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An overview of biopesticide regulatory frameworks in selected countries in Southern Africa

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Biopesticides are pest control products derived from microbes and botanical extracts. They are increasingly important as a key element in many pest management programs. The growing interest in biopesticides reflects the increasing global demand for more sustainable agricultural practices. Flexible policies and regulations are crucial to encourage responsible innovation and ensure the availability of effective and sustainable pest control products, including biopesticides, to support this shift. This review of biopesticide regulatory systems in six Southern African countries was done through desktop reviews of relevant legal documents and in-person interviews. Key factors to be considered in developing guidelines for biopesticide registration are addressed. Furthermore, this review examines the legislative processes in six Southern African nations: Botswana, Mozambique, South Africa, Tanzania, Zambia, and Zimbabwe. While sharing some commonalities, each country's legislative framework reflects unique constitutional and procedural characteristics. The study details the stages of bill passage, from initial drafting and introduction to presidential assent, highlighting variations in parliamentary structures, public participation, and the role of subsidiary legislation. Across these nations, the constitution serves as the supreme law, guiding the powers and procedures of their respective parliaments. The analysis underscores the importance of understanding these legislative processes for effective governance and law-making within the region, emphasizing the interplay between constitutional provisions, parliamentary practices, and executive authority in shaping national legislation. Additionally, the review identifies challenges that could hinder developing a regionally harmonized regulatory system for biopesticides. It ultimately makes recommendations for regulatory changes and legal steps that countries should take to integrate provisions of the harmonized guidelines into their national regulatory processes.

KEYWORDS

agrochemical registration, decision-making, food safety, harmonization, pest control, phytosanitary

1 Introduction

Agricultural exports significantly contribute to the economies of many countries in the Southern African Development Community (SADC)[1], with crop production estimated to account for 61 per cent. Despite the sector's various challenges, crops are the region's primary food source, employment, and income. However, some countries experience considerable economic losses due to the rejection of agricultural produce exports, which arise from non-compliance with relevant residue standards. The Southern African Pesticide Regulators Forum (SAPReF) [Southern Africa Development Community (SADC), 2021] attributes this to widespread overuse, misuse, mishandling, and mismanagement of pesticides. Exceedance of established maximum residue limits (MRLs) is particularly common, especially for crops where synthetic chemical pesticides control late-season pests. Biopesticides could significantly mitigate pesticide residues since most pest control products (except biochemical derivatives) are not subject to MRLs within importing countries (FAO, 2018). Biopesticides could enhance compliance with MRL requirements and promote regional and international trade. However, despite their advantages, biopesticides' widespread adoption and use are affected by challenges concerning their research, development, registration, and commercialization (Moshi and Matoju, 2017; Khursheed et al., 2022).

In recent years, there has been increasing consensus that the disparity in regulations among SADC member states adversely impacts their import–export transactions. Harmonization of regulations has the potential to reverse this trend, contributing substantially to the promotion of trade. To this end, some efforts toward harmonizing pesticide regulations within the SADC region have been undertaken recently [Southern Africa Development Community (SADC), 2021]. SAPReF, whose formation resulted from such efforts, is mandated to, *among other things,* (i) promote regional collaboration and harmonization of pesticide regulation and (ii) implement the objectives of the SADC Plant Protection Technical Committee and the Sanitary and Phytosanitary Annex to the SADC Protocol on Trade, which requires member states to take necessary measures to facilitate the simplification and harmonization of trade documentation and procedures.

It is acknowledged that the regulatory constraints impeding the research, development, and commercialization of biopesticides include:

1. Predictive and efficient regulatory processes are absent to ensure product safety and consistency without inhibiting commercialization.
2. More harmonization in the legislation of different SADC member states addressing product-relevant issues and concerns, which constrain and adversely impact import–export transactions, is needed.
3. Regulation of biopesticides by systems initially designed to oversee chemical pesticides creates market entry barriers, primarily by imposing burdensome costs on the industry.
4. Lack of human resource capacity well-versed in biopesticide regulation.
5. Lake of developed registration guidelines.

However, before creating and harmonizing guidelines, it is necessary to assess the legal frameworks in each country to ensure a clear understanding of what is needed to ensure that regional guidelines can be integrated into national legislation. Developing practical regulatory guidelines is expected to lead to increased approval of biopesticides by regulators, promoting more effective registration and commercial adoption of these products. Regulatory harmonization would also help eliminate trade barriers between countries and regions arising from differences in their respective standards. The increased availability of biopesticides would ultimately reduce heavy reliance on synthetic pesticides, thereby minimizing residue violations and promoting trade (Lengai et al., 2022).

2 Methodology

Including SADC countries' governmental websites, Google Scholar, PubMed, Scopus (Elsevier), Web of Science, Academia, and other relevant websites, *Harmonizing Regulations and Mitigating Pesticide Residues in the SADC Region* (STDF/PG/694), by the International Center for Genetic Engineering and Biotechnology (ICGEB), with funding from the Standards and Trade Development Facility (STDF). The countries selected were Botswana, Mozambique, South Africa, Tanzania, Zambia, and Zimbabwe. A comprehensive analysis was undertaken to assess the legal landscape of the biopesticide regulatory systems in these project countries. Information was obtained through consultations, meetings, and interviews (Supplementary Annex 1) with pesticide regulators and stakeholders through the Zoom communication platform, emails, and phones. Following a mapping exercise, it became apparent that it was essential to supplement this with in-country site visits and face-to-face engagements with relevant biopesticide regulators and stakeholders. A physical meeting was thus convened at SADC headquarters in Gaborone, Botswana, in July 2021.

The analysis comprised, among other things, a desktop review of the pertinent biopesticide-related legislation, regulations, and policies; administration of a survey to a targeted sample of regulators and other relevant stakeholders; virtual consultations with a similar target sample from the various project countries; and in-person engagements with regulators and policymakers predominantly representing the government of Botswana. The biopesticides regulatory frameworks for each project country reviewed against the normative elements articulated in the guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa (AATF, 2013). The guide provides a framework for developing clear, effective regulations for the use of microbial biopesticides in Sub-Saharan Africa. Key elements and provisions that should underpin a normative biopesticide framework to facilitate the harmonization of biopesticide regulatory systems across the six project countries are indicated in Supplementary Annex 2.

The information extracted from the review of biopesticides regulatory frameworks includes:

1. General scope of the pesticide regulatory framework.
2. Biopesticides registration framework.

1 The 16 SADC member states are Angola, Botswana, Comoros, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe.

3. Parallel registration and registration of equivalent or generic pesticides identity and ownership of biopesticides and information associated with the biopesticides.
4. post-registration controls-product stewardship.
5. Schedule of fees.
6. Factors contributing to integrating harmonized guidelines for biopesticide registration.
7. Recommendations for the review of regulations to facilitate the integration of harmonized guidelines for biopesticide registration.

The findings of this survey are also available online (Chinyama and Kyampaire, 2022) and Supplementary Annex 3 provides an overview of the legal landscape in the six project countries.

3 Biopesticides regulatory frameworks

3.1 The general scope of the biopesticides regulatory framework

3.1.1 Botswana

Biopesticides are regulated by the Agrochemicals Act 18 of 1999 (GoB, 1999). The main objective of the Act is to facilitate the registration and licensing of agrochemicals, control and regulate their importation, manufacture, distribution, use, and disposal to prevent pollution to the environment and guide on any other related matters. The Act envisages the appointment of a Registrar of Agrochemicals and the establishment of a National Agrochemicals Committee. The Registrar is mandated to, among other things, register agrochemicals by this Act, monitor their sale and use, test residues of agrochemicals, and develop a code of practice for the management of and dealings in agrochemicals, with the support of the Committee, which has an advisory and review function. Under this Act, no person can manufacture, import, distribute, sell, or dispose of an agrochemical unless formally licensed.

3.1.2 Mozambique

According to Diploma No. 153/2002, the Ministry of Agriculture and Rural Development is the lead agency responsible for the registration and issuing of permits for pesticides, subject to the approval of the National Directorate of Health, the National Directorate of Environment and the National Institute of Agricultural Research's Department of Animal Sciences (Ministry of Agriculture and Rural Development Mozambique Conservation Areas for Biodiversity and Development, 2020). The Regulation on Pesticides Management defines pesticides but does not provide biopesticides. In terms of the material recognized for registration, the Regulations make a clear distinction between "active ingredient" and "formulated product," as evidenced by the definitions of "production" and "packaging "(GoM, 2009).

3.1.3 South Africa

The Pesticide Management Policy, published in December 2010, is intended to encourage developing and using alternative pest control products and techniques to reduce over-dependence on chemical plant protection products (DAFF, 2010). In addition to this Policy, which advocates for the expedited registration of lower-risk products (including biopesticides) to complement synthetic chemical pesticides, South Africa also has well-developed guidelines on registering agricultural remedies. South Africa's established biopesticide regulatory system presents an ideal opportunity to contribute best practice insights towards a collaborative process of developing harmonized guidelines with other SADC countries. South Africa promotes biopesticides as part of Integrated Pest Management (IPM) programs through public-private partnerships involving the government, the agrochemicals industry, farmers, community-based organizations, non-governmental organizations, consumer groups, and other national stakeholders, and international initiatives.

Biopesticides are regulated by the Department of Agriculture, Land Reform and Rural Development (DALRRD) through the Directorate of Agricultural Inputs Control (AIC) under the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 (GoSA, 1947). This Act has been subject to several amendments. South Africa stands out in the biopesticide world with a robust policy framework promoting alternatives to chemical pest control (DAFF, 2010). Registration guidelines are well-established to pave the way for the biopesticides sector to flourish in South Africa. This robust system benefits farmers and positions South Africa as a valuable collaborator in developing harmonized biopesticide standards across the SADC region. Public-private partnerships further fuel the adoption of biopesticides by implementing IPM programs, while existing regulations under the Department of Agriculture ensure responsible use. Overall, South Africa's biopesticide landscape presents a promising model for sustainable pest control within its borders and across the region.

