

ANNEX 1

TERMS OF REFERENCE

Overcoming Barriers to Trade Through Regulatory Harmonization and Related Research with Biopesticides for Selected Countries within the SADC Region (STDF/PPG/694)

RATIONALE AND BACKGROUND

1. The agricultural sector accounts for a large share of the Gross Domestic Product (GDP) of the Southern African Development Community's (SADC) Member States¹; contributing between 4-27% of GDP and approximately 13% of overall export earnings. On average, the highest share (45%) of total SADC exports is to the Asia-Pacific (AP) Market, followed by the European Union (EU) (27%) and the rest of the world (15%). Trade within Africa is the smallest and of this the majority is intra-SADC trade.

2. With the exception of South Africa, SADC member states have largely been unable to meet SPS measures, resulting in a decrease in the agricultural export value of preferential market access offered by the EU and under the US Africa Growth Opportunities Act. Among SADC member states, and in Sub-Saharan Africa more generally, South Africa is one of the few countries with capacity to meet the international standards recognized in the WTO SPS Agreement.

3. One of the major constraints to SADC member states meeting SPS (as well as Pesticide Maximum Residue Level [MRL] limits) is high synthetic chemical pesticide residue in agricultural produce. According to the [Southern African Pesticide Regulators Forum \(SAPReF\)](#), "...countries in the region lack effective and fully operational systems for pesticide regulation and control and support to farmers on the best practices in sustainable pest management and pesticide use. Widespread overuse, misuse, mishandling and mismanagement of pesticides are all too common throughout the region."

4. Biopesticides are certain types of pesticides derived from natural materials such as animals, plants or microorganisms. They can include microorganisms (such as fungi and bacteria), beneficial insects, entomopathogenic nematodes, biochemical pesticides and biotechnology (genetically modified crops). Biopesticides offer opportunities to reduce chemical residue levels and to mitigate residue violations in export markets while providing pest control during the pre-harvest interval (PHI), particularly for late season pests, whose control by synthetic chemical pesticides is usually responsible for most of the residues found on agricultural produce. Most biopesticides by their nature are not subject to MRLs, and the residues of microorganisms used for pest control and management are therefore not subject to regulatory enforcement by importing countries.

5. The use of biopesticides is growing worldwide, offering an improved crop yields for farmers. Compared to the use of conventional pesticides, it brings forth environmental benefits, promoting ecological sustainability, preserving natural enemies and biodiversity. The use of biopesticides can also reduce the human and animal health hazards while decreasing the pesticide residues and improving the quality of the produce. Yet there are also certain risks associated with the use of biopesticides, including the unwitting spread of plant quarantine pests. Therefore, due attention must be paid to the IPPC's International Standards for Phytosanitary Measures (especially ISPM 3: Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and Other Beneficial Organisms and ISPM 11: Pest risk analysis for quarantine pests), as well as the provisions of the FAO and WHO [Guidelines for the registration of microbial, botanical and semiochemical pest control agents for plant protection and public health uses](#).²

6. While a significant number of biopesticides have been developed, very few have been registered and commercialized. The Southern African Pesticide Regulators Forum (SAPReF) has acknowledged this challenge and identified regulatory challenges as one of the main barriers to biopesticide research development and commercialization.

¹ Angola, Botswana, Comoros, Democratic Republic of Congo, Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Tanzania, Zambia and Zimbabwe

² See: www.who.int/whopes/resources/WHO_HTM_NTD_WHOPES_2017.05/en/

7. Overall, biopesticide regulation is a complex and dynamic field in the SADC region. The key challenge facing regulators is to develop predictive and efficient regulatory processes that ensure product safety and consistency without inhibiting commercialisation. This is especially vital for the many small and medium enterprises in this sector adversely affected by lengthy registration delays and disproportionate data demands, which may impede their willingness and ability to submit products for regulatory review. The proposed project will leverage on the efforts of these organizations to develop a harmonized biopesticide regulatory regime in the SADC, to ensure that more biopesticides reach the market, thereby diminishing disproportionate reliance on synthetic pesticides in agricultural production, enhancing trade prospects from the region. In addition, due attention will be given to phytosanitary import regulations in target markets to ensure that use of biopesticides does not create inadvertent trade barriers.

