Legal review of the biopesticide regulatory frameworks in selected countries in Southern Africa

Produced under the framework of the project: *"Enhancing trade through regulatory harmonisation and biopesticide-based residue mitigation in the SADC Region"* (STDF/PG/694), financed by:

STDF | STANDARDS *and* TRADE DEVELOPMENT FACILITY

May 2022

Prepared by Chifundo Chinyama and Dorothy Kyampaire on behalf of the International Centre for Genetic Engineering and Biotechnology (ICGEB)
Edited by Karen Hope and Dennis Ndolo

Disclaimers

STDF: The findings, interpretations, and conclusions expressed in this document are entirely those of the authors. They do not necessarily represent the view of the Standards and Trade Development Facility (STDF) or any of its partner agencies or donors.

ICGEB: Statements and opinions expressed in this document are those of the authors and do not necessarily correspond to policies or opinions of the International Centre for Genetic Engineering and Biotechnology (ICGEB).

ACRONYMS AND ABBREVIATIONS

AATF	African Agricultural Technology Foundation
AIC	Directorate of Agricultural Inputs Control
CBI	Confidential Business Information
DALRRD	Department of Agriculture, Land Reform and Rural Development
DCA	*Direcção de Ciências Animais* (Department of Animal Science)
DNS	*Direcção Nacional de Saúde* (National Directorate of Health)
DINAB	*Direcção Nacional do Ambiente* (National Environmental Directorate)
EAC	East African Community
EU	European Union
FAO	Food and Agriculture Organisation
GAP	Good Agricultural Practice
GRP	Good Regulatory Practice
ICGEB	International Centre for Genetic Engineering and Biotechnology
IIAM	*Instituto de Investigação Agrária de Moçambique* (National Institute for Agricultural Research)
MADER	*Ministério da Agricultura e Desenvolvimento Rural* (Ministry of Agriculture and Rural Development)
MRL	Maximum Residue Level
NCOP	National Council of Provinces
NPPAC	National Plant Protection Advisory Committee
RIA	Regulatory Impact Assessment
SADC	Southern African Development Community
SAPReF	Southern African Pesticide Regulators Forum
SPS	Sanitary and Phytosanitary Standards
STDF	Standards and Trade Development Facility
TPHPA	Tanzania Plant Health and Pesticides Authority
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

EXECUTIVE SUMMARY

This report provides a legal review of the biopesticides regulatory systems in six Southern African countries,[1] reviews the key factors to consider in the development of harmonised biopesticides guidelines for the participating countries, and identifies the challenges that could hinder the development of a regionally harmonised biopesticides regulatory process. To facilitate a clear understanding of what is required to ensure the integration of harmonised guidelines into national legislation, a detailed assessment of the legal landscape in each of the project countries was also conducted. Ultimately, recommendations are advanced for the regulatory changes and legal steps these project countries need to take to integrate provisions of harmonised regulatory guidelines into national regulatory processes.

When this assessment commenced, the COVID-19 pandemic was still prevalent, as were the travel and convening restrictions associated with it; hence, it was envisaged that consultations, meetings and interviews would be conducted online (using Zoom), via email and telephonically. However, it soon became apparent to the assessors that it was essential to supplement this with in-country site visits and face-to-face engagements, especially with relevant biopesticide regulators and stakeholders. Not only would this avail the most current information on biopesticide regulation, but also provide a realistic impression of the constraints and barriers needing to be addressed to facilitate the implementation of regional guidelines at a national level. A physical meeting was thus convened in Gaborone, Botswana in July 2021. COVID-19 restrictions precluded travel to the other participating countries during the study period. The report is, therefore, informed by desktop reviews of publicly available documents, virtual and in-person consultations and the documents and information derived therefrom.

ACKNOWLEDGEMENTS

The authors wish to acknowledge, among many others, the following participants for the invaluable information and insights they provided towards the survey:

- Botswana:
  Collen Mbereki, Principal Scientific Officer, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Kabelo Moaisi, Weed Scientist, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Kabo Kepaletswe, Agricultural Scientist, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Kuate Sebua, Head of Pest Management, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Mika Makata, Agrochemical Inspector, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Motsweri Mogome, Principal Horticultural Officer, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Joshua J. Molloi, Director of Crop Production, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Loitseng Sebetwane, Registrar of Agrochemicals, Pesticide Management/Crop Production Section, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Thomas Mogome, Chief Agronomist, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Tshepo Mosedame, Chemist, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Rebecca Kethobile, Microbiologist, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Refilwe Nasha, Principal Legislative Drafter, Attorney General's Chambers

  Onkemetse Daniel Pitso, Senior State Counsel, Attorney General's Chambers

  Shilla Lichina, Senior Scientific Officer, Ministry of Agricultural Development and Food Security, Department of Crop Production

  Zibari Phillime, Coordinator of Support Programme, Ministry of Agricultural Development and Food Security, Department of Crop Production

- Mozambique:
  Anastacio Luis, Agrochemicals Registrar, National Directorate of Agriculture Health and Biosafety

- South Africa:
  Maluta Mudzunga, Registrar of Agrochemicals, Department of Agriculture, Land Reform and Rural Development

- Tanzania:
  Ramadhan Kilewa, Research Scientist and Pesticides Regulator, Tanzania Plant Health and Pesticides Authority

- Zambia:
  Christopher Kanema, Principal Inspector and Head of Pesticides and Toxic Substances, Zambia Environmental Management Agency

- Zimbabwe:
  Kenneth Chipere, Principal Research Officer, Department of Research and Specialist Services/ Fertilizers, Farm Feeds and Remedies Institute

TABLE OF CONTENTS

1. BACKGROUND

The International Centre for Genetic Engineering and Biotechnology (ICGEB), in collaboration with other partners, is implementing a regional project (hereinafter 'the project') entitled: *"Enhancing Trade through Regulatory Harmonisation and Biopesticide-based Residue Mitigation in the SADC Region."* This project seeks to address the problem of low export market access by some countries in Southern Africa, owing to the non-compliance with existing maximum residue level (MRL) trade standards. This will be achieved, *inter alia*, by working with select countries to develop common biopesticide regulatory standards to enable reciprocal acceptance of data or registrations originating elsewhere; thereby enhancing biopesticide registration and use, and ultimately reducing reliance on synthetic chemical pesticides.

The Southern African Development Community (SADC) – headquartered in Gaborone, Botswana – is a regional economic community comprising 16 Member States.[1] The SADC Treaty was adopted by Member States in 1992, entering into force in 1993 and amended in 2001, 2007, 2008 and 2009. This Treaty is the Constitution, and thus the most fundamental law, of SADC. It stipulates the founding ideals and principles of SADC, spells out the objectives and obligations of Member States, and establishes the institutions of the Community that implement the ideals, principles, and objectives of the Community. SADC is constituted of a total of eight institutions of the Community, namely: (i) the Summit, (ii) the Organ on Politics, Defence and Security Cooperation, (iii) the Council of Ministers (Council), (iv) the Sectoral and Cluster Ministerial Committees, (v) the Standing Committee of Officials (Standing Committee), (vi) the Secretariat, (vii) the Tribunal, and (viii) the SADC National Committees.

Member States of the SADC cooperate in each area of applicable SADC law through the implementation of Protocols. Protocols to the Treaty are the legislative Acts of SADC whose primary role is to elaborate the objectives, scope and institutional mechanisms facilitating regional integration and cooperation. Protocols are approved by the Summit on the recommendation of the Council. The objectives of the SADC Community are provided under Article 5 of the Treaty. These are pursuant, *inter alia*, to the promotion of sustainable and equitable economic growth and socio-economic development;[2] the achievement of complementarity between national and

[1] Angola, Botswana, Comoros, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe.

