



SUMMARY OF THE EAC HARMONISED GUIDELINES FOR THE REGISTRATION OF BIOPESTICIDES AND BIOCONTROL AGENTS FOR PLANT PROTECTION

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PREAMBLE

East African Community (EAC) Partner States are progressively intensifying agriculture to meet the regional demands for food and exports. To achieve this, there is a need for development, at regional level, of efficient, competitive and sustainable agricultural sector that applies strict standards on the use of pesticides.

While plant protection is currently heavily dependent on the use of conventional pesticides, their excessive use may adversely affect human health and the environment. The alternative is to use the much safer bio-pesticides and bio-control agents.

Biopesticides and biocontrol agents are generally less toxic to humans and have less impact on the environment. They are recommended to augment the existing Integrated Pest Management (IPM) system. However, their registration system is still a challenge among EAC Partner States, where they are evaluated and registered following the same system for conventional chemical pesticides. This approach poses an unnecessarily high and inappropriate regulatory burden because much of the data requirements and evaluation criteria of chemical pesticides are not relevant to biological pest control agents. 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 to understand the biology of the particular agents and evaluate key issues of safety and environmental impact.

In view of these factors, a meeting of the EAC Technical Working Group on pesticides, held in Arusha in March 2019, prioritised the development of regionally harmonised guidelines for the registration of biopesticides and biocontrol agents. Harmonised guidelines will facilitate trade by significantly simplifying data requirements among Partner States and ensuring mutual recognition of work done within the region.

This document summarises the subsequent guidelines that have been developed by EAC Partner States towards ensuring harmonised data requirements, evaluations and decision making with regard to the registration of biopesticides and biocontrol agents to provide an acceptable level of protection for human and animal health and the environment. They have been developed on the premise of article 108 of EAC Treaty, which requires EAC Partner States to adopt common mechanisms to ensure safety, efficacy and potency of agricultural inputs.

SCOPE

The guidelines cover micro-organisms (bacteria, fungi, viruses, protozoa); macro-organisms (predators and parasitoids, insects and mites); and biochemical pesticides (botanicals and semiochemicals).

OBJECTIVES

- i. Provide EAC Partner States with a harmonised framework for registration of biopesticides and biocontrol agents.
- ii. Facilitate mutual recognition and sharing of data for registration of bio-pesticides and biocontrol agents amongst the EAC Partner States.
- iii. Facilitate best practices in the registration of biopesticides and biocontrol agents for plant protection.

GENERAL PROVISIONS

- i.** 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 authorised for any use.
- ii.** All efficacy trials involving biopesticides and biocontrol agents shall be approved by the national pesticides regulatory authority of the Partner State.
- iii.** Samples of the biopesticide products shall be sent to the regulatory authority for forwarding to the testing institution.
- iv.** Samples of the biocontrol agents shall be sent directly to the testing institution with approval of regulatory authority.
- v.** All dossiers shall be evaluated by expertise in microbial agents, macrobials agents and semiochemical agents to understand the biology of particular agents and evaluate key issues of safety and environmental impact.
- vi.** All trials associated with biopesticides and biocontrol agents shall be conducted in accordance with the approved EAC harmonised Guidelines for Efficacy Trials.
- vii.** 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.
- viii.** The criteria for accreditation shall be clearly indicated to guarantee standards of the approved EAC Harmonised Guidelines for Efficacy Trials.
- ix.** 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 Harmonised Guidelines for Efficacy Trials. The applicant shall ensure the protocols are compiled with.
- x.** 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.
- xi.** The cost of conducting efficacy trials of biopesticides or biocontrol agents authorised by the regulatory authority will be incurred by the applicant.
- xii.** 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.
- xiii.** Where the provisions of the European and Mediterranean Plant Protection Organisation (EPPO) guidelines conflict with these ones, the provisions of these guidelines shall prevail.
- xiv.** All applicants intending to import/export live organisms into or out of the EAC Partner States should seek clearance from the national plant protection organisation.

REGISTRATION OF BIOPESTICIDES AND BIOCONTROL AGENTS

1. MICROBIAL PESTICIDES

Microbial pesticides are microorganisms that 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).

For the registration of microbial biopesticide products, information on the following shall be required:

- i.** Systematic name consisting of genus and species names.
- ii.** Strain or isolate.