3.1.4 Tanzania

There needs to be stand-alone legislation for biopesticides and biological control agents. The legislation includes plant health issues, chemical pesticides, biopesticides, and biological control agents. Tanzania has previously participated in a project initiated by the East African Community (EAC), which developed the *Harmonized Guidelines for the Registration of Biopesticides and Biocontrol Agents for Plant Protection* [The East African Community (EAC), 2019]. These guidelines were approved by the EAC's 39th Council of Ministers in 2019. In 2020, Tanzania adopted a Plant Health Act, No. 4 of 2020, which aligned with these guidelines and made provisions for regulating biopesticides. The legal framework for biopesticides is established primarily by the Plant Health Act (GoT, 2020) and the Plant Health Regulations 2023 (GoT, 2023).

3.1.5 Zambia

The principal legislation governing pesticide use in Zambia is the Environmental Management Act No. 12 of 2011 (GoZ, 2011), implemented by the Environmental Management (Licensing) Regulations (GoZ, 2013). The Regulations deal with licensing activities such as air and water pollution, waste management, ozone-depleting substances, pesticides, and toxic substances. The Regulations do not define biopesticides; however, this is understood to fall within the broad definition of pesticides (although it is essential to note that biopesticides are not expressly mentioned or adequately described in this overarching definition). Concerning the material deemed eligible for registration, the regulations distinguish between "active ingredient" and "formulated product," such that the definition for "manufacturer" is an entity involved in the manufacturing of "a pesticide active ingredient or preparation of its formulation or product." This distinction is also evident in Form VIII of the Licensing Regulations, the application form for the registration of pesticides or toxic substances that separates

information to be entered for active agents and formulated products (GoZ, 2013). Overall, the regulations of biopesticides are similar to chemical pesticides in terms of data requirements.

3.1.6 Zimbabwe

The primary law governing pesticide use in Zimbabwe is the Fertilizers, Farm Feeds, and Remedies Act Cap—18:12 (GoZm, 1953) implemented by the Pesticides Regulations (GoZm, 2012). The Pesticides Regulations, amended in 2012, do not have a stand-alone definition of biopesticides; instead, "pesticides" also cover biopesticides (The Pesticides Regulations, 2012a, 2012b). No distinction is made, however, between "active ingredients" and "formulated products" (i.e., the definition of "pesticides" refers to "active ingredient" but does not make mention of "formulated product"), which casts doubt as to whether the application procedures envisage simultaneous or sequential registration of the active ingredient and formulated product. This distinction is essential as there may be circumstances when it is necessary to register the technical grade material separately. While the principal regulations are the Fertilizers, Farm Feeds and Remedies Act, and Pesticides Regulations, the National Biotechnology Authority Regulations S.I. 160 of 2018 (National Biotechnology Authority of Zimbabwe (NBA), 2018) includes input on biopesticides registration. However, the matter of duplication of roles, an incomplete definition of biopesticides, and data requirements for registration of biopesticide products need to be addressed in and across these pieces of legislation to effectively improve biopesticide registration in Zimbabwe.

3.2 Biopesticides registration framework

3.2.1 Botswana

The legislation provides for the registration of conventional chemicals and does not explicitly consider the approval of biopesticides and biological control agents for plant protection. The Agrochemicals Act defines "agrochemicals" as "live biological material"; however, whether this can include biopesticides is uncertain. Persons wishing to use, possess, import, manufacture, advertise, distribute, sell, or dispose of any agrochemical in Botswana must register with the Registrar (Agrochemicals Act, 1999). The Registrar is mandated to establish and maintain a register with the names of all agrochemicals registered under the Act.

An applicant registering an agrochemical is expected to not only apply but also submit two samples of the agrochemical, as well as any advertising material or experimental data in support of the efficacy of the chemical, complete toxicological data, methods of analysis, residue and phytotoxicity data of the agrochemical, and an application fee. Where the Registrar is satisfied with the application, applicants are issued a certificate of registration valid for five years. Where the Registrar is unhappy that application conditions have been fulfilled, an application may be rejected. The Agrochemicals Regulations provide for complete registration, which may be renewed after expiration through re-application to the Registrar. The Regulations also provide temporary permits for a single import of agrochemicals.

3.2.2 Mozambique

The Regulation on Pesticides Management lists registered pesticides, makes provisions for the office, gives a mandate to the Registrar, and makes it possible to establish a technical assessment committee to exercise oversight in matters beyond the technical scope of the Registrar (GoM, 2009). This institutional framework ensures transparency in the application, review, and recommendation processes. The Regulations provide for four registration categories: permanent, temporary, experimental, and emergency use. This confers considerable flexibility to the Registrar, who can register a biopesticide based on the completeness of data adduced and a satisfactory risk assessment outcome (AATF, 2013). The Regulations also stipulate timeframes for administrative decision-making. For instance, 120 days are envisaged to conclude application submission formalities, after which applicants are notified of the reasons for any necessary extensions (Article 11(5) of Decree No. 6/2009 approving the Regulation on Pesticides Management). Neither the Regulations nor any annexures thereto provide detailed elaborations of the data required for registration. This is outlined in a separate guidance document the regulator provides to the applicant.

3.2.3 South Africa

The Fertilizers, Farm Feeds, Agricultural Remedies, and Stock Remedies Act (Act 36 of 1947) mandated the registration of fertilizers, farm feeds, and other products. The Act subsumes the definitions for pesticides and biopesticides under the broader term "agricultural remedy" (GoSA, 1947). The *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa* confirms that "biopesticides," "bioproducts," and "biological products" denote "biological remedy," which is contemplated in the broader definitional term of "agricultural remedy" (DAFF, 2015b).

The Act provides for the appointment of a Registrar who is responsible for the registration of fertilizers, farm feeds, agricultural remedies, and stock remedies; authorizing the acquisition, disposal, or use of fertilizers and farm feeds, sterilizing plants and pest control operators; regulating or prohibiting the importation, sale, acquisition, disposal or use of fertilizers, farm feeds, agricultural remedies, and stock remedies; designating technical advisers and analysts; and providing for any other pertinent matters. Under the Act, the Minister is empowered to appoint an officer as the Registrar of Fertilizers, Farm Feeds, Agricultural Remedies, and Stock Remedies. Applicants wishing to manufacture, import, sell, and advertise agricultural remedies in South Africa must submit detailed information and data to the Registrar for evaluation.

The Guidelines stipulate the data and documents required to apply for registration of agricultural remedies in South Africa (DAFF, 2015b). While the Act does not make provision for the establishment of a formalized technical committee or panel to review applications and make recommendations to the Registrar, the Minister has the discretion to designate persons as technical advisers (to advise the Registrar) and analysts (to assess samples of fertilizers, farm feeds, and agricultural remedies) on an *ad hoc* basis, as stipulated in section 14 of the Act. Concerning registration, the Act does not prescribe specific categories of registration. The Guidelines provide flexibility for the AIC to consider various modes of registration, including emergency uses, minor uses, use for research purposes, and provisional registration. Provisional registrations terminate once the Department of Health has conducted a full toxicology risk assessment and the product is recommended for final approval by the Registrar (DAFF, 2015a; DAFF, 2015b). The Guidelines also provide clarity on the expected timeframes for administrative decision-making. For instance, 14 days are allocated for administrative verification, which entails screening applications "after receipt to ensure that non-data elements have been provided".

3.2.4 Tanzania

The Plant Health Act makes provision for the control of pesticides and biopesticides, establishes phytosanitary measures, regulates the importation and use of plants and plant products, prevents the introduction and spread of pests, and establishes the Tanzania Plant Health and Pesticides Authority (TPHPA). The TPHPA is an autonomous body under the Ministry of Agriculture, mandated to oversee the health of the country's plants, assume responsibility for the registration of pesticides and biopesticides, and ensure the licensing of dealers of pesticides and biopesticides. According to the Plant Health Act, unless stated otherwise, both biopesticides and pesticides are regulated using identical procedures. The Act enumerates its scope of application and provides key definitions, including "pesticides," "biopesticides," "active ingredient," and "formulation," among others.

The Plant Health Act provides a detailed definition of "pesticides," with paragraph (b) of the definition and an additional paragraph referencing biopesticides. The Act also provides standalone definitions of "biopesticide" and "biological control agent." This approach implies that wherever the Act makes a general reference to pesticides, this is to be understood to include biopesticides. Where it refers specifically to biopesticides, this restricts the focus exclusively to biopesticides.

The Act envisages a specific institutional structure to facilitate its implementation: a Board of Directors to assume a lead oversight role concerning the Director General and staff of the Authority mandated to operationalize the Act. The Act conceives of the Director General as assuming the dual responsibility of Registrar of Pesticides, whose functions include, among others, the registration of pesticides, collection, and maintenance of information relating to the importation, manufacture, distribution, sale, and use of pesticides and associated residues. The Act empowers the Board to convene Committees from among its members to support the proper discharge of its various functions. The Board has the discretion to (i) delegate to the TPHPA tasks beyond the scope of expertise of its members, (ii) coordinate with other institutions, and (iii) co-opt experts to undertake efficacy trials as stipulated in sections 8 and 15 of the Act.

The Act does not prescribe modes or categories of registration; instead, it enumerates the criteria for the registration and de-registration of pesticides as well as permissible and prohibited grounds for undertaking pesticide-related activities. Therefore, the Registrar of Pesticides may re-evaluate a registered pesticide if reasonable grounds for such a re-evaluation are identified [Section 17 of the Plant Health Act (No. 4 of 2020)]. The Registrar may also temporarily prohibit the importation, sale, distribution, or use of a pesticide if there is evidence of risk to the environment or human and animal health and may authorize the importation of unregistered pesticides for research or experimental use for a year or an extended period. According to the Act, the TPHPA may review, modify, or revoke a biopesticide import permit. At the same time, the Minister may authorize the importation and distribution of unregistered pesticides in the event of a phytosanitary emergency. The TPHPA confers considerable flexibility in making decisions post-registration once more information about the pesticide becomes available. The TPHPA is also empowered to authorize the importation of unregistered pesticides for experimental purposes or emergencies, subject to prescribed conditions.

