STEPS FOR REGISTRATION OF CANDIDATE AGRICULTURAL PESTICIDES UNDER HARMONIZED EAC EFFICACY TESTING GUIDELINES

1

Applicants/ registrants shall submit formal expression of interest (EOI) to the EAC Secretariat (office of the Deputy Secretary General Productive and Social Sectors) and copied to the host country's Regulatory Authority, indicating priority countries where the registrant would like to test their product(s). A letter of EOI shall contain the following:

- Confirmation of readiness to submit dossiers and study plans;
- evidence of availability of funds required to commence trials; and
- Status of MRLs and evidence of registration of candidate product(s) in the EAC region and elsewhere

2

Upon receiving the EOI from potential registrant, the EAC Secretariat will convene a meeting of the Technical Working Group (TWG) on Pesticides to review the request and provide the necessary guidance.

3 EAC will provide written feedback to the candidate registrant and inform them about decision of the TWG.

4

The registrant shall submit product dossier to regulatory authority of the host countries and pay Experimental Use Permit (EUP) fee

- The product dossier will conform to the harmonized guidelines on data requirements for the registration of conventional chemical pesticides, bio-pesticides and biocontrol agents for plant protection (available at **https://www.eac.int/documents/category/pesticides**).
- Payment for EUP (experimental use permit) shall be made to the regulatory authority of host country. The EUP fees rate shall be determined by the individual host country's regulatory authority.

5 **Regulatory authority (RA) evaluates dossier and shares report with TWG**

The RA of each host country shall independently evaluate the candidate product dossier.

6

Review of dossier evaluation report(s)

The EAC TWG will jointly review the dossier evaluation reports and make appropriate decision whether to "clear" the candidate product for participation in the harmonized testing system.

7 **Issuance of Experimental Use Permit (EUP) to registrants**

The RA of the host country shall issue experimental use permits to registrants and provide instructions for importing limited quantities of the candidate pesticide for experimental purposes only.

8 Development and submission of product study plans

A study plan for candidate products will be submitted to the designated regulatory authority of the host countries. A copy will be simultaneously sent to the EAC Secretariat. The study plan will detail product-specific requirements for a fair assessment of product efficacy. This is especially important for biologically based pesticides (including botanicals and microbial derived active ingredients), biologically active pesticides (living virus, bacteria, and fungi) and other pesticides with novel modes of action. Key components of the study plan will include an abstract giving a synopsis of the plan, introduction and objectives of the study, research problem and tentative answers, probable new information the study is likely to generate, schedules describing when and how the study will be conducted and references of relevant literature. The study plan will suggest an appropriate "reference insecticide" for inclusion in the product efficacy trial. The study plan will conform to the "Regional EAC Guidelines for Evaluating and Reporting the Efficacy of Pest Control Products for Plants – EAC Secretariat, Arusha, Tanzania, January 2019.

9 Evaluation and approval of product study plans

The regulatory authority will review the product study plans and also approve the "reference insecticide" or suggest an alternative material.

10 Assignment of testing center (TC) and/or lead scientist (LS) for efficacy test

The RA of every Partner State shall, as per directives of the 12th Sectoral Council on Agriculture and Food Security, designated credible testing institution(s) for the purposes of conducting the efficacy tests. The Technical Criteria for Designating Efficacy Trial Centers have been developed and approved for use.

11 Consultation between LS/TC, the registrant, and the regulatory authority

The lead scientist (study director) will convene a meeting between the testing center staff, the registrant, and a representative of the regulatory authority to review the product-specific study plan. Once all parties (LS, RA, registrant) are satisfied with the study plan, contact and communication between the company, the lead scientist, and testing center staff will be limited/minimal until the end of the product efficacy trial.

12 Submission of experimental sample(s) with proposed labels, and payment of the trial fees

Once the study plans are finalized, registrant will submit product samples with proposed labels to the lead scientist (study director) and pay the trial fees to the lead scientist or testing center. The regulatory authority and lead scientist will formally acknowledge receipt of the sample(s) and make the necessary arrangements for protection of Confidential Business Information. Labels will conform to the requirements of the individual host country regulatory authority.

13 Establishment of the first set of efficacy trials

The RA in collaboration with the identified testing centre will commence trials. The lead scientist will provide the day to day leadership in the management and monitoring of the trials. The efficacy trial procedures and site selection will conform to the "Regional EAC Guidelines for Evaluating and Reporting the Efficacy of Pest Control Products for Plants" – EAC Secretariat, Arusha, Tanzania, January 2019.

14 Mid-season site visit by Interim Technical Committee (ITC)

In line with regional harmonization goals, the EAC Secretariat in collaboration with partner institutions will facilitate physical visit to sites/ centres where the trials shall be established. The visits will serve a number of objectives including information gathering, knowledge sharing, capacity building, and opportunities for informed collective decision making.

15 Data collection and analysis

The lead scientist (study director) and testing center staff will be responsible for collection and analysis of the experimental data.

16 Interim report writing and submission

At the end of the first crop cycle, an interim report on the efficacy trial will be prepared by the lead scientist and submitted to the regulatory authority and the interim technical committee.

17 Establishment of second set of efficacy trials

Establishment of the second set of efficacy trials will follow the same requirements prescribed for the 1st trials.

The procedures and site selection for the second round of efficacy trials will conform to the "Regional EAC Guidelines for Evaluating and Reporting the Efficacy of Pest Control Products for Plants" – EAC Secretariat, Arusha, Tanzania, January 2019.

18 Mid-season site visits by Interim Technical Committee (ITC)

In line with regional harmonization goals, the EAC Secretariat in collaboration with partner institutions will facilitate physical visit to sites/ centres where the second trials will be taking place.

19 Data collection and analysis

Management and monitoring of trials will entail systematic collection and analysis of data to inform decision-making on registration of the product under trials. The lead scientist will be responsible for this task. At the end of the trials, a detailed report will be submitted to host country regulatory authority and the EAC Secretariat.

20 Report writing and submission

The lead scientist will write and submit a report summarizing the results of the efficacy trial to the host country regulatory authority.

21 Post- Trials evaluation meeting of TWG

The EAC Secretariat will convene a meeting of the TWG to evaluate trial results, formulate key recommendations and discuss changes required to enhance efficiency and effectiveness of efficacy trial procedures.

22 Registration determination by host country regulatory authority

The host country regulatory authority will determine the decision for registration based on efficacy trial results.

23 Communication of results to registrants

The regulatory authority will communicate the results of the efficacy trials and the registration decision to the registrant. The same communication will be copied to the EAC Secretariat for onward submission to the rest of EAC Partner States.

24 Appeal against the decision of the Regulatory authority

The registrant shall, upon receipt of the registration decision from the RA, if not satisfied, within 28 days submit an appeal to the EAC secretariat. The appeal shall show evidence of unfair decision-making process. The EAC secretariat shall convene a meeting involving the responsible RA and the TWG to review evidence presented by the applicant. The EAC secretariat shall communicate the outcome of the ITC decision to the registrant.

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