[2] Article 5(1)(a), SADC Treaty.

regional strategies and programmes;[3] the promotion and maximisation of productive use of the resources of the region;[4] and the entrenchment of poverty eradication in all SADC activities and programmes.[5]

Article 5(2) makes provision for the actions SADC commits to undertake to achieve the Community's objectives, including, *inter alia*, the harmonisation of political and socio-economic policies and plans of Member States;[6] development of policies aimed at the progressive elimination of obstacles to the free movement of capital and labour, goods and services among Member States;[7] and the promotion of the development, transfer and mastery of technology.[8]

The SADC Protocol on Trade[9] (Article 16(1)) holds that Member States shall base their Sanitary and Phytosanitary (SPS) measures on international standards, guidelines and recommendations so as to harmonise them for agricultural production. This project similarly recognises that regional trade can be bolstered by the development and implementation of harmonised regulatory frameworks consistent with relevant international standards (e.g. Food and Agriculture Organization (FAO)/ World Health Organisation (WHO) Joint Codex Alimentarius Commission guidelines) already ratified, and therefore more likely to be implemented by the project countries.

Use of Good Regulatory Practices (GRPs) can support work at the national and regional level to develop and design biopesticide regulations based on international standards. Good Regulatory Practices are internationally recognised processes, systems, tools, and methods used to improve the quality of regulatory measures and ensure that regulatory outcomes are effective, transparent, inclusive, and sustained. These practices help to improve processes associated with the design, development, and review of SPS measures, with various benefits for governments and the private sector (Figure 1). Benefits include ensuring that the adopted SPS measure achieves the intended policy objective(s) without creating unnecessary barriers to trade. They also generally support better policy making by allowing for various factors to be properly considered when SPS measures are developed and implemented. This includes trade, economic, and health factors, as well as environmental, social, and gender issues. Using GRPs improves alignment with international standards for food safety, and animal and plant health. The Standards and Trade Development Facility (STDF) has developed a GRP guide to address GRPs in the SPS context, targeted primarily at country-level SPS regulators in developing countries.[10] The project will support the use of GRPs as it will develop biopesticide regulatory guidelines in line with international standards and hence strengthen the effectiveness of biopesticide regulation. Additionally, studies will be conducted to promote the use of biopesticides to mitigate pesticide residues and facilitate trade.

[3] Article 5 (1)(e), SADC Treaty.
[4] Article 5 (1)(f), SADC Treaty.
[5] Article 5 (1)(j), SADC Treaty.
[6] Article 5 (2)(a), SADC Treaty.
[7] Article 5 (2)(d), SADC Treaty.
[8] Article 5 (2)(f), SADC Treaty.
[9] Protocol on Trade in the Southern African Development Community (SADC) Region, 1996.
[10] *Good regulatory practices to improve SPS measures: A practical guide*. Standards and Trade Development Facility (STDF), 2021.
https://www.standardsfacility.org/sites/default/files/STDF_GRP_Guide_EN.pdf

Figure 1. How can GRPs help SPS regulators?[11]

Select the *most appropriate* SPS measure	GRPs help SPS regulators assess regulatory options to choose the most appropriate and least-trade restrictive SPS measure.
Understand diverse (intended and unintended) impacts of SPS measures	GRPs help SPS regulators critically assess trade, economic, and health aspects of SPS measures, as well as environmental, social, gender and other aspects, as relevant. For instance, to consider how an SPS measure may influence value-addition, agriculture-based livelihoods, or women's participation in value chains.
Increase efficiency and effectiveness of SPS systems	GRPs help to identify and address overlaps and gaps in SPS regulatory frameworks, which also reduces the administrative burden of SPS systems.
Improve compliance with SPS measures	GRPs provide opportunities for public and private sector stakeholders to comment on SPS requirements, which helps to improve understanding and compliance.
Use international standards and align with international SPS provisions	GRPs foster greater alignment with international standards, reinforce compliance with and benefit from the WTO SPS Agreement (Annex 4) and trade agreements.
Mitigate costs	GRPs help to assess the costs associated with SPS requirements and select the most cost-efficient SPS measure. GRPs also help to assess risks early on and plan contingency strategies. By fostering better compliance with SPS measures, they contribute to reducing enforcement costs.
Encourage inclusive SPS policies and inclusive trade	GRPs allow for the consideration of cross-cutting issues, taking into account the interests of MSMEs, youth, small farmers, women and other groups.
Enhance good governance and inter-agency cooperation	GRPs contribute to data-driven and evidence-based policy making based on the domestic legal tradition and institutional framework. This encourages synergies between SPS measures and broader regulatory systems and initiatives, from a whole-of-government perspective.

[11] Ibid, 16.

2. KEY ELEMENTS OF THE NORMATIVE FRAMEWORK FOR HARMONISED BIOPESTICIDE REGULATORY SYSTEM IN THE SIX PROJECT COUNTRIES

To assess the legal landscape of the biopesticides regulatory systems in the six project countries, a comprehensive analysis was undertaken. This analysis comprised, *inter alia*, a desktop review of the pertinent biopesticide-related legislation, regulations and policies; administration of a survey to a targeted sample of biopesticides regulators and other relevant stakeholders; virtual consultations with a similar target sample from the various project countries; and an in-country site visit to SADC's headquarters in Botswana to conduct in-person engagements with regulators and policymakers predominantly representing the Botswana government.

The biopesticides regulatory frameworks for each project country was reviewed against the normative elements articulated in the *Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa* (2013), developed by the African Agricultural Technology Foundation (AATF). Although this guide is applied primarily to normative assessments of microbial pesticides prior to their registration, there is nothing constraining its use to evaluate biopesticides more broadly. Moreover, this requires very little modification to the existing elements.

Table 1 indicates several key elements or provisions that should underpin a normative biopesticide framework to facilitate the harmonisation of biopesticides regulatory systems across the six project countries.

Table 1: Key elements of a biopesticides regulatory framework.

	Key Element	Significance/Purpose
1	A biopesticide definition, or pesticide definition that encompasses biopesticides.	Clear legal definitions describing biopesticides to enable a determination as to whether/the extent to which biopesticides are covered under the scope of the legislation.
2	Provision for a register of biopesticides.	Such a register is recommended to be shared with regional bodies so as to make it accessible to other countries within the region.
3	Provision for a Registration Committee and secondment of experts to perform specific risk assessments.	This would facilitate the provision of specialist technical advice from experts in respective fields.
4	Provision for multiple registration categories for biopesticides.	This provides regulators and/or registrars with a level of flexibility and responsiveness to identified needs and circumstances.
5	Requiring businesses dealing with pesticides/biopesticides to formally register products, subject to licensing.	The imperative of registration would confer responsibility and product stewardship upon the registrant in whose name the biopesticide is registered.
6	A schedule or annex with detailed data requirements for the registration dossier for biopesticides.	A schedule or annex would enumerate the minimum data requirements for the registration of different categories of biopesticides, establishing common data requirements and equivalent registration systems. This would pave the way for the harmonisation of biopesticide registration, regionally and even continentally.[12]
7	Provisions distinguishing public from confidential data.	Provisions distinguishing public from confidential information would ensure the establishment of protocols to uphold the confidentiality of proprietary information, particularly pertinent to the determination of the extent to which confidential information may be shared with other regulatory bodies.
8	Data requirements, including plans or models for biopesticides labelling and advertisement.	Accurate labelling of pesticides is essential for their safe and efficient use. Therefore, labelling plans submitted with the registration form should be scrutinised by regulators for conformity with prescribed standards.[13]
9	Provisions for the monitoring of post-registration/authorisation controls.	Monitoring controls are imperative to ensure compliance with prescribed standards and reduce risks associated with biopesticide use. Registrants should thus be required to submit plans for post-registration controls, which they