The Plant Protection Regulations, 1998 stipulate clear registration categories, namely: provisional registration, where registration is deferred pending compliance with other requirements; registration for restricted use, for example, if the pesticide is highly toxic or subject to Free, Prior, and Informed Consent (FPIC) and registration for experimental use (GoT, 1998). Generally, the Act and Regulations show consistency with recommended normative frameworks that allow regulators a wide ambit of discretion concerning the registration of pesticides under various circumstances. However, these documents need to be more vocal on the timeframes for such administrative decisions. The Plant Health Regulations, 2023, which have replaced the Plant Protection Regulations of 1998, have a provision for the registration of three categories of pesticides: synthetic pesticides, biopesticides, and biological control agents.

Regarding checklists for data and other information dossiers and files to be submitted to support registration applications, the Plant Health Act does not specify a Schedule enumerating the requisite documents but points to the Regulations, which guide all registration. The Act states, "A person applying for registration of a pesticide shall comply with procedures and requirements prescribed in the regulations" (GoT, 2020). Under the Plant Protection Regulations, "every application for pesticide registration, or renewal of registration shall be made on a form specified in the Third Schedule to the Regulations." It shall be accompanied by several documents, including a "dossier containing additional information to determine the suitability of the pesticide".

3.2.5 Zambia

Part V of the Licensing Regulations deals with the licensing of various activities associated with the use of pesticides, including the manufacture, import, export, storage, distribution, blending, processing, and re-processing of pesticides and toxic substances (GoZ, 2013). The Regulations do not specify pesticides register; however, this can be inferred as applicants are required to provide the pesticide product registration number on their application forms. Additionally, the Regulations do not designate an office of the Registrar of Pesticides but only stipulate the licensing procedures for activities associated with the use of pesticides. The Regulations also do not provide for establishing a specialized committee or panel to assess pesticide registration applications. Neither is a provision made for the co-opting of experts; however, this can be provided under the Environmental Management Act, which offers advisory committees with the ability to support the board functions of the Zambia Environmental Management Agency (GoZ, 2011). Currently, no advisory committees assess pesticide registration or licensing applications.

The Regulations further stipulate detailed data requirements for the licensing of activities associated with pesticide usage, which include the submission of a detailed application form, the inspection of the registrant's business premises, the provision of a signed confidentiality declaration to safeguard confidential business information, and labeling, packaging and advertising requirements. The Regulations do not, however, make provision for the various licensing or registration categories; neither do they indicate timeframes for decision-making and the communication of the outcomes thereof to registrants. It is unclear, therefore, whether the responsible officer has the flexibility to issue provisional licenses pending further data, particularly concerning trial products indicated on Form VIII of the Regulations' First Schedule. Form VIII is also relevant because it makes provision for post-licensing modifications, making it possible for registrants to amend or acquire a new license where changes to a product's use or composition have been made (GoZ, 2013).

3.2.6 Zimbabwe

The Pesticides Regulations do not specify the establishment of a product register; however, this is implied by various legislative provisions, for instance, the designation of a Registering Officer tasked with registering pesticides (GoZm, 2012). Furthermore, the Regulations do not guide the application review procedure, the timeframes for administrative decision-making, the co-opting of experts to undertake efficacy trials, or the establishment of a technical panel to review applications and make recommendations for registration. The Regulations recognize a registering officer as possessing the official responsibility for decision-making regarding the registration of pesticides following the submission of relevant documents.

Regarding registration categories, only complete registration is available under the Regulations. However, it is also possible to acquire provisional registration, notwithstanding no such provision is made in the Regulations. This can be remedied by expressly making provision for various registration categories within the Regulations and their Schedules, conferring greater flexibility to regulators regarding how to respond to the multiple needs presented. Thus, in addition to the complete registration and renewals currently availed by the Regulations, provisions could also be made for pre-submission consultation, provisional registration, and registration of product modifications. The pre-submission consultation would allow the registrant to (i) assess whether a pesticide can be registered and (ii) apply for any necessary waivers. The provisional registration is helpful for pesticides subject to trials or for which submission of additional data is required. Modifications of existing registration allow registrants who have identified additional uses, discontinued products, or changed formulations to register such modifications (AATF, 2013).

3.3 Parallel registration and registration of equivalent or generic pesticides

3.3.1 Botswana

Although Botswana permits parallel registration and the registration of equivalents (products considered to be identical or very similar in terms of composition, quality, safety, efficacy, and intended use to an already registered product), current Agrochemicals Regulations do not make express provision for this. However, it is essential to note that while the terms "parallel registration" and "equivalents" are not expressly stated, Form 1 of the First Schedule requires applicants to provide any prior registration details from the country of origin.

3.3.2 Mozambique

The Regulation on Pesticides Management does not provide for parallel registration or the registration of equivalent pesticides. However, applicants are required to indicate if the pesticide for which they seek registration is already registered elsewhere in the SADC region. Prior registration of a pesticide within the area is thus an important consideration. However, whether and to what extent this influences a regulator's decision to award registration is currently unclear.

3.3.3 South Africa

The Fertilizer, Farm Feeds, Agricultural Remedies, and Stock Remedies Act does not expressly provide for parallel or equivalent registrations. The Guidelines recognize the AIC as possessing the mandate to perform a complete evaluation, as consideration of whether another regulatory authority has conferred approval is not a criterion for registration. It is possible that this only relates to full, complete registration, as the survey indicated that both parallel registration and registration of equivalents are permitted. The Guidelines state that "if a remedy containing a new active ingredient is already registered by one or more of the registration authorities of the United States of America (USA), European Union (EU), United Kingdom (UK), Japan or Australia, toxicological risk assessment reports from the registration authorities concerned, together with a toxicological risk assessment by an independent and accredited toxicologist, can be submitted in support of a provisional registration" (DAFF, 2015a; DAFF, 2015b).

3.3.4 Tanzania

Neither the Plant Health Act nor the Plant Protection Regulations make specific provisions for parallel or equivalent pesticide registration. However, the Act permits the TPHPA to use information from a country having a harmonized pesticide regulation framework consistent with that of Tanzania if "the proposed uses of the pesticide are similar" and "the pesticide contains one or more active ingredients present in any pesticide that is already registered." Under Form 3 of the Third Schedule, the Regulations require applicants to stipulate the recommended pesticide use proposed by authorized bodies outside Tanzania. The details about the legislative process in Tanzania and the various stages of the Bill are presented under Supplementary Annex 4. Figure 4 provides the schematic to illustrate the legislative process in Tanzania.

3.3.5 Zambia

The Licensing Regulations do not expressly provide for parallel registration or licensing of generic pesticides. However, Form VIII requires that an applicant disclose whether the pesticide or toxic substance they seek to register is already registered in another jurisdiction. Thus, the section of Form VIII that identifies the pesticide expressly asks applicants to declare if the product is registered in the country of source, formulation, or manufacture, in a SADC country or any other country. This suggests that information about prior registration may impact a registrant's prospects of obtaining a pesticide license or registration. Survey results indicated, however, that parallel registration and the registration of generics are not provided for under the Regulations.

3.3.6 Zimbabwe

The survey showed that the registering officer accepts applications to register parallel and equivalent pesticides. However, this practice is not reflected in the Pesticides Regulations, nor are procedures indicated for the application process to be followed by registrants or the assessment undertaken by the registering officer. It is essential to formalize this by expressly providing procedural guidance for registering generic or patent-expired pesticides and identifying and registering identical pesticides already registered in other countries.

Regarding the gap between member states on equivalent and parallel registration, it is essential to mark the need for regulatory harmonization in SADC member states.

3.4 Identity and ownership of biopesticides and information associated with the biopesticides

3.4.1 Botswana

The Agrochemicals Regulations provide a list of documents applicants must submit to the Registrar. Form 1 of the First Schedule was intended for each applicant's full particulars and comprehensive details of the agrochemical product. In addition to providing their contact and business registration details, applicants must disclose product particulars such as the active ingredient, toxicology, and formulation. Neither the Act nor the Regulations expressly require applicants to submit a "disclosure declaration" form when disclosing confidential data. This, however, appears to be an oversight, as a document of this nature provides regulators with guidance on the information permissible to be shared with other regulatory bodies.

3.4.2 Mozambique

The Regulation on Pesticides Management makes provision for businesses importing, distributing, manufacturing, and selling pesticides to apply for registration, subject to inspection of operations and premises (GoM, 2009). However, the Regulations do not stipulate whether a disclosure declaration must accompany the submission of confidential data. This is a consideration since such a declaration is instrumental in providing clear guidance to regulators on the substantive nature and scope of the confidential information, they are permitted to share with other public bodies to evaluate applicants' data. The survey indicated that institutions and personnel accessing registration documents must uphold confidentiality. However, while this may be the norm, failure to explicitly entrench it within the legal framework runs counter to established international practice, which calls for a disclosure declaration detailing the "extent to which the confidential data may be shared with other official regulatory bodies" to accompany any confidential information made accessible to state entities (AATF, 2013).

3.4.3 South Africa

The Fertilizer, Farm Feeds, Agricultural Remedies, and Stock Remedies Act needs to detail the information required on the product for which registration is sought or the applicant's identity. Guidance on the registration process and a substantive elaboration of the particulars sought about the applicant and product are provided by both the *Guidelines on the Data Required for Registration of Biological/ Biopesticides Remedies in South Africa* (DAFF, 2015b) and the *Guidelines on the Data and Documents Required for Registration of Agricultural Remedies in South Africa* (DAFF, 2015a).