8. South Africa has very well-developed guidelines on the registration of agricultural remedies, including biopesticides. This presents a very good opportunity for South-South cooperation between South Africa and other SADC countries, facilitating the sharing of technical advice and best practices. The Southern African Economic and Research Council suggests that some of the trade challenges between SADC countries could be addressed by: i) adopting common and mutually recognized standards and ii) harmonizing regulations across the region. Facilitating trade at an international level therefore requires the development of harmonized regulations, based on relevant international standards, including Codex standards for food safety and IPPC standards for plant health.

STDF Project Preparation Grant

9. In March 2019, the STDF Working Group approved a Project Preparation Grant (PPG) entitled "Overcoming Barriers to Trade Through Regulatory Harmonization and Related Research with Biopesticides for Selected Countries within the SADC Region" (STDF/PPG/694), which was requested by SAPReF, a sub-committee of SADC's Plant Protection Technical Committee (established under the SADC SPS Annex VIII to the SADC Protocol on Trade).

10. A number of other organizations provided letters indicating their support for the PPG request. These include the Directorate of Plant Protection Ministry of Agriculture, Democratic Republic of Congo, Department of Plant Health, Ministry of Agriculture and Food Safety, Mozambique, Tropical Pesticides Research Institute of Tanzania, Eswatini Environment Authority, the National Biotechnology Authority of Zimbabwe, as well as the following private sector organizations CropLife Southern Africa, South African Bioproducts Organisation, the African Agricultural Technology Foundation, the International Biocontrol Manufacturers Association, as well as ICGEB, IR-4, United States Department of Agriculture (USDA), University Eduardo Mondlane, Mozambique and the University of Zambia. IR-4 and the have committed to provide technical support for this PPG and the resulting project. APAARI has offered to be a technical knowledge-sharing partner, based on the ongoing related PPG in the Asia and Pacific region (STDF/PPG/634).

11. The aim of the PPG is to prepare a proposal for a regional project (for consideration by the STDF and/or other donors) to develop a clear and coordinated strategy on how to promote the inclusion of biopesticides into IPM programmes in selected SADC member states. This is expected to help reduce the reliance on synthetic chemical pesticides, decrease residue levels, and increase SPS compliance and facilitate trade. The resulting project would build an innovative and collaborative approach to help mitigate conventional pesticide residues through the incorporation of biopesticides into national IPM programmes and Good Agricultural Practices (GAP) for specific crops (to be selected through work under the PPG). It would encourage and strengthen collaboration among regulators, biopesticide registrants and the private sector, and other interested international partners.

12. The PPG in SADC is closely related to an STDF PPG on biopesticides in the Asia Pacific region (STDF/PPG/634), which was developed in consultation with the ASEAN Expert Working Group on MRLs, IR-4 Rutgers University, USDA and Crop Life Asia, and is being implemented by the Asia-Pacific Association of Agricultural Research Institutions (APAARI).³ Both PPGs include a focus on biopesticide regulatory harmonization (major focus in the Africa PPG, minor focus in the Asia PPG) and residue mitigation using biopesticides (major focus in the Asia PPG, smaller component in the Africa PPG).

³ See: www.standardsfacility.org/PPG-634

13. The PPG in SADC will build on and learn from experiences under the PPG in Asia, by not only inviting an expert from the Asia PPG to the SADC PPG workshop but also ensuring regular inputs from APPARI into the proposal to be developed under this PPG. USDA, IR-4 and APAARI are already working together on the Asia PPG and have agreed to actively provide inputs into the SADC proposal development. Furthermore, the engagement of an expert from IR-4 to serve as a consultant for both the Asia and SADC PPGs will ensure tight linkages of the work to be undertaken in both regions.

14. The work to be carried out under this PPG will be linked to other relevant work related to international standards (Codex and IPPC), as well as (ongoing) work by the OECD on biopesticides. This includes: (i) work of the OECD Expert Group on Biopesticides (EGBD) on biopesticides; (ii) ongoing discussions and work in the Codex Committee on Pesticide Residues (CCPR)⁴ on specialty and tropical crops and (iii) the work led by Chile on international biopesticide regulatory harmonization. The provisions of the [International Code of Conduct on Pesticide Management](#) will also be taken into consideration. Work under the PPG should also pay attention, wherever possible, to any plant health concerns linked to the use of biopesticides through attention to the relevant standards of the International Plant Protection Convention (IPPC), which also address the export, shipment, import and release of bio-control agents.⁵