[12] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa* (African Agricultural Technology Foundation, 2013), 13.
[13] Ibid, 38.

		should be obligated to implement subject to sanction and penalty for the failure to do so.
10	Provisions for legally recognised exceptions to the mandatory requirement for registration prior to sanctioned biopesticides usage.	This will allow regulators some discretionary flexibility to recognise exceptional circumstances, preferably tightly circumscribed, under which the use of non-registered biopesticides is legally permitted.
11	Provisions for the parallel or equivalent registrations of biopesticide products in countries with harmonised regulatory systems.	The existence of a harmonised regional approach would optimise the efficiency of application, evaluation and registration processes. This could be achieved through the utilisation of data from equivalent pesticide regimes in other countries within the harmonised system, substantially reducing testing requirements.[14]
12	Schedule of fees.	It is advisable to indicate all fees in secondary legislation since amendments to such legislation (in contrast to primary legislation) are not contingent upon Parliamentary adoption. It is important to ensure effective coordination between the regulatory structures of the respective countries within the harmonised system. This will discourage registrants from engaging in 'forum shopping'; that is, exploiting perceived laxity or cost benefits in specific countries, thereby burdening some registration systems to the detriment of others.[15]

[14] Ibid, 13.
[15] Ibid, 41.

3. REVIEW OF BIOPESTICIDES REGULATORY FRAMEWORKS IN PROJECT COUNTRIES

3.1 Botswana Biopesticides Regulatory Framework

3.1.1 General scope of the pesticides regulatory framework

In Botswana, biopesticides are regulated by the Agrochemicals Act, Cap. 35:09. 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 to provide guidance 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 in accordance with 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 is permitted to manufacture, import, distribute, sell or dispose an agrochemical unless formally licensed to do so.[16] The Act is currently under review: a draft amendment Bill has been submitted to the Attorney General for legal drafting and clearance after undergoing several stakeholder consultations.

3.1.2 Biopesticides registration framework

This legislation provides for the registration of conventional chemicals and does not specifically consider the approval of biopesticides and biological control agents for plant protection. The Act provides a definition of "agrochemicals"[17] which includes the term "live biological material"; however, it is uncertain whether this can be interpreted to include biopesticides.

Persons who wish to use, possess, import, manufacture, advertise, distribute, sell or dispose of any agrochemical in Botswana (Section 10) are required to register with the Registrar. The Registrar is

[16] Summary of the Act available at http://www.fao.org/faolex/results/details/en/c/LEX-FAOC091415

[17] "agrochemical" means: "*any organic, inorganic or live biological material intended or offered for sale for purposes of destruction, control, repulsion, attraction or prevention of any undesirable life forms injurious to plant and animal growth; or promotion or inhibition of plant growth such as fertilisers, growth regulators, hormones, defoliants or legume inoculants*".

mandated to establish and maintain a register with the names of all agrochemicals registered under the Act.

To register an agrochemical, an applicant is expected to not only submit an application, but also two samples of the agrochemical, as well as any advertising material or experimental data in support of the efficacy of the chemical, full toxicological data, methods of analysis, residue and phytotoxicity data of the agrochemical, and an application fee of P500. Where the Registrar is satisfied with the application, applicants are issued a certificate of registration valid for five years. Where the Registrar is not satisfied that application conditions have been fulfilled, an application may be rejected.

In terms of categories for registration, the Regulations provide for full registration, which may be renewed after expiration through re-application to the Registrar. The Regulations also make provision for temporary permits for the purposes of import for research and experimentation.[18]

3.1.3 Parallel registration and registration of equivalent or generic pesticides

Although survey respondents indicated that Botswana permits parallel registration and the registration of equivalents, current Regulations do not make express provision for this. It is important to note, however, 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.

3.1.4 Identity and ownership of biopesticides and information associated with the biopesticide

The Regulations provide a list of documents applicants are to submit to the Registrar.[19] Form 1 of the First Schedule is intended for the full particulars of each applicant as well as comprehensive details of the agrochemical product. In addition to providing their contact and business registration details, applicants are also required to disclose product particulars such as the active ingredient, toxicology and formulation. Both the Act and the Regulations do not 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.

3.1.5 Post-registration controls – Product stewardship

The Regulations provide for post-registration controls and product stewardship by the registrant, which include: detailed requirements for labelling and advertising, conditions for safe- handling,[20] safe-disposal,[21] the licensee's record-keeping[22] and various other duties.

3.1.6 Schedule of fees

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

[18] Regulation 5 of the Agrochemicals Regulations [Chapter 35:09].
[19] Regulation 3 of the Agrochemicals Regulations [Chapter 35:09].
[20] Regulation 11 of the Agrochemicals Regulations [Chapter 35:09].
[21] Regulation 12 of the Agrochemicals Regulations [Chapter 35:09].
[22] Regulation 9 of the Agrochemicals Regulations [Chapter 35:09].

3.1.7 Factors contributing to the integration of harmonised guidelines for biopesticides registration

Survey responses indicate that Botswana is receptive to considering a harmonised biopesticides regulatory framework. Respondents did not identify any challenges relating to biopesticide registration that could potentially adversely impact the integration of harmonised guidelines. A legislative review was advised to isolate the key factors that would facilitate the country's successful integration of harmonised guidelines. It was proposed that harmonised guidelines may best be integrated by the drafting of Regulations under a new law.

3.1.8 Recommendations for the review of regulations to facilitate the integration of harmonised guidelines for biopesticides registration

The following recommendations highlight the revisions to the regulatory framework that are needed to fully integrate harmonised guidelines for biopesticides registration:

a) A clear and concise definition of biopesticides;

b) A chapter devoted specifically to biopesticides;

c) Provision regarding data or information deemed strictly confidential and thus requiring submission of a "disclosure declaration";

d) Stipulation of clear timeframes for administrative decision-making, to enhance efficiency and transparency;

e) Conferral of provisional registrations for biopesticides subject to trial, or for which registrants are required to submit additional data;

f) Provisions within the Regulations or Schedule for parallel or equivalent product registrations.

3.2 Mozambique Biopesticides Regulatory Framework

3.2.1 General scope of the pesticides regulatory framework

According to Diploma No. 153/2002, the Ministry of Agriculture and Rural Development (Ministério da Agricultura e Desenvolvimento Rural - MADER), through its Registration Unit, is the lead agency responsible for the registration and issuing of permits for pesticides; subject to the approval of the National Directorate of Health (Direcção Nacional de Saúde - DNS), the National Directorate of Environment (Direcção Nacional do Ambiente - DINAB) and the National Institute of Agricultural Research's Department of Animal Science (Instituto de Investigação Agraria de Moçambique/ Direcção de Ciências Animais – IIAM/DCA).[23]

In terms of the Regulations' scope relating to biopesticides, the Regulations do provide a definition of pesticides but do not make express provision for biopesticides. In terms of the material recognised for registration, the Regulations make a clear distinction between "active ingredient" and "formulated product", as evidenced by the definitions of "production" and "packaging".[24]

3.2.2 Biopesticides registration framework

The Regulations list registered pesticides, make provision for the office and mandate of the Registrar,[25] and make it possible to establish a technical assessment committee to exercise oversight in matters beyond the technical scope of the Registrar.[26] This institutional framework is pivotal to ensuring transparency in the application, review and recommendation processes.