In terms of provisions upholding the confidentiality of data, the Act restrains anyone handling information from disclosing any details save to the Minister or another person dispensing duties prescribed under the Act or as compelled by a Court (GoSA, 1947). The *Guidelines on the Data and Documents Required for Registration* distinguish the type of information expected to be confidential. For instance, the Guidelines assert that AIC staff must uphold the confidentiality of Confidential Business Information (CBI) submitted by applicants. CBI in the context of an agricultural remedy is defined by CropLife International as: "technical and formulation specifications, including a confidential statement on formula, certificate of composition documents, and 5-batch analysis reports; the process of chemistry and the route of manufacture, including manufacturing description, reports; analytical methods on "non-relevant" impurities of the manufacturing process; and other specific documents which are commercially sensitive, for example, market share information, names, and addresses of scientists." Although CBI is protected in perpetuity, this does not prevent the applicant from accessing CBI documents upon request.

3.4.4 Tanzania

The Plant Health Act does not include a Schedule outlining the prescribed pesticides or biopesticide registration application protocols but refers to the Regulations' application procedures. Part 3 of the Third Schedule of the Regulations provides the application form for pesticide and biopesticide registration. It requires applicants to provide their personal details and pertinent information about the product they seek to register. The form attests to the confidentiality of the information provided. The Regulations further stipulate that all documents are securely stored by the Head of the Plant Protection Division of the Ministry of Agriculture, who may only reproduce these documents with the formal consent of the Minister. This study flagged this regulatory provision as one that should be considered for revision.

3.4.5 Zambia

Adequate information is lacking about the identity and ownership of biopesticides and the data associated with them.

3.4.6 Zimbabwe

Concerning the ownership of pesticides, including biopesticides, Form P.1 of the First Schedule of the Pesticides Regulations requires each applicant to provide business contact details and information on the product for which registration is sought. The Regulations do not, however, distinguish confidential from public data, although the survey showed that the Official Secrets Act may cover this. Nonetheless, it is essential to note that the Official Secrets Act [Chapter 11:09] (The Zimbabwe Regulation, 2012) may not be the most appropriate law to protect registrants' propriety information or determine what information should be availed to public servants. The language of the Official Secrets Act implies that it was not enacted to protect commercial information but rather to "prohibit the disclosure for any purpose prejudicial to the safety or interests of Zimbabwe of information which might be useful to an enemy" (The Official Secrets Act, 2002, 2020). Therefore, it is essential to ensure that the regulations provide a disclosure declaration indicating with whom (e.g., the public or other regulatory agencies) confidential data may be shared and to what extent.

3.5 Post-registration controls – product stewardship

3.5.1 Botswana

The Agrochemicals Regulations provide for post-registration controls and product stewardship by the registrant. This includes, among other duties, detailed requirements for labeling and advertising, conditions for safe handling and disposal, and the licensee's record-keeping.

3.5.2 Mozambique

The Regulation on Pesticides Management provides for post-registration controls and registrants' post-product stewardship, which includes compliance with detailed labeling and advertising conditions. These are, however, not exhaustively provided in the Annexure to the Regulations but may be provided by the regulator. The Regulations empower the National Directorate of Agricultural Services to award registration certificates subject to conditions, such as calling for the submission of quarterly reports to the Registrar. For instance, the Regulation on Pesticides Management provides that "the pesticide traders shall provide quarterly information to the Registrar about the amounts of pesticides acquired, sold and the respective stocks; in case they have branches in different towns or locations, they shall provide these data split up by establishment (GoM, 2009). It is incumbent on the Registrar to define the months in which this information shall be provided. The Regulations also authorize inspectors to monitor and enforce pesticide importation, storage, application, production, trading, elimination, handling, and quality control standards. Additionally, the Regulations outline the modes of appeal available to registrants who are dissatisfied with the decisions of the Registrar; such appeals are addressed to the Minister. Furthermore, the Registrar has the authority to revoke a pesticide registration, and registrants may also voluntarily seek to terminate a valid registration.

In summary, post-registration controls are essential for balancing effective pest management and environmental protection. They contribute to safe, sustainable pesticide use in the member states.

3.5.3 South Africa

The Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act provides various post-registration controls including, but not limited to, ordering the discontinuation of the use of specific equipment by the operator if it is found to be unsuitable for administering an agricultural remedy; powers to enter premises, examine documents, analyze samples, and seize a farming remedy; and any additional conditions as may be determined by the Registrar.

3.5.4 Tanzania

The Plant Protection Regulations (GoT, 1998) provide detailed procedures for monitoring the registrant's post-registration compliance. Key examples of these controls include labeling, packaging, and advertising; manufacturing safety guidelines and laboratory quality controls; pesticide handlers' clearance and licensing; the maintenance of product records by pesticide manufacturers and importers; the provision by registrants of information concerning the safest, most practical method of disposal of pesticides and empty pesticide packaging; and the duty of biological control agents to ensure the training of pesticide distributors.

3.5.5 Zambia

The Licensing Regulations contain general provisions relating to licensing and inspection; however, not all conditions elaborated for each license are in-depth, and more expansive conditions may be attached to each license certificate. Specific conditions featured in the Schedules of the Regulations pertaining to activities such as the labelling, transportation, conditions for storage, and disposal of pesticides.

3.5.6 Zimbabwe

The Pesticides Regulations contain provisions for post-registration controls and registrants' product stewardship, which includes labeling and advertising criteria as conditions for registration. The Registering Officer may attach conditions to a registering certificate, requiring, for example, an applicant to provide quarterly reports. The Regulations do not, however, guide the contents of such a quarterly report. Thus, it is unclear whether a registrant is required to provide emerging data on efficacy and toxicity or to indicate whether all those handling pesticides are appropriately trained and thus possess knowledge of safe and efficient usage measures (AATF, 2013).

Moreover, the Regulations do not include a specific provision for the revocation of registration or a registrant's voluntary withdrawal. However, the survey indicated that the Registering Officer can withdraw the registration. The cancellation of registration is mentioned solely about the prescribed validity period of registration. It is included as one of the grounds on which registrants may seek leave to appeal a decision of the Registering Officer. The Fertilizers, Farm Feeds, and Remedies Act provides for the cancellation of registration of fertilizers, remedies, farm feeds, or sterilizing plants. However, it is unclear whether this includes pesticides under the Regulations.

3.6 Schedule of fees

3.6.1 Botswana

The Agrochemicals Act enumerates the charges associated with agrochemical registration but does not include a Schedule of fees. Instead, the fee amounts are indicated in the Agrochemicals Regulations.

3.6.2 Mozambique

Fees are indicated in the Annexure to the Regulations and may be revised by the Ministers responsible for agriculture and finance. This arrangement allows regulators to amend fees promptly, particularly in acute/protracted inflation cases.

3.6.3 South Africa

Prescribed fees are not fixed by statute, which gives regulators greater flexibility to publish amended tariffs in a Government Gazette at the commencement of each financial year.

3.6.4 Tanzania

All fees associated with pesticide and biopesticide applications are fixed by statute in the Regulations' Sixteenth Schedule, which is reflected in United States Dollars. The survey indicated that TPHPA can amend these fees in liaison with the relevant Ministry.

3.6.5 Zambia

Fees are fixed by statute, with a schedule of fees provided in the Regulations indicating the respective costs for the various licenses. The survey showed that the Minister can amend these fees without the involvement of Parliament. However, even if the Minister is not required to table the amended Regulations containing a revised fee Schedule before Parliament, such changes are subject to the scrutiny of the Business Regulatory Review Agency, which requires a Regulatory

Impact Assessment (RIA) to be undertaken as part of this review process. Once approved, the RIA report and the revised fee schedule are submitted to the Ministry of Justice for vetting, after which the responsible Minister publishes the revised fees in the government gazette. This procedure, which can be construed as rigorous and bureaucratic, may impede the expeditious revision of fees. This motivates the consideration of an alternative, more seamlessly coordinated mechanism for harmonizing fees between regional regulators, mainly to discourage 'forum shopping' by registrants.

3.6.6 Zimbabwe

Fees are statutorily fixed in the Second Schedule of the Pesticides Regulations. However, some degree of flexibility is provided, with the regulator permitted to review and update fees subject to their formal amendment by the designated Minister. The Minister is responsible for referring proposed fee amendments to a parliamentary committee for approval through the appropriate channels. This procedure is less cumbersome than procedures for enacting a bill into law.

3.7 Factors contributing to the integration of harmonized guidelines for biopesticide registration

Diverse policies, complex procedures, global efforts, and innovative practices contribute to the significant variation in regulation and registration processes across countries where a uniform regional or global model is lacking. All the surveyed countries are receptive to considering a harmonized biopesticides regulatory framework.

3.7.1 Botswana

No biopesticide registration challenges were identified that could adversely impact the integration of harmonized guidelines. A legislative review was advised to isolate the key factors that would facilitate the country's successful integration of harmonized guidelines. It was proposed that harmonized guidelines may best be integrated by drafting Regulations under a new law. The *East African Community Harmonized Guidelines for the Registration of Biopesticides and Biocontrol Agents for Plant Protection* emphasize the unique biological properties of these natural agents [The East African Community (EAC), 2019]. Expertise in microbial ecology, bacteriology, virology, and protozoology is crucial to assess their safety, environmental impact, and suitability. To facilitate effective registration, Partner State regulatory authorities should involve scientists with proven expertise in these fields (FAO, 2012; The East African Community (EAC), 2019; Ashaolu et al., 2022).

3.7.2 Mozambique

The factors identified as necessary to integrate harmonized guidelines include undertaking a legislative review, developing technical capacity, generating agricultural sector demand for biopesticides, and mobilizing the political will to change the direction of existing biopesticides policy.

