Aquatic invertebrates • Algae • Bees • Representative natural enemies • Earthworms • Soil micro organisms • Representative non target plant **TIER 2** • Birds (1 species) reproduction and NOEL • Aquatic organisms (2 species) reproduction, BCF & NOEL		
	Environmental fate – Behaviour in the soil, surface & ground water • Persistence of active agent, • Mobility of active agent, • Major metabolites where appropriate	R	
C. Efficacy			
14	Field and laboratory study		R
D. Residue			
15	Residue data	CR	

Abbreviations: R = Required **CR = Conditionally Required**

3.4 SEMIOCHEMICALS

Semiochemicals are active substances used in plant protection and public health products and have a non-toxic, target specific, mode of action and are of natural occurrence. They are generally effective at very low rates, often comparable to levels that occur naturally. They may be volatile and can dissipate and/or degrade rapidly in the environment. These chemicals pose low risk to human health and the environment. Different types of semiochemicals are:

i. **Allelochemicals** produced by individuals of one species that modify the behaviour of individuals of a different species (i.e. an interspecific effect). They include allomones (emitting species benefits), kairomones (receiving species benefits) and synomones (both species benefit).

ii. **Pheromones** produced by individuals of a species that modify the behaviour of other individuals of the same species (i.e. an intraspecific effect).

iii. **Straight-chained lepidopteran pheromones** (SCLPs) are a group of pheromones consisting of unbranched aliphatics having a chain of 9 to 18 carbons, containing up to three double bonds, ending in an alcohol, acetate or aldehyde functional group.

3.4.1. Data requirements for registration of Semiochemicals

i. Common name proposed/accepted by ISO or others standard of international organizations, (if any)
ii. Trade name or manufacturer's code number
iii. The composition of the semiochemical and its formulated products
iv. Chemical and technical information of the semiochemicals and its intended use (Pheromones, mating disruption or kairomones).
v. Production process and quality control
vi. Content (%) and nature of components included in the formulation and appearance.
vii. Analytical method for active ingredient
viii. Validated laboratory report of five batch analysis
ix. Information about packaging and labeling
x. Peer reviewed reports from the scientific journal may be accepted.
xi. On case by case basis other information may be required by the regulatory authority.

Disclaimer: The above requirements shall be applicable only for a pure formulation of a semiochemical. Where a semiochemical is combined with;

a. a conventional insecticide in a formulation, the requirements for the registration for conventional pesticides shall be required.
b. a microbial in a formulation the requirements for the registration for semiochemical and microbials shall be required.

Table 3: Summary of data requirements for registration of Semiochemicals

(Pheromones, disrupting hormones and other semiochemicals)

No.	Status of data requirements	Active agent (A.I.)	Formulation
A. Physical and Chemical Characteristics			
1	Systematic name	R	
2	Common name (if available)	R	
3	Trade name		R
4	Chemical and technical information	R	R
5	Source or origin	R	
6	Physical properties: (Specification of the product) • Colour, • Odour, • Physical state, • Stability (temperature, metals). • Solubility in water and other solvents • UV/visible absorption • Volatility (Henry's law constant) • Octanol/water partition coefficient • Submission of analytical standards (samples). • Corrosion characteristics • Water pressure • Vapor pressure	R	R
7	Composition of the product • g/kg or g/L of TGAI • g/kg or g/L of all ingredients exceeding 1g/kg	R	R
8	Content (%) and nature of components		R
9	Production process and quality control • Description of starting materials, production process and potential impurities • Manufacturer name and address • Flowchart of manufacturing process	R	R
10	Test procedure and criteria for identification • Identity by spectral confirmation, including one or more of UV/ IR/NMR/MS	R	R
11	Impurities	R	
	Analytical method for active ingredient • Analytical data and methodology (including spectral confirmation of identity) • Analytical methodology and data for impurities of toxicological concern.	R	
12	Validated laboratory report of five batch analysis	R	R
13	Packaging and labeling		R

No.	Status of data requirements	Active agent (A.I.)	Formulation
C. Efficacy			
14	Field and laboratory study • Efficacy Summary • Description of pest problem and AI's mode of action (May be addressed by qualitative description). • Efficacy trials of product, used as directed on label, including reportin • Sustainability considerations (compatibility with integrated pest management; contribution to risk reduction)g of adverse effects to site (e.g., phytotoxicity) (May be addressed by qualitative description).		R
D. Residue			
15	Residue data and Analytical method for residues.	CR	