The Regulations make provision for four categories of registration, namely: permanent, temporary, experimental and emergency use. This confers considerable flexibility to the Registrar, who has the

---

[23] Ministry of Agriculture and Rural Development, *Mozambique Conservation Areas for Biodiversity and Development- Phase II: updated Pest Management Plan 2020,* 6. available at https://www.biofund.org.mz/wp-content/uploads/2018/07/PMP-MozBio-Phase-2.pdf

[24] Definition 43. Production: "*the manufacture of a technical product, active substance, pesticide formulation or reformulation*."
Definition 20. Packaging: "*all containers used for directly packing the active substances, formulated products of pesticides or their by-products, including the external wrapping used to protect the pesticide containers against possible leakages, deformations and other accidents during handling and/or transportation*."

[25] Article 4 of the Decree No. 6/2009 approving the Regulation on Pesticides Management provides for powers of the Registrar.

[26] Article 5 of the Decree No. 6/2009 approving the Regulation on Pesticides Management provides for Technical Assessment Committee for Pesticides Registration.

discretion to register a biopesticide based on the level of completeness of data adduced and a satisfactory risk assessment outcome.[27]

The Regulations also stipulate timeframes for administrative decision-making. For instance, 120 days is envisaged to conclude application submission formalities, after which applicants are to be notified of the reasons for any extensions deemed necessary.[28] Neither the Regulations, nor any annexures thereto, provide detailed elaborations of the data required for registration. This is outlined in a separate guidance document which the regulator provides to the applicant.

3.2.3 Parallel registration and registration of equivalent or generic pesticides

The Regulations do 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 region is thus an important consideration. However, it is currently unclear whether, and/or to what extent, this influences a regulator's decision to award registration.

3.2.4 Identity and ownership of biopesticides and information associated with the biopesticide

The Regulations make provision for businesses importing, distributing, manufacturing, and selling pesticides to apply for their registration, subject to inspection of operations and premises. However, the Regulations do not stipulate whether a disclosure declaration must accompany submission of confidential data. This is an important 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 involved in the evaluation of applicants' data. Survey respondents were of the view that institutions and personnel accessing registration documents are required to uphold the confidentiality thereof. 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.[29]

3.2.5 Post-registration controls – Product stewardship

The Regulations provide for post registration controls and registrants' post product stewardship, which includes compliance with detailed labelling and advertising conditions. These are, however, not exhaustively provided in the annexure to the Regulations, but may be provided by the regulator.[30]

The Regulations empower the National Directorate of Agricultural Services (DNSA) to award registration certificates that are subject to conditions, for example, calling for the submission of quarterly reports to the registrar.[31] The Regulations also authorise inspectors to monitor and enforce

---

[27] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa*, 39.
[28] Article 11(5) of the Decree No. 6/2009 approving the Regulation on Pesticides Management
[29] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa*,17.
[30] Article 12 and Article 43 of the Decree No. 6/2009 approving the Regulation on Pesticides Management deals with labelling and trading of pesticides respectively.
[31] For instance, Article 44(3) of the Decree No. 6/2009 approving 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. It is incumbent on the Registrar to define*

standards relating to pesticide importation, storage, application, production, trading, elimination, handling and quality control.[32] 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.[33] Furthermore, the registrar has the authority to revoke a pesticides registration, and registrants may also voluntarily seek to terminate a valid registration.

3.2.6 Schedule of fees

Fees are indicated in Annexure to the Regulations and may be revised by the Ministers responsible for agriculture and finance. Such an arrangement gives regulators greater flexibility to promptly amend fees, particularly in cases of acute/protracted inflation.

3.2.7 Factors contributing to the integration of harmonised guidelines for biopesticides registration

Survey respondents indicated that Mozambique is receptive to consider a regionally harmonised biopesticides regulatory system. The factors identified as necessary to integrate harmonised guidelines include: undertaking a legislative review; developing technical capacity; generating agricultural sector demand for biopesticides; and, mobilising 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, *inter alia*: a lack of registered biopesticides in the country; paucity 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.

3.2.8 Recommendations for the review of regulations facilitating the integration of harmonised guidelines for biopesticides registration

The following recommendations highlight the revisions to the regulatory framework that are needed to fully integrate harmonised guidelines for biopesticides registration:

a) A clear, concise and stand-alone definition of biopesticides;

b) Provision for parallel registration and the registration of generic pesticides, subject to restrictions; and,

c) Provision within the Regulations of measures safeguarding confidential data.

the months in which this information shall be provided."

[32] Article 56 of the Decree No. 6/2009 approving the Regulation on Pesticides Management provides for Inspection and Control.

[33] Article 16 of the Decree No. 6/2009 approving the Regulation on Pesticides Management provides for cancellation of pesticide registration and the appeal procedure against decisions of key decision makers.

3.3 South Africa Biopesticides Regulatory Framework

3.3.1 General scope of the pesticides regulatory framework

South Africa published its Pesticide Management Policy[34] in December 2010. The Policy is intended to encourage the development and use of alternative pest control products and techniques, so as to reduce over-dependence on chemical plant protection products. 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 the registration of agricultural remedies. South Africa's established biopesticide regulatory system presents an ideal opportunity for it to contribute best practice insights towards a collaborative process of developing harmonised guidelines with other SADC countries.

South Africa's promotion of the use of biopesticides as part of Integrated Pest Management programmes is accomplished through public-private partnerships involving government, the agrochemicals industry, farmers, community-based organisations, non-governmental organisations, consumer groups, and other national stakeholders and international initiatives. Biopesticides in South Africa 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. This Act, which was assented to on 3 June 1947, and commenced on 1 June 1948, has been subject to several amendments.

3.3.2 Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947)

The Act provides for the appointment of a Registrar of Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies, who is responsible for: the registration of fertilisers, farm feeds, agricultural remedies and stock remedies; authorising the acquisition, disposal or use of fertilisers and farm feeds, sterilising plants and pest control operators; regulating or prohibiting the importation, sale, acquisition, disposal or use of fertilisers, farm feeds, agricultural remedies and stock remedies; designating technical advisers and analysts; and providing for any other pertinent matters.[35]

[34] Department of Agriculture, Forestry and Fisheries (DAFF) South Africa Pesticide Management Policy 2010. (Department of Agriculture, Forestry and Fisheries).
[35] Preamble of the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947).

The Act subsumes the definitions for pesticides and biopesticides under the broader term of "agricultural remedy".[36] The Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa (2015)[37] confirms that "biopesticides", "bioproducts" and "biological products" denote "biological remedy"[38], which is contemplated in the broader definitional term of "agricultural remedy".[39]

3.3.3 Biopesticides registration framework

Under the Act, the Minister is empowered to designate an officer as the Registrar of Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies.[40] Applicants wishing to manufacture, import, sell and advertise agricultural remedies in South Africa must submit to the Registrar detailed information and data for evaluation.[41] The Guidelines stipulate the data and documents required to apply for registration of agricultural remedies in South Africa.[42] While the Act does not make provision for the establishment of a formalised 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 fertilisers, farm feeds and agricultural remedies) on an *ad hoc* basis.[43]

With respect to 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.[44] Provisional registrations terminate once a full toxicology risk assessment has been conducted by the Department of Health and the product is recommended for final approval by the Registrar.[45] The Guidelines also provide clarity on the expected timeframes for administrative decision-making. For instance, 14 days are allocated for administrative verification, which entails the screening of applications "after receipt to ensure that non-data elements have been provided".[46]

---

[36] Agricultural remedy means "*means any chemical substance or biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used-(a) for the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any chemical substance, biological remedy or other remedy in so far as it is controlled…*"

[37] Department of Agriculture, Forestry and Fisheries (DAFF) *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa* (Department of Agriculture, Forestry and Fisheries 2015), 2.

[38] Refer to Definitions, *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa.*

[39] Department of Agriculture, Forestry and Fisheries (DAFF) *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa* (Department of Agriculture, Forestry and Fisheries 2015), 2.

[40] Section 2 of the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947).