The constraints to the adoption of biopesticides into Good Agricultural Practice (GAP) cited included, among other things, lack of registered biopesticides in the country, scarcity of biopesticides promotion by companies; the disproportionate dominance of chemical pesticides (hence more competitive pricing and corresponding demand) stifling the adoption of biopesticides; and poor demand among farmers who perceive biopesticides as less effective than chemical pesticides. Mozambique cautiously embraces the idea of a regionally harmonized biopesticide regulatory system, recognizing its potential benefits. However, transforming this vision into reality demands addressing several hurdles:

1 The country's legal framework needs a thorough review to accommodate biopesticides effectively. Building technical expertise within regulatory bodies and the industry is critical, as well as ensuring proper biopesticide evaluation and registration procedures.
2 Boosting demand among farmers is crucial, and this can be achieved through targeted awareness campaigns and incentive programs encouraging the adoption of biopesticides.
3 Securing strong political buy-in is essential, with policymakers prioritizing biopesticides for successful implementation.

Beyond regulatory challenges, integrating biopesticides into Good Agricultural Practices (GAP) faces additional obstacles. The limited availability of registered biopesticides in Mozambique significantly hampers adoption. Weak industry promotion further suppresses demand, while the entrenched presence of chemical pesticides, with their competitive pricing and established usage patterns, poses a substantial obstacle. Additionally, farmers often express concerns about the efficacy of biopesticides compared to their chemical counterparts, highlighting the need for effective communication and education initiatives to build trust and confidence in these safer pest control products. Overcoming these challenges is crucial for Mozambique to successfully integrate biopesticides into its agricultural practices, promoting environmental sustainability and improved human health outcomes.

3.7.3 South Africa

The drafting of Regulations under a novel law is a step towards realizing the integration of harmonized guidelines in South Africa. The critical challenge affecting biopesticide registration (with the potential to impact the integration of harmonized guidelines negatively) was the struggle companies experienced in providing scientific data to support their applications. Additionally, the agricultural sector's lack of demand for biopesticides was the most significant constraint to successfully integrating these products into GAP. Overall, South Africa welcomes the idea of a harmonized biopesticide regulatory framework but has to overcome several challenges that may hinder the harmonization efforts. Drafting of Regulations under a new law is a crucial step. The relevant companies must be tuned to provide the scientific data for biopesticide registration.

3.7.4 Tanzania

The factors identified as crucial for the integration of harmonized guidelines include increased transparency, especially in the application process, the stipulation of data requirements, and an indication of evaluation procedures, either redrafting the Regulations under another law or establishing a 'stand-alone' legal instrument; preparing a code of practice or administrative guidance document; and developing technical capacity, leveraging political will, and increasing product demand within the agricultural sector. The survey also showed that the slow performance

of biopesticides in controlling crop pests and diseases impedes their integration into GAP.

3.7.5 Zambia

The following factors are identified as strengthening the case for adopting harmonized guidelines for biopesticide registration: the development of Regulations under a novel law and the development of a code of practice or administrative guide to build technical capacity. The significant challenges that could constrain biopesticide registration and affect the integration of a harmonized regulatory framework include:

- Lack of transparency in the application process.
- Lack of data requirements and evaluations.
- Uncertainty in the timeframes assigned for decision-making, evaluations, and communication of the outcomes to registrants.

The survey also highlighted the inadequacy of requirements dealing with registration data and efficacy trials as the most substantial threat to integrating biopesticides into GAP.

3.7.6 Zimbabwe

The factors contributing to the integration of harmonized guidelines for a biopesticides regulatory framework include drafting Regulations under another law or establishing a 'stand-alone' legal instrument; the imperative to prepare a code of practice or administrative guide; developing technical capacity; leveraging political will to spearhead a change in policy direction; and engender demand for the product within the agricultural sector. The survey also identified the absence of relevant policy as the most substantial constraint to integrating biopesticides into GAP and attaining harmonized guidelines for biopesticide registration.

3.8 Recommendations for the review of regulations to facilitate the integration of harmonized guidelines for biopesticide registration

The following recommendations highlight the revisions to the regulatory framework needed to integrate harmonized guidelines for biopesticide registration:

3.8.1 Botswana

1. A clear and concise definition of biopesticides.
2. A chapter in the law devoted to biopesticides or stand-alone regulation.
3. Provision regarding data or information deemed strictly confidential and thus requiring submission of a "disclosure declaration".
4. Stipulation of clear timeframes for administrative decision-making to enhance predictability, efficiency, and transparency.
5. Conferral of categories of registrations; provisional registrations for biopesticides subject to trial, or for which registrants must submit additional data.
6. Provisions within the Regulations or Schedule for parallel or equivalent product registrations.

3.8.2 Mozambique

1. A clear, concise, and stand-alone definition of biopesticides.
2. Provision for parallel registration and generic pesticides is subject to restrictions.
3. Provision within the Regulations of measures safeguarding confidential data.

3.8.3 South Africa

1. The main recommendation for revising the existing regulatory framework to fully accommodate harmonized guidelines for biopesticide registration is to establish clear procedures for parallel registration and the registration of equivalents.
2. The Guidelines can help regulators determine whether to consider data obtained for already registered biopesticides or those containing equivalent active ingredients from generic manufacturers registered in other countries in the region.

3.8.4 Tanzania

1. Stipulation of clear timeframes for administrative decision-making relating to registration and licensing to bolster efficiency and accountability.
2. Provisions for parallel and generic product registration, with restrictions.
3. Stipulated criteria to secure provisional licenses. This is important because, although the survey showed that provisional licensing is recognized, the Regulations currently need to reflect the conditions that must be met to qualify for a provisional registration.
4. The Plant Health Act 2020 repealed the Plant Protection Act, Cap. *133 (No. 13/2017)* and the Tropical Pesticides Research Institute *Act, Cap. 161 (No 18/1979)*; consequently, the provisions in the repealed Acts were merged into the new one—however, the Regulations made in terms of *Section 42 of Cap. One hundred thirty-three* retain their legal enforceability under the new Act. This is due to Section *65(3)* of the Plant Health Act, which upholds all subsidiary legislation and exemptions stipulated in repealed Acts—to the extent that they are consistent with the Act – as if they are made under the Act itself. Any provisions within the Regulations inconsistent with the new Act must thus be repealed to ensure complete alignment with the new Act.

3.8.5 Zambia

1. A clear and concise definition of biopesticides.
2. Designation of a technical committee/panel and registrar to increase transparency in reviewing applications for biopesticide registration.
3. Provisions for the co-option of expertise deemed necessary to evaluate all aspects of product efficacy and adverse effects.
4. A clear elaboration of all pesticide and biopesticide registration procedure components, distinguished from pesticide and biopesticide licensing activities.
5. Stipulation of clear timeframes for administrative decision-making relating to registration and licensing.
6. Provisions for parallel and generic product registrations are subject to restrictions.
7. Elaborate post-registration controls and registrants' product stewardship, which may include facilitating capacity building for biopesticides distributors, extension workers, and users.

8. Provision for the registration of biopesticides in emergency circumstances. The survey indicated this is permitted; however, the current Regulations do not expressly provide it.
9. The development of a code of practice or administrative guide to facilitate technical capacitation.

3.8.6 Zimbabwe

1. A clear and concise definition of biopesticides.
2. Designation of an advisory committee for assessing applications for biopesticide registration.
3. In the definition, there is a clear distinction between active ingredients and formulated products.
4. An express provision in the Regulations for establishing a register of biopesticides.
5. Stipulation of clear timeframes for administrative decision-making regarding registration and licensing.
6. Provisions for parallel registration and registration of generics, with restrictions.
7. Elaborated post-registration controls and registrant product stewardship, including details on what is substantively required in the registrants' quarterly reports.
8. Provision for the registration of biopesticides in emergency cases.
9. Provision outlining the procedure for parallel registration and registration of generic biopesticides (The survey indicated this is possible, yet the Regulations do not have provisions to facilitate this process).
10. Stipulated criteria within the Regulations for provisional licenses (The survey indicated that provisional licenses are already conferred, notwithstanding the Regulations' current silence on this).
11. Provision within the Regulations of a "disclosure declaration" to establish what data or information is deemed strictly confidential.
12. Adequate provision within the Regulations for the revocation or voluntary revocation of registration.

4 Key considerations in the development of harmonized biopesticide guidelines

Countries in the SADC region, particularly the six project countries, have divergent policy positions, some devoid of any biopesticides policy. The parameters proposed for harmonized biopesticide guidelines include the normative legislative framework, minimal registration data requirements, efficacy testing, technical evaluation of registration data, registration and licensing, and post-registration monitoring. Most still need well-established biopesticide regulatory frameworks, and most countries rely on processes better suited to conventional pesticides. For example, the registration process for a biopesticide developed from harmless types of *Aspergillus flavus* and used for managing aflatoxins in Zambia was unreasonably protracted, as the country did not have a pre-existing biopesticide regulatory framework. Lesotho, similarly, does not have guidelines and regulations to guide the registration of biopesticides. In Eswatini, in contrast, even though the Pesticide Management Act makes provision for the regulation of biopesticides, these are yet to come into force; pesticide regulation is, therefore, handled by the Eswatini Environmental Authority, while the country establishes institutions specifically mandated to regulate the use of pesticides (including biopesticides). In Zimbabwe, biopesticides are regulated by the provisions of the Fertilizers, Farm Feeds and Remedies Act, the Pesticides Regulations, and the National Biotechnology Authority Act. While Tanzania has policies that make some reference to the regulation of biopesticides (including, among others, the Plant Protection Act, Tropical Pesticides Research Institute Act, and the Environment Management Act), the country has no clear and comprehensive legislative, policy, and regulatory guidelines facilitating the development, registration, commercialization, and use of these products. However, Tanzania has recently participated in an initiative (the experiences of which would guide the development of some of the outputs of this proposed project) to develop *Harmonized Guidelines for the Registration of Biopesticides and Biocontrol Agents for Plant Protection* within the EAC. South Africa has a Pesticide Management Policy, which encourages developing and using alternative pest control products and techniques to reduce over-dependence on chemical plant protection products. The South Africa Pesticide Management Policy also advocates expediting the registration of lower-risk products, including biopesticides, to complement synthetic chemical pesticides. South Africa also has well-developed guidelines on the registration of agricultural remedies.