15. The work to be carried out in SADC will be designed and implemented in close cooperation with stakeholders involved in other relevant on-going/planned initiatives in Africa to learn from relevant experiences, build synergies and improve results. This includes:

- Ongoing regional efforts to address challenges pertaining to biopesticide registration by the African Agricultural Technology Foundation (AATF) including work to develop a comprehensive guidance document for the registration of microbial biopesticides in sub-Saharan Africa.
- EU-funded Regional Economic Integration Support (REIS) programme through which SAPReF reviewed and aligned Regional Guidelines for the Regulation of Plant Protection Products with the revised WHO/FAO International Code of Conduct for Management of Pesticides (including biopesticides).
- FAO support (March 2018) to SAPReF to identify regulatory challenges to pesticide research development and commercialisation and find ways to fast-track registration of biopesticides.
- UNIDO project "Capacity Strengthening and Technical Assistance for the Implementation of Stockholm Convention National Implementation Plan (NIPs) in Africa LDCs of the COMESA and SADC sub-regions," and UNIDO support to develop a draft regional strategy on production and application of biopesticides in the COMESA and SADC sub-regions.
- COMESA-EAC-SADC Tripartite Free Trade Area which *inter alia* provides for measures to address technical barriers to trade and sanitary and phytosanitary measures.

Representatives from each of the above-mentioned entities will be invited to the PPG workshop to ensure their views on the proposed project are effectively captured. They will also be requested to review the draft project proposal produced through the PPG to ensure no pertinent views are left out and that complementarities and synergies are identified wherever possible.

Work carried out under the PPG will seek to learn from relevant experience and lessons related to registration that have been faced by individual countries in Africa. To this end, representatives of the Kenya flower sector, which has experience in this area, will also be consulted during the development of the proposal.

Scope of the SADC PPG

IPM is the cornerstone to reduce the use of conventional pesticides and this PPG and the resulting project will be based on this concept. Since pesticide residues are primarily determined by the last application of the crop growing period, the PPG will specifically focus on the last application to develop the mitigation approach. FAO will be engaged as a key partner to provide advice and guidance regarding the most effective IPM practices based on the identified crop-residue concerns. The PPG will cover the targeted use of biopesticides at the end of the crop growing period, in

⁴ The 50th CCPR in April 2018 established an electronic working group chaired by Chile and co-chaired by India and USA to prepare discussion paper for consideration at the next session on potential guidelines on biological and mineral compounds used as pesticides of low public health concern.

⁵ Notably, ISPM 3 (Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and Other Beneficial Organisms) and ISPM 11 (Pest risk analysis for quarantine pests).

combination with IPM during the rest of the crop production. This approach will combine the advantages of conventional pesticides with the advantages of biopesticides at the end of the season.

16. The focus of this PPG is expected to be on microbials (such as bacteria, fungi and viruses) and biochemical biopesticides (such as plant extracts and minerals). The selection will take into account IR-4's existing list of exempt products and will be based upon the target pest at the end of the season. The final selection will be further discussed and clarified with FAO (including FAO experts involved in the IPM Programme, as well as the Codex and IPPC Secretariat) as part of the inception work.

The main thrust of the SADC PPG will be on regulatory/registration barriers for biopesticides and developing a strategy to provide incentives or reduce the barriers for new registrations. The PPG will identify these barriers and develop a regional plan to address them. It is expected that the PPG would result in a full project proposal that includes both a registration/regulatory component for SADC countries, and also a research component that may include more countries throughout Africa (and links to the research work that will be done in Asia).

17. It is unlikely that all SADC countries involved in the regulatory harmonization component of the PPG will be ready to step forward with the residue mitigation component. Preparatory work under the PPG will discuss and identify the most relevant SADC countries to be involved in both components in order to target the PPG resources most effectively.

18. South Africa and Tanzania are likely to be most able to participate in research / residue mitigation activities under the regional project to result from the PPG. There may be opportunities to enable selected other SADC countries to benefit from this, for instance by enabling them to attend / observe GLP group lab and field trainings, though the feasibility of this would be assessed during the PPG work. In addition, the PPG will consider if there may be opportunities to benefit from the collaboration of any other African countries (notably Kenya, Uganda, Senegal and Ghana that were involved in the regional STDF project on MRLs, STDF/PG/359) in the residue mitigation studies to be carried out under the resulting project.