[41] Section 3(1)(a) of the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947) provides: "*that an application for registration of a fertiliser, farm feed, agricultural remedy, stock remedy, sterilizing plant or pest control operator shall be made to the registrar in the prescribed manner and shall be accompanied by the prescribed application fee*".

[42] Department of Agriculture, Forestry and Fisheries (DAFF) *Guidelines on the Data and Documents Required for Registration of Agricultural Remedies in South Africa* (Department of Agriculture, Forestry and Fisheries 2015).

[43] Section 14 the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947).

[44] Department of Agriculture, Forestry and Fisheries (DAFF) *Guideline on the Data and Documents required for Registration of Agricultural Remedies in South Africa* (Department of Agriculture, Forestry and Fisheries,2015), 3.

[45] Department of Agriculture, Forestry and Fisheries (DAFF) *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa,*5-6.

[46] Department of Agriculture, Forestry and Fisheries (DAFF) *Guideline on the Data and Documents required for Registration of Agricultural Remedies in South Africa,* 8.

3.3.4 Parallel registration and registration of equivalent or generic pesticides

The Act does not expressly provide for parallel or equivalent registrations. The Guidelines recognise the AIC as possessing the mandate to perform a full evaluation, as consideration of whether approval has been conferred by another regulatory authority is not a criterion for registration. It is possible that this only relates to full registration, as survey respondents indicated that both parallel registration and registration of equivalents is 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".[47]

3.3.5 Identity and ownership of biopesticides and information associated with the biopesticide

The Act does not state in detail what information is required on the product for which registration is sought or the identity of the applicant. Guidance on the registration process and a substantive elaboration of the particulars sought pertaining to the applicant and product are provided by both the Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa (2015) and the Guidelines on the Data and Documents Required for Registration of Agricultural Remedies in South Africa (2015).[48]

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.[49] The *Guidelines on the Data and Documents Required for Registration* distinguish the type of information expected to be maintained as confidential. For instance, the Guidelines assert that AIC staff are required to 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 confidential statement on formula, certificate of composition documents, and 5-batch analysis reports; 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 will not prevent the applicant from accessing CBI documents upon request.

3.3.6 Post-registration controls – Product Stewardship

The Act provides various post-registration controls including, but not limited to: ordering the discontinuation of the use of certain equipment by the operator if it is found to be unsuitable for administering an agricultural remedy[50]; powers to enter premises, examine documents, analyse samples and seize an agricultural remedy[51]; and any additional conditions as may be determined by the Registrar.[52]

---

[47] Department of Agriculture, Forestry and Fisheries (DAFF) *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa,* 5.
[48] *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa* (2015) and *Guidelines on the Data and Documents Required for Registration of Agricultural Remedies in South Africa* (2015).
[49] Section 1 of 14 in the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947).
[50] Section 6A of 14 in the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947).
[51] Section 15 of 14 in the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947).
[52] Section 3(3) of 14 in the Fertiliser, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of

3.3.7 Schedule of fees

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.

3.3.8 Factors contributing to the integration of harmonised guidelines for biopesticides registration

Survey responses indicated that South Africa is receptive to considering a harmonised biopesticides regulatory framework. The drafting of Regulations under a novel law was identified by respondents as a step towards realising the integration of harmonised guidelines in South Africa.

The key challenges respondents noted as affecting biopesticides registration (with the potential to negatively impact the integration of harmonised guidelines), was the struggle companies experience in providing scientific data in support of their applications. In terms of the integration of biopesticides into GAP, the greatest constraint identified by respondents was a lack of demand for biopesticides in the agricultural sector.

3.3.9 Recommendations for the review of regulations to facilitate the integration of harmonised guidelines for biopesticides registration

The establishment of clear procedures for parallel registration and the registration of equivalents is the main recommendation for revisions to the existing regulatory framework, in order to fully accommodate harmonised guidelines for biopesticides registration. The Guidelines can provide guidance as to whether regulators will consider data obtained for already registered biopesticides, or containing equivalent active ingredients from generic manufacturers registered in other countries in the region.

1947).

3.4 Tanzania Biopesticides Regulatory Framework

3.4.1 General scope of the pesticides regulatory framework

Tanzania has previously participated in a project initiated by the East African Community (EAC), which developed the *East African Community Harmonised Guidelines for the Registration of Biopesticides and Biocontrol Agents for Plant Protection*. These guidelines were approved by the EAC's 39th Council of Ministers on 28 November 2019. In 2020, Tanzania adopted a Plant Health Act aligned to these guidelines, which makes provision for the regulation of biopesticides.

3.4.2 The Plant Health Act, No. 4 of 2020

Tanzania's legal framework for biopesticides is established primarily by the Plant Health Act, No. 4 of 2020[53] and the Plant Protection Regulations, 1998.[54] The Plant Health Act was assented to by the President on 17 June 2020, repealing the Plant Protection Act, Cap. 133 (No. 13/1997) and the Tropical Pesticides Research Institute Act, Cap. 161 (No. 18/1979).

The main objective of this Act is to make provision for the control of pesticides and biopesticides, establish phytosanitary measures, regulate the importation and use of plants and plant products, prevent the introduction and spread of pests, and establish the Tanzania Plant Health and Pesticides Authority (TPHPA).[55] 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.[56] According to the Plant Health Act, unless stated otherwise, both biopesticides and pesticides are regulated by means of identical procedures.

The Act enumerates its scope of application and provides key definitions, including "pesticides", "biopesticides", "active ingredient" and "formulation", among others.

[53] This Act repealed the Plant Protection Act, Cap. 133 (No. 13/2017) and the Tropical Pesticides Research Institute Act, Cap. 161 (No. 18/1979 in section 65(1) of Plant Health Act.
[54] These Regulations remained in force as per section 31(d) of the Interpretation Act [Cap. 1 R.E. 2019].
[55] Preamble of The Plant Health Act (No. 4 of 2020).
[56] Section 4 of the Plant Health Act (No. 4 of 2020).

3.4.3 Plant Protection Regulations, 1998

Tanzania's Plant Protection Regulations, 1998, which derive from the repealed Plant Protection Act, No. 13 of 1997, repealed the Pesticides Control Regulations, 1984. The Regulations were preserved by the transitional provisions of the Plant Health Act, No. 4 of 2020[57] and are, therefore, still in force and to be read together with the provisions of the Plant Health Act, No. 4 of 2020. While the Plant Regulations define "pesticides", they are silent on "biopesticides". However, it is important to note that all definitions and provisions found in the Regulations are applicable only to the extent to which they are consistent with the Plant Health Act, No. 4 of 2020, whose definitions thus supersede those contained in the Regulations (and which, as noted above, does proffer a definition of biopesticides).

3.4.4 Biopesticides registration framework

The Plant Health Act provides a detailed definition of "pesticides", with paragraph (b) of the definitional paragraph clearly referencing biopesticides.[58] The Act additionally provides stand-alone definitions of "biopesticide" and "biological control agent". The following is the implication of this approach: wherever the Act makes general reference to pesticides, this is to be understood to include biopesticides; and 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 in respect of the Director General and staff of the Authority mandated to operationalise the Act.[59] 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.[60] 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.[61]

In terms of registration, 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 pesticides-related activities. The Registrar may, therefore, initiate a re-evaluation of a registered pesticide if reasonable grounds for such a re-evaluation are identified.[62] 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;[63] and may authorise importation of unregistered pesticides for research or experimental use for a year or an

[57] Section 65(3) of Plant Health Act (No. 20 of 2020) provides that: "*Any subsidiary legislation and all exemptions made or given under the provisions of the repealed Acts, which were in force immediately before the commencement of this Act shall, so far as they are not inconsistent with the provisions of this Act, remain in force as if they were made under this Act*".