However, the successful integration of regional guidelines for a harmonized biopesticide regulatory system faces several potential constraints:

1. Misaligned priorities among project countries can hinder collective efforts, as varying levels of commitment can disrupt progress.
2. Harmonization necessitates laborious legal revisions, the extent of which depends on each country's legal system. Domesticating regional guidelines typically involves legal drafting, consultations, validations, approvals, and domestication itself, all of which require significant human and financial resources, infrastructure, time, and political will.
3. Low biopesticide demand within agricultural sectors may discourage governments from investing in promotional activities or resource allocation for domestication.
4. Differences in the technical capacities to evaluate biopesticide registration data decisions for authorization and post-registration monitoring can impede efficient implementation, even after successful domestication.

Addressing these constraints is crucial for effectively realizing a harmonized biopesticide regulatory system across the project countries.

5 Requirements to ensure the ultimate integration of harmonized guidelines into national regulatory processes

Either statutory amendments to principal legislation or changes to subsidiary national-level legislation (Regulations) are required to ensure the integration of harmonized regional biopesticide guidelines into the national regulatory processes of the project countries. However, domesticating these guidelines is expected to vary from country to country according to public consultation processes, regulatory impact assessments (RIAs), parliamentary approvals, and official publications needed for the respective countries.

5.1 The legislative processes in the selected SADC member states

Understanding the legislative process is necessary, as once guidelines are developed, they need to be domesticated, i.e., the provisions need to be incorporated into national regulatory processes. This section presents schematic illustrations of the legislative processes in the project countries. Detailed procedures of the stages of bills and subsidiary legislation for these countries are provided in supplementary Annex 4. Schematics to illustrate the legislative processes in 1) Botswana, 2) Mozambique, 3) South Africa, 4) Tanzania, 5) Zambia, and 6) Zimbabwe.

1. **Botswana**
   Botswana is recognized as one of Africa's best examples of a vibrant Parliamentary democracy (Figure 1).
2. **Mozambique**
   Parliament is Mozambique's legislative body, which can approve all matters by a simple majority unless otherwise stipulated in the Constitution. The details of the legislative process in Mozambique are presented in (Supplementary Annex 4) (Figure 2).
3. **South Africa**
   The constitution of the Republic of South Africa is the country's supreme law. Chapter 4 of the Constitution outlines the national legislative process and provides that Parliament is the National legislature. Figure 3 shows the details of the schematic illustration of the legislative process in South Africa, which are presented in the Supplementary Annex 4.
4. **Tanzania**
   Article 64(1) of the Constitution of the Republic of Tanzania vests legislative powers in Parliament in all matters concerning mainland Tanzania. Details about the legislative process in Tanzania and the various stages of the Bill (Figure 4) are presented under the Supplementary Annex 4.
5. **Zambia**
   The constitution of Zambia is the country's supreme law; therefore, any other law inconsistent with the Constitution is void to the extent of its inconsistency. Legislation refers to laws passed by Parliament and assented to by the President—the power to pass legislation vests in the National Assembly. Article 78(2) of the Constitution provides that the National Assembly must scrutinize legislation brought to Parliament before its submission to the President for assent (Supplementary Annex 4) (Figure 5).
5. **Tanzania**
   Zimbabwe's legislative authority vests in the President and Parliament. The supplementary file in Annex 4 presents the details of the legislative process in Zimbabwe and the various stages of Billing. The schematic presentation of the legislative process in Zimbabwe is summarized in Figure 6.

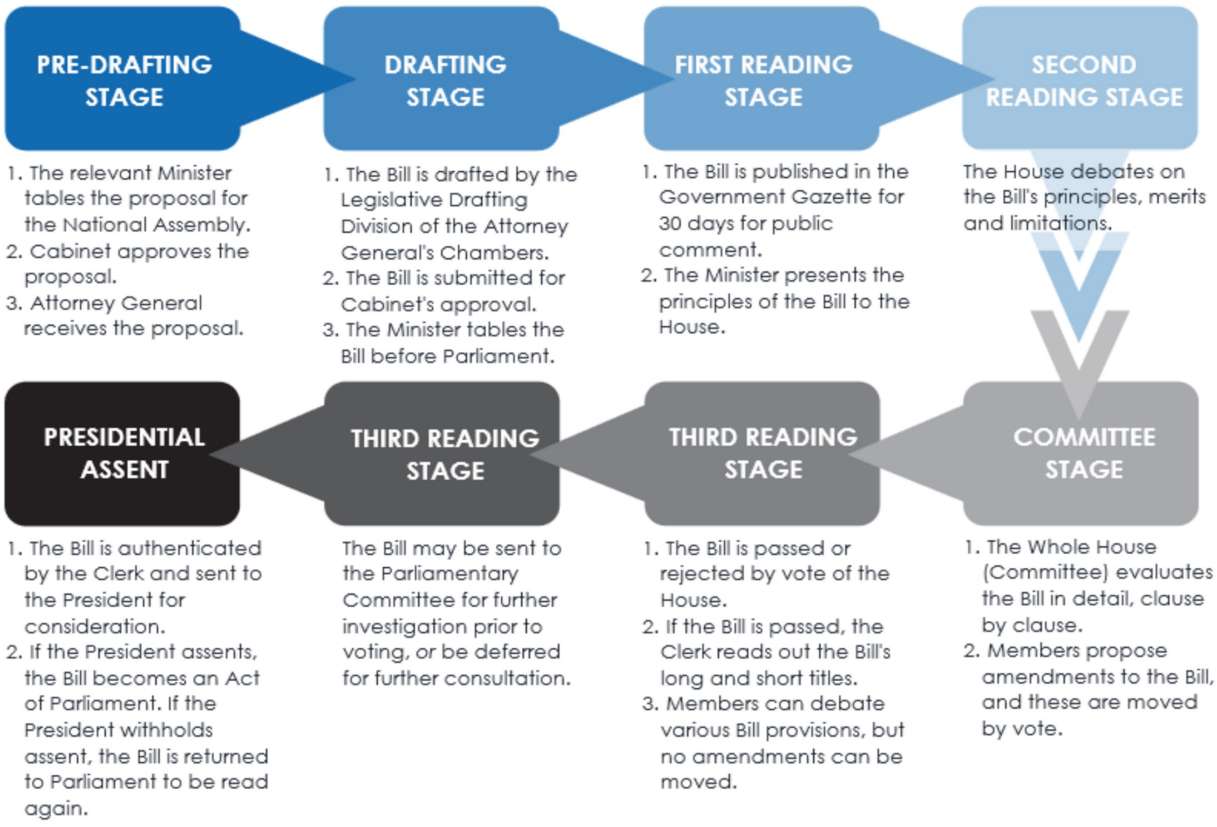

FIGURE 1
Schematic to illustrate the legislative process in Botswana.

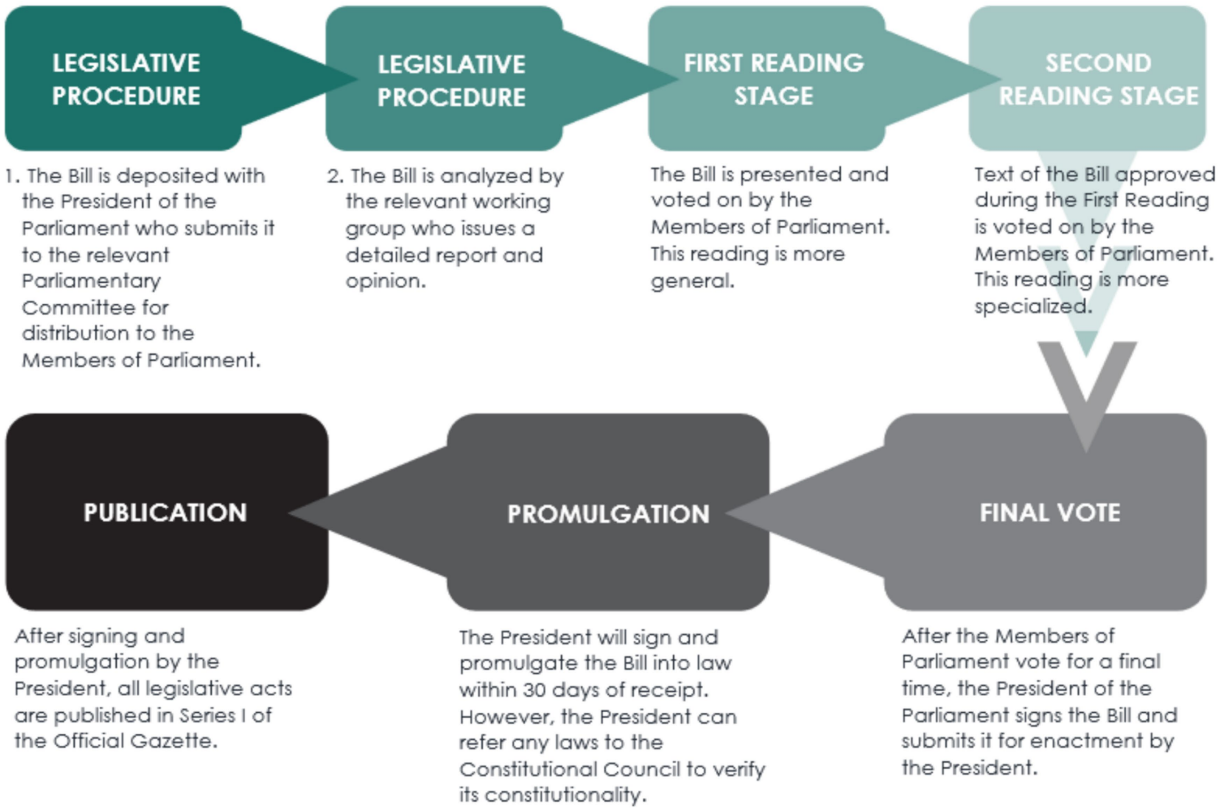

FIGURE 2
Schematic to illustrate the legislative process in Mozambique.