- iii. Source or origin, host range, and mode of action.
- iv. Biological properties.
- v. Active agent (technical grade) and its composition.
- vi. Impurities and contaminants.
- vii. Physical chemical properties of formulated product.
- viii. Production process and quality control.
- ix. Test procedure and criteria for identification of each microbial.
- x. Shelf life claim.
- xi. Quality verification report from a laboratory recognised by the regulatory authority, to confirm that content of the active agent is the same as the composition declared.
- xii. Bioefficacy from local trials carried out in accordance with the approved EAC Harmonised Guidelines for Evaluating and Reporting the Efficacy of Pest Control Products for Plants.
- xiii. Laboratory study reports as may be required depending on proposed uses.
- xiv. Packaging and labelling material.
- xv. Labels and leaflets as required by the respective Partner States' labelling regulations.
- xvi. Infectivity and pathogenicity or toxicity to test animals.
- xvii. Human health hazard.
- xviii. Ecotoxicological and Environmental fate relating to effect on non-target organisms and on the environment.
- xix. Residue details if microbes are suspected to produce residues of concern on food or feeds.

2. BIOCHEMICAL PESTICIDES

A biochemical pesticide is a pest control product whose active ingredient is 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.

A) BOTANICAL/PLANT EXTRACTS

These consist of one or more components extracted from plants through such processes as pressing, milling, crushing, distillation and/or other methods of extractions. Information needed for the registration of botanical products are as follows:

- i. Nomenclature
- ii. Source or origin
- iii. Physical and chemical properties of active ingredient and formulated product.
- iv. Composition of the product (both active and inert ingredients).
- v. Manufacturing process and the name and address of the manufacturer.
- vi. Test procedures and criteria for identification of the active ingredients.
- vii. Impurities in the plant extracts.
- viii. Storage stability based on test conducted under various prescribed conditions.
- ix. 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.
- x. Packaging material
- xi. Labels and leaflets as required by the respective partner states labelling regulations.
- xii. Human health hazard.
- xiii. Ecotoxicological and Environmental fate relating to effect on non-target organisms and on the environment.
- xiv. Efficacy and laboratory studies
- xv. Residue details if plant extracts are suspected to produce any residue of concern on food or feed items.

B) 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. Semiochemicals include Allelochemicals, Pheromones and Straight-chained lepidopteran pheromones. The following information is required for their registration:

- i. Common name proposed/accepted by ISO or other standard of international organisations.
- 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 labelling.
- x. Peer reviewed reports from the scientific journal may be accepted.
- xi. On case-by-case basis, other information as may be required by the regulatory authority.

3. MACROBIALS

These include predators and parasitoids. The following information shall be required by the regulatory authority for the registration of predators and parasitoids:

- i. Taxonomic identity along with classification (e.g. phylum, class, order, family, genus, species), including common names and history of any recorded name change.
- ii. Information on physical characteristics.
- iii. Bionomics and lifecycle of the organism, including behavioural characteristics such as predator/prey relationships, life history and life cycle information.
- iv. Information on the efficacy. 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.
- v. Information on host/prey range of biocontrol agents shall be provided.
- vi. Information on negative intra-guild predation effects for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely.
- vii. Information on competition and displacement.
- viii. Information on hybridisation of the natural enemy with indigenous strains or biotypes of the same or very closely related natural enemy species.
- ix. Effects of natural enemy on plants if the biological control agent is potentially a facultative herbivore and if there is a potential for phytotoxic effects.
- x. Information on the potential for establishment and dispersal.
- xi. Information on possible indirect effects on individual species and/or ecosystem.

- xii. Information on environmental benefits of release of biological control agents compared to current or alternative pest management methods.
- xiii. Information for assessment of any potential environmental risks.
- xiv. Information for assessment of efficacy of biological control agent, including methods for the evaluation of quality and purity (quality control) of biological control agents, benefits of use of biological control agents, and summary of assessment of efficacy.
- xv. For native or established natural enemies and on biological control agents, long use, substantially reduced information requirements may be appropriate.
- xvi. Assessment of safety and effects on human health.
- xvii. Safety and effects on human health in manufacturing, market handling, and storage in commercial warehouses and farms as well as application in farms. Peer reviewed report from the scientific journals may be accepted.
- xviii. The type of packing material used. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.
- xix. A draft label and or leaflet as required by the respective Partner State labelling regulations.

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