Objectives, Expected results, Deliverables

19. The aim of the PPG is to develop a proposal for a regional project to promote the use of biopesticides, especially for late season pests in key export crops, in the SADC region, thereby overcoming pesticide residues as barriers to trade. This regional project in selected countries in the SADC region is expected to focus primarily on biopesticide regulatory harmonization, with a smaller component on residue mitigation using biopesticides.

20. Subject to further discussions with key partners and stakeholders, the resulting project is expected to strengthen regulatory capacity on biopesticides in the SADC region, to promote harmonization of the registration process and help to remove regulatory barriers to the use of biopesticides, and support SADC countries to implement concrete actions to promote utilization of specific pesticides. This may include support to develop the regulatory infrastructure needed to facilitate the registration of biopesticides, and facilitate the integration of biopesticides as a GAP for tropical crops.

21. Information gathered through work carried out under the PPG – including on tolerance exemptions in African countries – would be shared with stakeholders responsible for the OECD work on global harmonization led by Chile.

22. The following questions will be considered as part of the PPG work:

- What are the key export crops from the selected SADC countries involved in the PPG that would benefit most from using an IPM approach for reducing pesticide MRLs to gain market access?
- What are the key residue issues impacting international trade in these crops?
- What are the MRL standards for these commodities in key export destinations?
- What sorts of products would be considered as biopesticides within SADC, and would therefore fall under the ambit of biopesticide regulatory agencies?

- What are the regulatory and other barriers to the research, development and commercialization of these biopesticides?
- What are the other regional and international initiatives making efforts towards or having successfully developed guidance material for biopesticide evaluation, and how can these be leveraged to develop a strategy for the SADC region?
- What efforts will be undertaken at both regional and country level to ensure adoption of the guidelines?
- How could biopesticides be promoted and integrated into larger pest management approaches within the SADC countries?
- How could grower outreach programmes be used to promote the use of biopesticides in export promotion programmes and domestic markets?
- What is the foreseen impact of the proposed interventions on trade from and within the SADC region?
- How can a system be developed for the recognition of efficacy data within the region?

23. The project proposal should, *inter alia*:

- Clearly elaborate the purpose, scope, specific objectives, and expected outcomes, outputs and activities of the proposed project, based on a coherent logical framework. The logical framework should include indicators to measure performance, sources of verification and any key risks and assumptions.
- Clearly identify the roles and responsibilities of all concerned public and private stakeholders, with clarity on the proposed project implementation and management arrangements.
- Identify linkages, synergies and complementarities to relevant activities and projects supported by donors and development partners.
- Identify and provide for linkages with relevant awareness raising and training activities for farmers in order to promote IPM and biopesticides.
- Include a detailed estimate of the budget required to implement the proposed project and, where possible, identify possible donors and/or private sector support for specific components.
- Consider cross-cutting issues related to gender and environmental aspects.
- Include a detailed work plan and timetable for project implementation.
- Identify and assess the possible risks and challenges faced in the proposed project, as well as risk mitigation strategies to ensure its success and sustainability.

24. During the PPG, discussions will be held with relevant regulatory and research institutions in SADC countries to foster their involvement in the development of the full proposal. Ministries responsible for agriculture and trade will also be engaged to assure their participation and ensure the relevant trade-related concerns are factored into the development of the full proposal. Equally importantly, efforts will be undertaken to ensure broad government support. As already mentioned there exists a good opportunity for South-South cooperation between South Africa and other SADC countries and to this end consultations have been made with Mr Thilivhali Nephumbada (Technical Advisor, Agricultural Remedies: Department of Agriculture, Forestry and Fisheries, South Africa) who has confirmed that South Africa is willing to share its expertise with the other countries in the region.

Role of ICGEB

25. The PPG will be implemented by ICGEB, in close collaboration with IR-4, USDA, technical experts from participating countries in the region, and other partners including FAO. ICGEB will work closely with IR-4, Rutgers University, which will provide technical expertise to the work to be carried out.