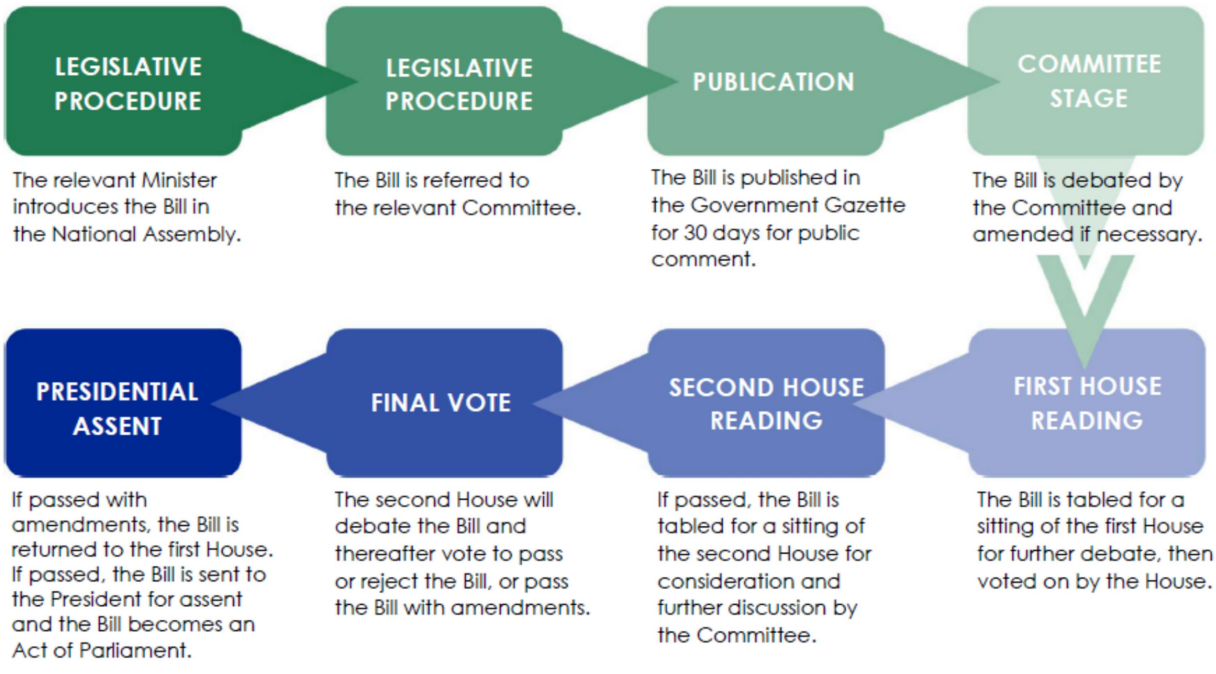

FIGURE 3
Schematic to illustrate the legislative process in South Africa.

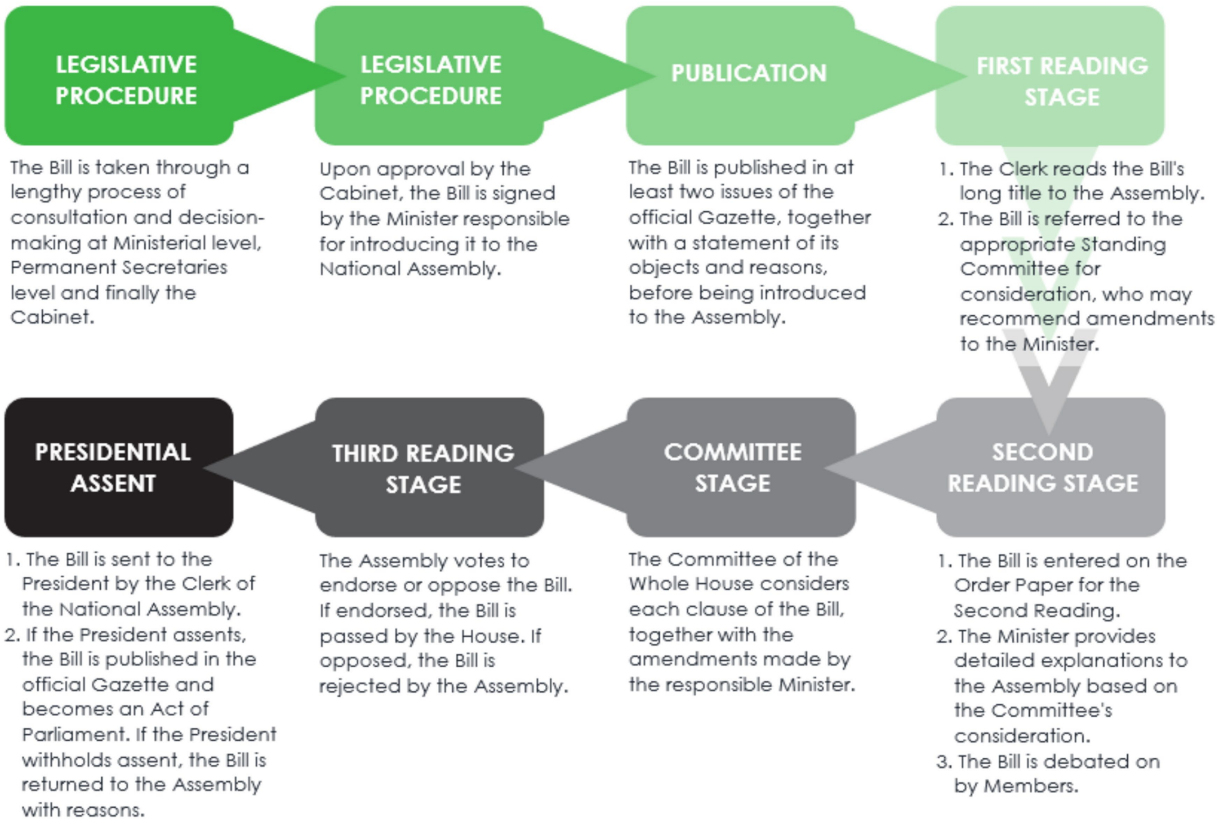

FIGURE 4
Schematic to illustrate the legislative process in Tanzania.

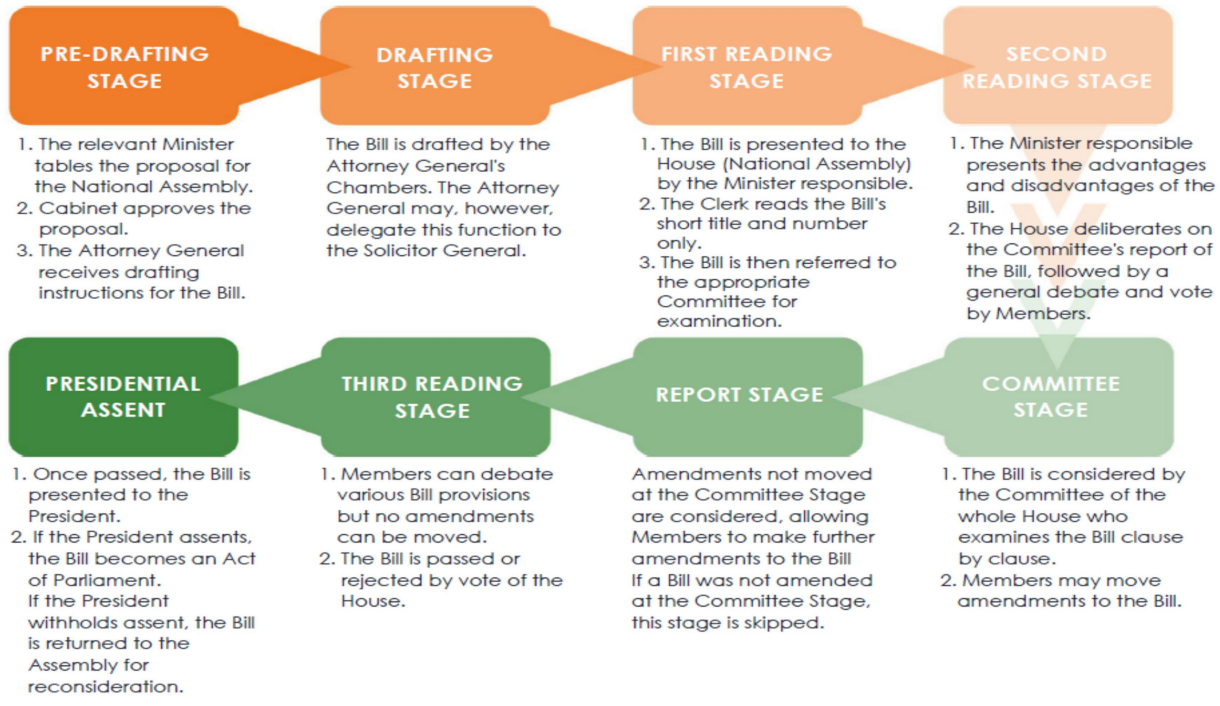

FIGURE 5
Schematic to illustrate the legislative process in Zambia.