[58] Paragraph (b) of the definition of pesticides provides that: "*substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing premature fall of fruit and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport to include bio-pesticides, biocontrol agents, biochemical and gradients.*"

[59] Section 7 of the Plant Health Act (No. 4 of 2020).

[60] Section 13(2)(a)(e) and (3) of the Plant Health Act (No. 4 of 2020).

[61] Section 8(2) and 15(3) of the Plant Health Act (No. 4 of 2020).

[62] Section 17 of the of the Plant Health Act (No. 4 of 2020).

[63] Section 10 of the of the Plant Health Act (No. 4 of 2020).

extended period.[64] The TPHPA may review, modify or revoke a biopesticide import permit;[65] while the Minister may authorise importation and distribution of unregistered pesticides in the event of a phytosanitary emergency.[66] The TPHPA is conferred considerable flexibility to make decisions post-registration once more information pertaining to the pesticide becomes available. The TPHPA is also empowered to authorise the importation of unregistered pesticides for experimental purposes or emergencies, subject to prescribed conditions.

In contrast, the Regulations stipulate clear registration categories, namely: provisional registration, where registration is deferred pending compliance with other requirements;[67] registration for restricted use, for example if the pesticide is highly toxic or subject to Free, Prior and Informed Consent (FPIC);[68] and registration for experimental use.[69] Generally, the Act and Regulations show consistency with recommended normative frameworks that allow regulators a wide ambit of discretion with respect to the registration of pesticides under various circumstances. However, the Act and Regulations are both silent on the timeframes in which such administrative decisions must be made.

With regards to checklists for data and other information dossiers and files to be submitted in support of registration applications, the Act does not specify a Schedule enumerating the requisite documents but points instead to the Regulations, which provide guidance on all registration requirements.[70] Under the Regulations, "every application for pesticide registration, or renewal of registration, shall be made on a form specified in the Third Schedule to the Regulations" and shall be accompanied by several documents including a "dossier containing additional information to determine the suitability of the pesticide".[71]

3.4.5 Parallel registration and registration of equivalent or generic pesticides

Neither the Act nor the Regulations make specific provision for parallel or equivalent pesticides registration. However, the Act permits the TPHPA to use information from a country having a harmonised pesticides regulation framework consistent with that of Tanzania if "the proposed uses of the pesticide are similar" and/or "the pesticide contains one or more active ingredients present in any pesticide that is already registered".[72] Under Form 3 of the Third Schedule, the regulations further require applicants to stipulate the recommended pesticide use proposed by authorised bodies outside Tanzania.

3.4.6 Identity and ownership of biopesticides and information associated with the biopesticide

The Act does not include a Schedule outlining the prescribed pesticides or biopesticides registration application protocols, referring instead to the Regulations' application procedures. Part 3 of the Third Schedule of the Regulations provides the application form for pesticide and biopesticide registration, which requires applicants to provide their personal details and pertinent information about the product they seek to register.[73] The form attests to the confidentiality of the

[64] Section 25(1) of the of the Plant Health Act (No. 4 of 2020).
[65] Section 22(3) of the of the Plant Health Act (No. 4 of 2020).
[66] Section 26 of the Plant Health Act (No. 4 of 2020).
[67] Regulation 26 of the Plant Protection Regulations 1984.
[68] Regulation 27 of the Plant Protection Regulations 1984.
[69] Regulation 28 of the Plant Protection Regulations 1984.
[70] Section 14(2) of the Plant Health Act (No. 4 of 2020) provides "A *person applying for registration of a pesticide shall comply with procedures and requirements prescribed in the regulations*".
[71] Regulation 19 of the Pesticides Control Regulations 1984.
[72] Section 16 of the Plant Health Act (No. 4 of 2020).
[73] Information about the product includes, but is not limited to, the following: details of the product; physical properties and toxicology; safety precautions; analytical methods; and biological data.

information provided, the Regulations further stipulating 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 assent of the Minister. This study flagged this regulatory provision as one which should be considered for revision.

3.4.7 Post-Registration controls – Product Stewardship

The Regulations provide detailed procedures for monitoring registrant's post-registration compliance. Key examples of these controls include: labelling, packaging and advertising; manufacturing safety guidelines and laboratory quality controls;[74] pesticide handlers' clearance and licensing;[75] the maintenance of product records by pesticide manufacturers and importers; [76] the provision by registrants of information concerning the safest, most practical method of disposal of pesticides and empty pesticide packaging;[77] and the duty of biological control agents to ensure the training of pesticide distributors.[78]

3.4.8 Schedule of fees

All fees associated with pesticide and biopesticide applications are fixed by statute in the Regulations' Sixteenth Schedule, where they are reflected in United States Dollars. Survey respondents indicated that these fees can be amended by TPHPA in liaison with the relevant Ministry.

3.4.9 Factors contributing to the integration of harmonised guidelines for biopesticides registration

Survey responses affirmed that Tanzania would be willing to consider a harmonised biopesticides regulatory framework. The factors identified by respondents as crucial for the integration of harmonised guidelines include: increased transparency, especially in relation to the application process, stipulation of data requirements and indication of evaluation procedures; either re-drafting 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 country surveys further revealed, specifically in reference to the integration of biopesticides into GAP, that the most substantial constraint to this is the slow performance of biopesticides in controlling crop pests and diseases.

3.4.10 Recommendations for the review of regulations to facilitate the integration of harmonised guidelines for biopesticides registration

The following recommendations highlight the revisions to the regulatory framework that are needed to fully integrate harmonised guidelines for biopesticides registration:

a) Stipulation of clear timeframes for administrative decision-making relating to registration and licensing, to bolster efficiency and accountability;

b) Provisions for parallel and/or generic product registration, with restrictions;

c) Clearly stipulated criteria to secure provisional licenses. This is important because, although survey respondents confirmed that provisional licensing is recognised, the

[74] Regulation 30 of the of the Plant Protection Regulations 1984.
[75] Regulation 31 of the of the Plant Protection Regulations 1984.
[76] Regulation 32 of the of the Plant Protection Regulations 1984.
[77] Regulation 36 of the of the Plant Protection Regulations 1984.
[78] Regulation 45(a) of the of the Plant Protection Regulations 1984.

Regulations do not currently reflect the conditions that must be met to qualify for a provisional registration; and

d) 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. 133 retain their legal enforceability under the new Act. This is due to Section 65(3)[79] 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 which are inconsistent with the new Act will thus need to be repealed in order to ensure full alignment with the new Act.

[79] Section 65(3) Any subsidiary legislation and all exemptions made or given under the provisions of the repealed Acts, which were in force immediately before the commencement of this Act shall, so far as they are not inconsistent with the provisions of this Act, remain in force as if they were made under this Act.

3.5 Zambia Biopesticides Regulatory Framework

3.5.1 General scope of the pesticides regulatory framework

The principal legislation governing pesticide use in Zambia is the Environmental Management Act No. 12 of 2011, implemented by the Environmental Management (Licensing) Regulations S.I. No. 112 of 2013. The Regulations deal with the licensing of various activities such as air and water pollution, waste management, ozone depleting substances, as well as pesticides and toxic substances.[80]

The Regulations do not have a definition of biopesticides; however, this is understood to fall within the broad definition of pesticides (although it is important to note that biopesticides are not expressly mentioned or adequately described in this overarching definition). With respect to 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 clear on Form VIII, the application form for the registration of pesticides or toxic substances. On the section relating to toxicology, Form VIII separates information to be entered for active agents and formulated products.