26. ICGEB's role under the PPG will be as follows:

1. Identify and follow-up with relevant experts from SADC countries⁶ to be invited to participate in the PPG workshop, as well as relevant private sector stakeholders, academic organizations, and other international organizations and bilateral partners. The final set of

⁶ While SADC includes Angola, Botswana, Democratic Republic of Congo, Eswatini, Lesotho, Malawi, Mozambique, Namibia, Tanzania, Zambia, Zimbabwe and South Africa, only a smaller, selected group of these countries will be included in the PPG work and meetings organized, and in the resulting project.

countries to be involved in the resulting project will be selected by ICGEB in cooperation with IR-4 and other relevant partners, based on their expected role in and contribution to the resulting project, the clear commitment of the relevant government authorities, as well as discussions with international partners on the project approach and methodology, and aspects related to the feasibility of the project design.

2. Organise the PPG workshop to discuss and collect key inputs for the project proposal. To reduce costs, efforts will be made to organise the PPG workshop on the margins of another already scheduled meeting (e.g. SAPReF, SADC).
3. Explore further and analyse the linkages, synergies and complementarities with other relevant projects, as well as related work by FAO, Codex, IPPC, OECD, USDA, IR-4 and others, including to:
 - i. Seek the support/inputs of international organizations, including FAO in terms of collecting guidance on relevant IPM and GAP policies, and linkages to ISPMs.
 - ii. Liaise with IR-4, USDA and others to identify other relevant stakeholders and partners from the relevant projects or programmes.
 - iii. Learn from relevant experiences elsewhere in Africa (including with the horticultural sector in Kenya), and identify and develop synergies with the related STDF PPG in Asia.
 - iv. Coordinate with other key stakeholders to seek their buy-in and engagement in the implementation of this PPG and support for the resultant project proposal.
 - v. Contact and hold discussions with relevant private sectors stakeholders, including local registrants, biopesticide manufacturers, CropLife South Africa, The International Biocontrol Manufacturers Association and the South African Bioproducts Organization).
4. Lead and coordinate the technical work to be carried out under this PPG, in close coordination with other partners. This will be expected to include the following:
 - i. development of the agenda and supporting documentation for the PPG planning meeting;
 - ii. organization of the research team and its work; facilitation of the PPG planning meeting;
 - iii. development of surveys and consultations to determine relevant priority crops/conventional pesticides/registered biopesticides to be included in the resulting project;
 - iv. development of the comprehensive priority list of crops/conventional pesticides/registered biopesticides to be covered by the resulting project;
 - v. consultations and engagement with FAO on relevant IPM practices;
 - vi. provision of inputs to the regional project proposal including on the budget and technical scope;
 - vii. consultations on the draft regional project proposal with relevant stakeholders including FAO, Codex, IPPC, USDA, IR-4, the beneficiary countries to obtain feedback and comments and revise the draft project proposal as required.
5. Take the lead on developing a regional project based on the discussions and outcomes of the PPG meeting and other interviews / consultations related to this PPG, as well as other relevant information and comments received, in collaboration with IR-4 and other relevant stakeholders.
6. In collaboration with APAARI, USDA and IR-4, identify opportunities for complementarities and synergies between the regional project to be developed in SADC through the PPG and the project that is emerging from the STDF PPG in Asia.
7. Obtain letters of support for the resulting project proposal from key public and private sector stakeholders in the region. As appropriate, these letters should include a clear expression of support for the proposed project, and demonstrate clear commitment to take actions needed to ensure the success and sustainability of the project. At a minimum, letters of support are expected from relevant government authorities in the countries to participate in and/or benefit from the proposed project, as well as the relevant private sector stakeholders.

8. Use this PPG to support dialogue on biopesticides among international, regional and national organizations, as well as with the private sector, and relevant development partners and donors. This will involve consultations with relevant donors in the region (including bilateral donors, as well as the private sector) to explore options to mobilize additional funding sources for the resulting project that would complement the requested STDF contribution, as well as the expected in-kind contribution from the participating countries.⁷

In addition to the regional project proposal, ICGEB will deliver a short report on the implementation and outcomes of this PPG, within one month of its completion. This report should not only provide information on each of the points listed above but also describe the activities implemented, the results achieved, and the key stakeholders involved and/or consulted. Copies of relevant documents produced under the PPG must also be attached. Any relevant documents identified during the course of the PPG should be provided to the STDF for inclusion in the STDF online Library.

TIMEFRAME

The planned starting date is 10 August 2019 with a completion date of end July 2020.

BUDGET

The budget included in the PPG application and approved by the STDF Working Group for implementation of the PPG is US\$41,295.

⁷ For details on the amount of the in-kind contribution, see: www.standardsfacility.org/project-grants