Abbreviations: R = Required CR = Conditionally Required

3.5 MACROBIALS

These guidelines cover registration of:

i. Predators
ii. Parasitoids

3.5.1. Required information on predators and parasitoids

a. The following information shall be required by the regulatory authority for the registration of predators and parasitoids:
b. Taxonomic identity along with classification (e.g. phylum, class, order, family, genus, species), including common names and history of any recorded name change; with accession number of voucher specimen deposited in recognized museum or culture collection.
c. Information on physical characteristics: morphology, appearance, sexual dimorphism, height, length, weight and size, winged/wingless.
d. Bionomics and lifecycle of the organism, including behavioural characteristics such as predator/prey relationships, life history and life cycle information; for example, mode of reproduction, seasonal pattern of reproduction; reproductive potential (number of eggs, young, generations), and longevity.
e. Information on the efficacy is important to prevent the introduction and release of ineffective biocontrol agents. A biological control agent is considered effective if it can cause a statistically significant reduction of at least 10 percent in the number of pest organisms, of direct and indirect crop damage, or of yield loss. All relevant information to judge the efficacy of a biocontrol agent shall be provided. Summary of the information on crop, against pest, and conditions the agent is shown to be effective, the role and strength of the agent would be in IPM programmes.
f. Host range. Available information on host/prey range of biocontrol agents shall be provided. Monophagous and oligophagous biocontrol agents are expected to pose no or very limited potential risks to non-target organisms, whereas polyphagous biocontrol agents may affect them directly and indirectly.
g. Intra-guild predation. Provide available information on negative intraguild predation effects for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely.
h. Information on competition and displacement shall be summited to the regulatory authority.
i. Potential for hybridisation with indigenous strains or biotypes. Provide available information on hybridisation of the natural enemy with indigenous strains or biotypes of the same or very closely related natural enemy species.

j. Effects on plants: Effects of natural enemy on plants shall be provided if the biological control agent is potentially a facultative herbivore and if there is a potential for phytotoxic effects.

k. Available information on the potential for establishment and dispersal shall be provided.

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

Key factors that need to be considered include:

– abiotic factors: The matching of climates of the area of origin and area of release.

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

- **Potential for dispersal:** The probability of a temporal and spatial encounter between the biological control agent and non-target species to determine the potential for dispersal of the biocontrol agent.

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

m. Available information on environmental benefits – information on the beneficial effects of release of biological control agents compared to current or alternative pest management methods. Information for assessment of any potential environmental risks.

n. Information for assessment of efficacy of biological control agent

- Methods for the evaluation of quality and purity (quality control) of biological control agents.
- Benefits of use of biological control agents.
- Summary of assessment of efficacy.

o. For native or established natural enemies and on biological control agents, long use, substantially reduced information requirements may be appropriate

p. Assessment of safety and effects on human health

q. Safety and effects on human health in manufacturing, market handling, and storage in commercial warehouses and farms as well as application in farms shall be provided to the regulatory authority. Peer reviewed report from the scientific journals may be accepted.

r. **Packaging and labelling**

i. **Packaging material**

The type of packing material used shall be stated. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.

ii. **Labels and leaflets**

A draft label and or leaflet as required by the respective Partner State labelling regulations shall be submitted to the regulatory authority for evaluation.

3.5.2. Data requirements for registration of macrobial pest control products

The dossier accompanying the application must provide full details of the information requested in this list. If the product contains more than one active agent, a separate dossier for each active agent should be provided.