3.5.2 Biopesticides registration framework

Part V of the Licensing Regulations deals with the licensing of various activities associated with the use of pesticides, including manufacture, import, export, storage, distribution, blending, processing and re-processing of pesticides and toxic substances. The Regulations do not specify a pesticides register; however, this can be inferred as applicants are required to provide the pesticide product registration number on their application forms.[81]

The Regulations do not designate an office of the Registrar of Pesticides, only stipulating licensing procedures for activities associated with the use of pesticides.[82] The Regulations also do not provide for the establishment of a specialised committee or panel to assess pesticide registration applications. Neither is provision made for the co-opting of experts; however, this can be provided for under the principal Act, which provides for advisory committees to support the board functions

[80] Part V of the Licencing regulations S.I. No. 112 of 2013.
[81] First Schedule, Form VIII of the Licensing Regulations S.I. No. 112 of 2013.
[82] Regulation 31 of the Licencing regulations S.I. No. 112 of 2013.

of the Zambia Environmental Management Agency.[83] Currently there are no advisory committees to assess pesticide registration or licensing applications.

The Regulations further stipulate detailed data requirements for the licensing of activities associated with pesticides usage, which include: submission of a detailed application form; the inspection of the registrant's business premises; provision of a signed confidentiality declaration to safeguard confidential business information; and labelling, 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 licences pending further data, particularly in respect of trial products indicated on Form VIII of the Regulations' First Schedule.[84] 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 modifications to a product's use or composition have been made.[85]

3.5.3 Parallel registration and registration of equivalent or generic pesticides

The 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 deals with the identification of 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 pertaining to prior registration may impact a registrant's prospects of obtaining a pesticide licence or registration. Survey results indicated, however, that parallel registration and the registration of generics is not provided for under the Regulations.

3.5.4 Post-registration controls – Product Stewardship

The Regulations contain general provisions relating to licensing and inspection; however, not all conditions elaborated for each licence are in-depth, and more expansive conditions may be attached to each licence certificate. Specific conditions pertaining to activities (such as the labelling, transportation, storage and disposal of pesticides) feature in Schedules of the Regulations.[86]

3.5.5 Schedule of fees

Fees are fixed by statute, with a Schedule of fees provided in the Regulations indicating the respective costs for the various licenses. Survey respondents were of the opinion that these fees can be amended by the Minister 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 that require a Regulatory Impact Assessment (RIA) be undertaken as part of this review process. Once approved, the RIA report is submitted together with the revised fees Schedule to

---

[83] Section 2 of the Environmental Management Act [No.12 of 2011] allows the Board of the Zambia Environmental Management Agency "*may constitute a committee or delegate to the committee such functions of the Board as it considers necessary…*"

[84] When applying for a pesticide and toxic substances under Form VIII the applicant may indicate on line 2 for product identification whether the product is Trial Product or a Non-Trial product

[85] Form VIII allows the applicant to select from several activities that may be licensed which includes re-formulation, re-processing, re-packaging and changing composition.

[86] Tenth Schedule provides for conditions for transportation of pesticides, Eleventh Schedule provides for conditions for labelling of pesticides, Twelfth Schedule deals with conditions for storage of pesticides and Thirteenth schedule with conditions on disposal of pesticides.

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, particularly during inflation-pressured times. This motivates for consideration of an alternative, more seamlessly coordinated mechanism for the harmonisation of fees between regional regulators, especially to discourage 'forum shopping' by registrants.[87]

3.5.6 Factors contributing to the integration of harmonised guidelines for biopesticides registration

Survey respondents indicated that Zambia is receptive to consider a regionally harmonised regulatory system for biopesticides. The following are factors identified as strengthening the case for adoption of harmonised guidelines for biopesticides 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 major challenges cited by survey respondents as having the potential to constrain biopesticides registration and affect integration of a harmonised regulatory framework include: lack of transparency in the application process; lack of data requirements and evaluations; and uncertainty in the timeframes assigned for decision-making, evaluations and communication of the outcomes thereof to registrants.

The country survey highlighted the absence, or inadequacy, of requirements dealing with registration data and efficacy trials as the most substantial threat to the integration of biopesticides into GAP.

3.5.7 Recommendations for the review of regulations to facilitate the integration of harmonised guidelines for biopesticides registration

The following recommendations highlight the revision to the regulatory framework needed to effectively integrate harmonised guidelines for biopesticides registration:

a) A clear and concise definition of biopesticides;

b) Designation of a technical committee/ panel and registrar, to increase transparency in the review of biopesticide registration applications;

c) Provisions for the co-option of expertise deemed necessary to undertake evaluations into all aspects of product efficacy and adverse effects;

d) A clear elaboration of all components of the pesticide and biopesticide registration procedure, distinguished from pesticide and biopesticide licensing activities;

e) Stipulation of clear timeframes for administrative decision-making relating to registration and licensing;

f) Provisions for parallel and/or generic product registrations, subject to restrictions;

g) Clearly elaborated post-registration controls and registrants' product stewardship, which may include facilitating capacity building for biopesticides distributors, extension workers and users;

h) Provision for the registration of biopesticides in emergency circumstances. Survey respondents indicated that this is permitted; however, the current Regulations do not expressly make provision for it;

i) The development of a code of practice or administrative guide to facilitate technical capacitation.

[87] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa,* 41.

3.6 Zimbabwe Biopesticides Regulatory Framework

3.6.1 General scope of the pesticides regulatory framework

The primary law governing pesticide use in Zimbabwe is the Fertilisers, Farm Feeds and Remedies Act [Chapter 18:12] implemented by the Pesticide Regulations Statutory Instrument (S.I.) 144 of 2012. The Pesticides Regulations were amended in 2012, replacing the previous Pesticides Regulations of 1977.

The Regulations do not have a stand-alone definition of biopesticides; rather, the definition of "pesticides" also covers biopesticides. 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 important as there may be circumstances when it is necessary to register the technical grade material separately, for example, to determine equivalence.[88]

While the principal regulations are the afore-mentioned Fertilisers, Farm Feeds and Remedies Act [Chapter 18:12] and Pesticides Regulations (S.I. 144 of 2012), the National Biotechnology Authority (Agricultural Biotechnology Products) Regulations of 2018 (S.I. 160 of 2018) includes input on biopesticides registration in Zimbabwe.[89] 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 so as to effectively improve biopesticides registration in Zimbabwe.

3.6.2 Biopesticides registration framework

The 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.[90] Furthermore, the Regulations do not provide guidance on 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

[88] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa,*13 and 32.
[89] Agricultural Biotechnology Products Regulations, 2018 (S.I. 160 of 2018).
[90] Regulation 3(1) of the Pesticides Regulations (S.I. 144 of 2012).

make recommendations for registration. The Regulations recognise a registering officer as possessing the official responsibility for decision-making pertaining to the registration of pesticides following the submission of relevant documents.

In terms of registration categories, only full registration is availed under the Regulations. However, survey respondents indicated that 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/or its Schedules, conferring greater flexibility to regulators regarding how to respond to the various needs presented. Thus, in addition to the full registration and renewals currently availed by the Regulations, provision 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 waivers deemed necessary. The provisional registration is useful for pesticides subject to trials, or for which submission of additional data is required. Modifications of existing registration makes it possible for registrants who have identified additional uses, discontinued products, or changed formulations to register such modifications.[91]

3.6.3 Parallel registration and registration of equivalent or generic pesticides

Survey respondents indicated that applications for the registration of parallel and equivalent pesticides are accepted by the registering officer. As the Regulations currently stand, this practice is not clearly reflected, neither are procedures indicated for the application process to be followed by registrants or the assessment undertaken by the registering officer. It is important to formalise this by expressly providing procedural guidance for the registration of generic or patent-expired pesticides, and the identification and registration of identical pesticides already registered in other countries.