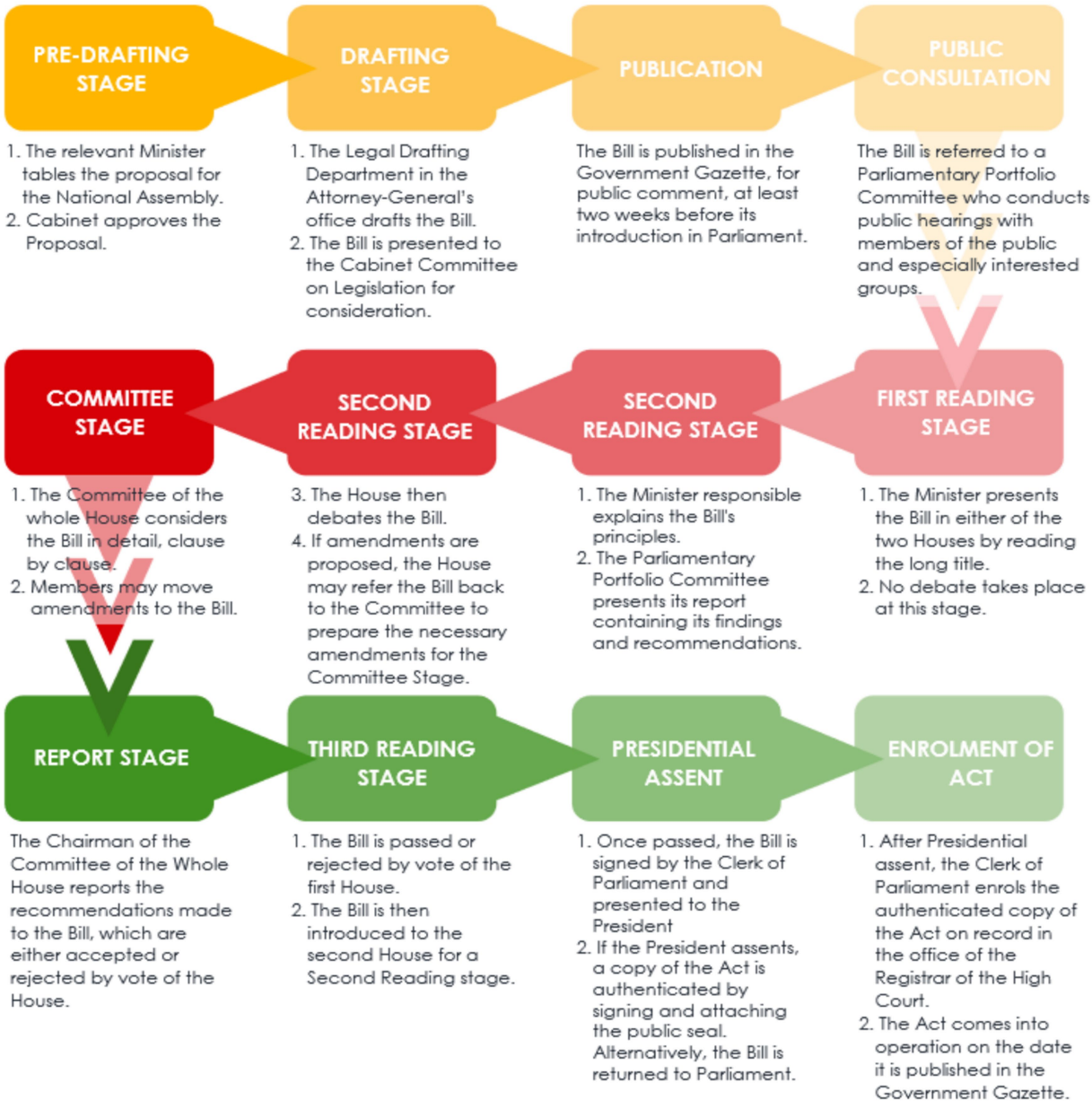

FIGURE 6
Schematic to illustrate the legislative process in Zimbabwe.

6 The regulatory changes and legal steps project countries will need to take to integrate provisions of the harmonized regulatory guidelines into relevant national legislation

6.1 Regulatory changes in the project countries

Regulatory harmonization presupposes consensus among the participating project countries to develop and mutually recognize uniform technical guidelines. The regional harmonized guidelines for biopesticides thus provide a normative framework whose adoption by the participating project countries entrenches a harmonized biopesticides regulatory system. Domestication of the harmonized regional biopesticides guidelines requires a statutory change to national-level principal laws and changes to the six project countries' subsidiary legislation (regulations). However, the process for domesticating these guidelines is anticipated to vary from country to country, with differences in, for example, public consultation processes, regulatory impact assessment, legislative processes, parliamentary approvals, official publications and the time to completion.

Domestication is the process whereby member states incorporate into domestic/national laws and processes – provisions of regional guidelines and instruments to which they commit themselves as parties to bilateral or multilateral arrangements (international obligations), such that the rights and duties contained in the said arrangement become legally

applicable and enforceable within their state territory (Frans, 2015). The exact format and contents of the legislation in each country will depend on the legal system of the country concerned, namely its constitution, applicable international obligations, existing legislation, available institutional infrastructure, relevant policies, and government priorities and resources. It is also essential for the bill to consider the economic and social situation and any relevant contextual circumstances of the country, such as its primary crops, pest problems, vector-borne diseases, dietary patterns, biopesticides needed, the population's levels of literacy, the climate, and the environment, etc. Properly weighing these factors should help drafters ensure a well-designed legal framework for controlling biopesticides tailored to and responsive to the national context. Ideally, countries will already have implemented a biopesticide policy, which can be reflected in the legislation to be developed.

6.2 Factors to consider before revising or drafting national biopesticide legislation

6.2.1 Analysis of the national legal and institutional frameworks relevant to biopesticide management

Analysis of national legislation should consider the national legal system and review all national legislation directly or indirectly affecting biopesticide management in all areas of the biopesticide lifecycle. This entails an analysis of the existing regional and international provisions and guidelines and precisely where they respond to the national gaps. It is necessary to understand the legislative process for each project country (Supplementary Annex 4), as once the harmonized biopesticide guidelines are developed, they need to be domesticated. That is, the provisions need to be incorporated into national regulatory processes.

As part of this Analysis, it is essential to collect information from various stakeholders, including farmers, extension staff, and local government representatives, on the problems they attribute to the management of biopesticides and to determine why these issues exist and why legislation has not yet improved the situation, as this may point to gaps or weaknesses in the bill or in the institutional infrastructure for implementation of the legislation. A review of biopesticide-related (e.g., agricultural, environmental) government policies should also be undertaken.

6.2.2 Identification of technical needs and regulatory failures

The Identification of technical needs and regulatory failures through reference to field realities and experiences, new biopesticide policy objectives, existing legislation, and international recommendations.

6.2.3 Drafting: constituting a national team of legal drafters and technical experts

The legislative processes in the six selected project countries are reviewed in detail and presented in the Supplementary Annex 4. Technical experts should identify the regulatory failures of existing legislation and share them with drafters for insight into the missing elements and overlaps to be addressed by national biopesticide legislation. The regulatory failures requiring attention should inform the drafting process for the new law. Diffuse legislation may also trigger regulatory reform; however, the respective countries must decide whether to amend, repeal, and replace existing legislation or incorporate regional harmonized guidelines into their subsidiary legislation.

6.2.4 Key stakeholder review of drafts

Most countries require stakeholder participation in legislative revision. Thus, it is imperative to involve all relevant stakeholders in the various stages of the legislative process. Effective stakeholder participation strengthens the prospects of developing a law that is contextually suited to national circumstances, and that takes account of local capacities. Stakeholder participation also facilitates heightened awareness, ownership, and more expansive dissemination and adherence.

7 Recommendations

7.1 Recommendations for the development and adoption of guidelines for harmonized biopesticides regulatory systems in the project countries

1. Work closely with the SAPReF to ensure that the development of harmonized regional guidelines is incorporated into its Strategic Plan.
2. Establish a Technical Working Group comprising SAPReF focal points, legal drafters, and technical government officials from the project countries to undertake the preparation of the draft harmonized regional guidelines on biopesticides, along with timeframes for the domestication of guidelines into national legislation.
3. Prioritize measures to avert duplication of efforts with SADC, which is currently revising the SADC Pesticide Guidelines that make provision for biopesticides.
4. Convene broader consultations in project countries to garner increased political buy-in, ownership, and support for the harmonized regional guidelines.
5. Engage experts to facilitate the provision of technical support for the development of the regional harmonized biopesticides guidelines.
6. Convene consultations to facilitate project countries' agreement on the following: the critical elements and priority areas for a normative biopesticides legal framework, harmonized data protection and sharing procedures, and unified lists of the minimum data required for the registration of different biopesticides categories.
7. Provide financial support to facilitate the convening of planning and implementation meetings within project countries and at the regional level.

7.2 Recommendations about the biopesticides legal framework at the project country level

1. Review existing legislation within the six participating project countries to ensure that it is in line with the regional guidelines, facilitating a harmonized biopesticides registration system.

2. Provide technical assistance in revising existing legislation related to biopesticides.
3. Elaborate, within project countries' legal frameworks, the registration process for biopesticides and conventional pesticides.
4. Facilitate agreement among project countries on a follow-up action plan for integrating or domesticating the regional guidelines, with clearly stipulated timeframes and assignation of lead persons/institutions mandated to implement each task.
5. Take stock of regulatory measures in check to ensure that new guidelines fit well in the overall regulatory framework and are consistent with existing measures.
6. Link new/revised regulatory measures to broader policy initiatives.

7.3 Recommendations to ensure effective harmonization of biopesticides registration in project countries

1. Implement a regional training program to strengthen the capacities and upgrade the skills of staff tasked with performing efficacy evaluations as part of the biopesticides registration process.
2. Support project countries' development of awareness materials and strategies regarding the benefits of integrating biopesticides into GAP.

Author contributions

KM: Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – review & editing, Writing – original draft, Conceptualization. DK: Data curation, Writing – original draft, Writing – review & editing. CM: Methodology, Writing – review & editing, Writing – original draft. SS-W: Writing – original draft, Writing – review & editing. CC: Writing – original draft, Writing – review & editing. OB: Writing – original draft, Writing – review & editing. GK: Writing – original draft, Writing – review & editing. DN: Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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The author(s) declare that no Gen AI was used in the creation of this manuscript.

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Supplementary material

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