Table 4: Summary of data requirements for registration of a Macrobials

Pest control product

a. Designation / identity

No.	STATUS OF DATA REQUIREMENTS	Active agent (A.I.)	Formulated product
1.1	Common name	R	
1.2	Full taxonomic name including isolate, strain or subspecies (where appropriate)	R	
1.3	Full taxonomic classification	R	
1.4	Methods of identification and enumeration	R	R
1.5	Manufacturer or development code	R	
1.6	Source, name and address of manufacturer /formulator and address and location of manufacturing plants	R	R
1.7	Methods of production, substrates and quality control	R	R
1.8	Collection and culture reference number where culture is deposited	R	
1.9	Formulation type and code		R
1.10	Source and specifications for components included in the formulation		R
1.11	Evidence of registration/approval in other countries		R
1.12	Validated laboratory report of five batch analysis	R	R
C. Efficacy			
1.13	Efficacy summary of field and laboratory study		R

b) biological/physical properties of the macrobial agents

No.	Status of data requirements	Active agent (A.I.)	Formulated product
2.1	History of the macro-organism and its uses. Natural occurrence and geographical distribution	R	
2.2	Description of the target organism(s) and mode of action	R	
2.3	Host specificity range and effects on species other than the target harmful organism	R	
2.4	Development stages/life cycle of the macro-organism	R	
2.5	Invasiveness, dispersal and colonisation ability	R	
2.6	Effect of environmental parameters on stability and survival (UV, temperature, soil pH, humidity, etc.) of macrobial agents	R	
2.7	Relationships to known plant, animal or human parasites/pests and any known hyper parasite of macrobial	R	
2.8	Genetic stability of macrobial agent	R	
2.9	Information on the production of metabolites (relevant to entomopathogenic nematodes)	CR	
2.10	Biological function in the control of insects, mites, ticks, nematodes, weeds, molluscs, etc	R	

No.	Status of data requirements	Active agent (A.I.)	Formulated product
2.11	Information on the occurrence or potential development of resistance of the target organism(s) and resistance management strategy.	R	
2.12	Methods to prevent loss of predation or parasitic properties of the seed stock of the macro-organism	R	
2.13	Recommended methods and precautions concerning handling, storage, or transport	R	
2.14	Procedures for destruction or decontamination	R	R
2.15	Physical state (solid, liquid etc)		R
2.16	Colour		R
2.17	Storage stability in proposed packaging		R
2.18	Shelf life		R
2.19	Water content (humidity)		R
2.20	Type and size of packaging		R
2.21	Labeling		R

c) Biosafety

Hazard data may be waived where there is sufficient evidence that there are no safety concerns. This would be based on results of medical surveillance and published data

No.	Status of data requirements	Active agent (A.I.)	Formulated product
3.1	Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)	R	R
3.2	Discussion of the effects of repeated human exposure	R	R

d) 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.

No.	Status of data requirements	Active agent (A.I.)	Formulated product
4.1	Aquatic organisms	CR	
4.2	Aquatic invertebrate	CR	
4.3	Bees	CR	
4.4	Representative natural enemies	CR	
4.5	Persistence of active agent (days)	R	
4.6	Mobility of active agent	R	

Abbreviations: R = Required CR = Conditionally Required

4. REFERENCES

Black, R. (2013). A guide to the development of regulatory frameworks for microbial biopesticides in Sub-Saharan Africa.

FAO. (2012). GUIDANCE FOR HARMONIZING PESTICIDE REGULATORY MANAGEMENT IN SOUTHEAST ASIA. *Electronic Publishing Policy and Support Branch Communication Division*.

FAO. (2018). *International code of conduct on pesticide management: guidelines for the registration of microbial, botanical and semiochemical pest control agents for plant protection and public health uses*: Food & Agriculture Org.

https://croplife-r9qnrxt3qxgjra4.netdna-ssl.com/wp-content/uploads/2017/04/Technical-Monograph

Pest control products board (2003). Application for the registration of a microbial pest control product, Form p2 PCPB, Nairobi, Kenya

APPENDIX 1: Application Form for the Registration of a Biopesticide Product in Partner States of the East African Community (EAC)

East African Community

One People, One Destiny

National logo/crown

Draft – Form A1 (revised – 1 March 2018)

Information for applicants

1. The applicant is the natural or legal person that manufactures the pest control product and/or places it on the market. After approval of the registration, the applicant will become the registration holder of the product.
2. The applicant shall be a legal entity in – *name of EAC country* –, or be represented by a local agent who is a permanent resident in – *name of EAC country* – and duly recognized by the national pesticide registration authority.
3. The application form shall be completed by a person duly authorized by the applicant.
4. The application shall be submitted in triplicate to:

– name and address of the national pesticide registration authority –

1. Every application must be accompanied by:
   b. proof of payment of the application fee as prescribed by the national pesticide registration authority;
   c. three (3) copies of the draft label
   d. three (3) copies of the technical dossier as per the data requirements detailed in List I (active ingredient) and List II (formulated product).
2. The applicant may be required to submit:
   a. Registration authorization letter: In case the applicant is not the owner of the TGAI/product, provide a letter in which the owner of the TGAI/product authorizes the applicant to apply for registration;
   b. sample of the pest control product, for bio efficacy trial purposes;
   c. a sample of the pest control product for residue trial purposes (where applicable);
   d. a sample of the technical grade of its active ingredient(s)/ agent(s);
   e. a sample of the analytical standard of its active ingredient(s) (Applicable for only Biochemicals);
   f. any other sample as may be required by the pesticide registration authority

1	PRODUCT	
1.1	Product name (brand name)	
1.2	Type of formulation (CropLife code)	
1.3	Active ingredient(s)/Agent (s) (common name)	
1.4	Active ingredient/Agent (s) concentration(s)	
1.5	Patent status and expiry date (if applicable)	
1.6	Quick Response (QR) code (if available)	

2	APPLICANT	
2.1	Applicant name (corporate name of company)	
2.2	Status	☐ manufacturer ☐ formulator ☐ other…
2.3	Business registration number	
2.4	Physical address	
2.5	Postal address	
2.6	Telephone number	
2.7	E-mail address	
2.8	Web site	
2.9	Contact person at applicant company	
2.10	Contact person telephone number	
3	**LOCAL AGENT**	
3.1	Local agent name (corporate name of company) (if different from applicant)	
3.2	Status	☐ formulator ☐ importer ☐ distributor ☐ other….
3.3	Business registration number	
3.4	Physical address	
3.5	Postal address	
3.6	Telephone number	
3.7	E-mail address	
3.8	Contact person at local agent	
3.9	Contact person telephone number	

4	PURPOSE OF APPLICATION	
a	☐ New pest control product containing a new active ingredient (a.i.)/Agent	
b	☐ New pest control product containing an active ingredient/Agent already registered in the country	
c	☐ New source of active ingredient/Agent and/or formulation of an existing registration	
d	☐ Amendment or extension to an existing registration	
e	☐ Registration transfer (between registrants)	
f	☐ Other (specify):	…

5	INTENDED USE			
5.1	Function/category of product (more functions/categories possible)	☐ Insecticide	☐ Fungicide	☐ Herbicide
		☐ Acaricide	☐ Rodenticide	☐ Molluscicide
		☐ Bactericide	☐ Defoliant	☐ Plant growth regulator
		☐ Semio Chemical		
		☐ Other (specify):	…	
5.2	Type of use (more types possible)	☐ Agriculture	☐ Veterinary	☐ Public health
		☐ Household	☐ Forestry	☐ Industrial
		☐ Other (specify):	…	

5.3	Category of Biopesticide	☐ Microbial	☐ Macrobial	
		☐ Botanicals	☐ Semio chemicals	
5.4	Target pest(s)/disease(s) and crop(s)/use(s)	1	...	
		2	...	
		3	...	
		...		
6	**HAZARD CLASSIFICATION (FOR BIOCHEMICALS)**			
6.1	WHO Hazard Class of the formulated product	☐ Class Ia	☐ Class Ib	☐ Class II
		☐ Class III	☐ Class U	
6.2	GHS classification of the formulated product (list all classifiable hazards)			
	Physical hazards	...		
	Health hazards	...		
	Environmental hazards	...		

7	**DECLARATION**	
	For and on behalf of ..... I hereby certify that the above mentioned information, as well as the data provided in the technical dossier, in support of this application are true, correct and complete.	
	..... Name in full (print)	..... Signature
	..... Official title	..... Date
	Official stamp of applicant/company	
8	**FOR OFFICIAL USE**	
	Application No: ...	Remarks: ....
	Reception date: ...	
	Fees received: ☐ Yes ☐ No	
	Amount paid:	
	Status of application:	☐ Approved ☐ Rejected ☐ Pending

THE EAST AFRICAN COMMUNITY

East African Community

EAC Close, Afrika Mashariki Road

P.O. Box 1096, Arusha, United Republic of Tanzania

Tel: +255 (0)27 216 2100

Fax: +255 (0)27 216 2190

Email: eac@eachq.org

www.eac.int