3.6.4 Identity and ownership of biopesticides and information associated with the biopesticide

With respect to the ownership of pesticides (including biopesticides), Form P.1 of the First Schedule requires each applicant to provide business contact details as well as information on the product for which registration is sought.[92] The Regulations do not, however, distinguish confidential from public data, although survey respondents were of the view that this may be covered by the Official Secrets Act. Nonetheless, it is important to note that the Official Secrets Act [Chapter 11:09] may not be the most appropriate law to govern the protection of registrants' propriety information or determining 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".[93] Therefore, it is important to ensure that the Regulations make provision for a disclosure declaration indicating with whom (e.g. the public, other regulatory agencies) and to what extent confidential data may be shared.[94]

---

[91] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa*, 18.

[92] Regulation 5 of the Pesticides Regulations (S.I. 144 of 2012).

[93] The Official Secrets Act [Chapter 11:09] preamble provides that the purpose of the Act is "*to prohibit the disclosure for any purpose prejudicial to the safety or interests of Zimbabwe of information which might be useful to an enemy; to make provision for the purpose of preventing persons from obtaining or disclosing official secrets in Zimbabwe; to prevent unauthorised persons from making sketches, plans or models of and to prevent trespass upon defence works, fortifications, military reserves and other prohibited places; and to provide for matters incidental to the foregoing*".

[94] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory*

3.6.5 Post-registration controls – Product Stewardship

The Regulations contain provisions for post-registration controls and registrants' product stewardship, which includes labelling 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.[95] The Regulations do not, however, provide guidance on what the contents of such a quarterly report ought to be. 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 on safe and efficient usage measures.[96]

Moreover, the Regulations do not include a specific provision for the revocation of registration or a registrant's voluntary withdrawal, although survey respondents indicated that the Registering Officer has the authority to withdraw the registration. Reference to the cancellation of registration is mentioned solely in relation to the prescribed validity period of registration[97] and is included as one of the grounds on which registrants may seek leave to appeal a decision of the Registering Officer.[98]

The principal Act provides for the cancellation of registration of fertilisers, remedies, farm feeds or sterilising plants.[99] However, it is unclear whether this includes pesticides under the Regulations.

3.6.6 Schedule of fees

Fees are statutorily fixed in the second Schedule of the 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, who is responsible to refer proposed fee amendments to a parliamentary committee for approval through the appropriate channels. This procedure is less cumbersome than procedures for the enactment of a bill into law.

3.6.7 Factors contributing to the integration of harmonised guidelines for biopesticides registration

Survey respondents indicated that Zimbabwe is receptive to consider harmonised biopesticides regulations. The factors identified as contributing to the integration of harmonised guidelines for a biopesticides regulatory framework were: the need to draft Regulations under another law or establish a 'stand-alone' legal instrument; the imperative to prepare a code of practice or administrative guide; develop technical capacity; leverage political will to spearhead a change in policy direction; and engender demand for the product within the agricultural sector. In terms of integrating biopesticides into GAP, the country survey identified the absence of relevant policy as the most substantial constraint to the attainment of harmonised guidelines for biopesticides registration.

Frameworks for Microbial Biopesticides in Sub-Saharan Africa, 17.
[95] Regulation 6 of the Pesticides Regulations (S.I. 144 of 2012).
[96] African Agricultural Technology Foundation (AATF), *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa*, 42.
[97] Regulation 3(5) Pesticide Regulations (S.I. 144 of 2012).
[98] Regulation 10(a) Pesticides Regulations (S.I. 144 of 2012).
[99] Section 5 of the Fertilisers, Farm Feeds and Remedies [chapter 18:12] relating to Cancellation of Registration.

3.6.8 Recommendations for the review of regulations to facilitate the integration of harmonised guidelines for biopesticides registration

The following recommendations highlight the revisions to the regulatory framework that are needed to effectively integrate harmonised guidelines for biopesticides registration:

a) A clear and concise definition of biopesticides;

b) Designation of an advisory committee for assessing applications for biopesticide registration;

c) A clear distinction, in the definition, between active ingredient and formulated product;

d) Express provision, in the Regulations, for the establishment of a register of biopesticides;

e) Stipulation of clear timeframes for administrative decision-making relating to registration and licensing;

f) Provisions for parallel registration and/or registration of generics, with restrictions;

g) Clearly elaborated post-registration controls and registrant product stewardship, including details on what is substantively required in the registrants' quarterly reports;

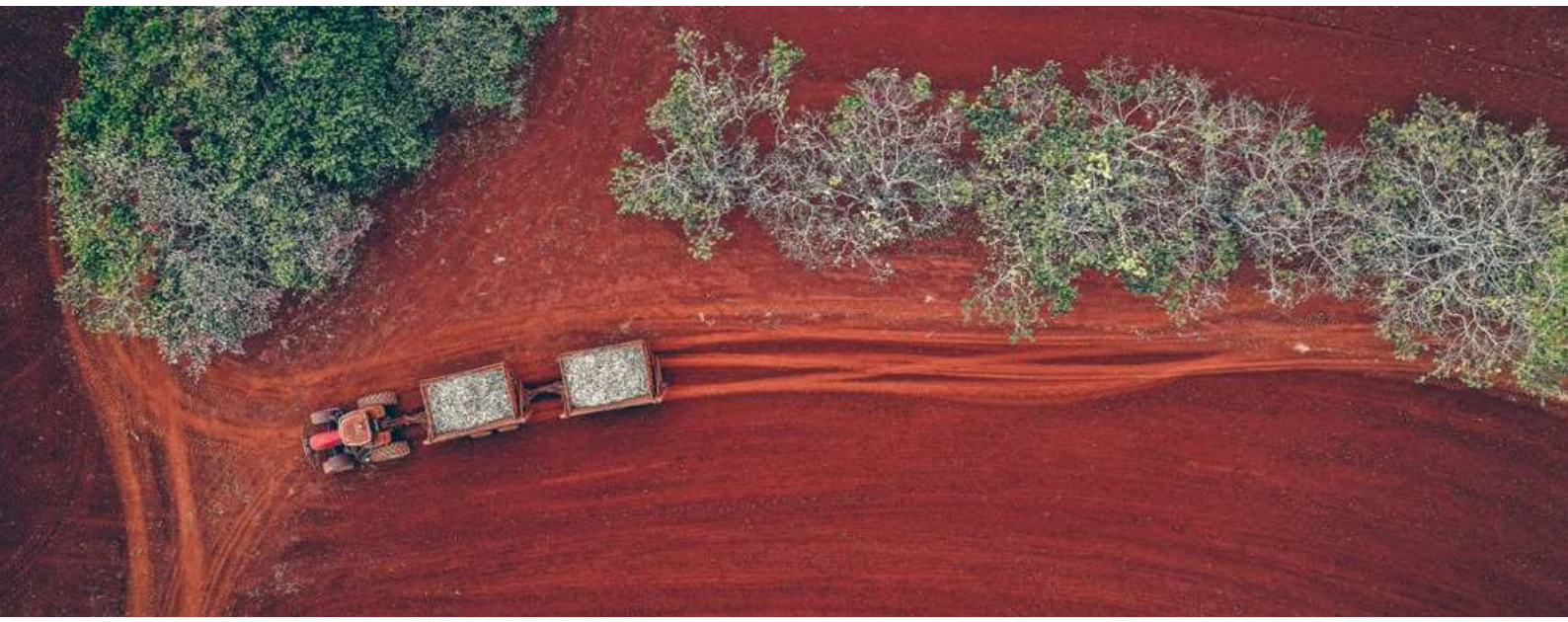
h) Provision for the registration of biopesticides in emergency cases;

i) Provision outlining the procedure for parallel registration and registration of generic biopesticides. (Survey respondents indicated that this is possible, yet the Regulations do not have provisions to facilitate this process);

j) Clearly stipulated criteria within the Regulations for provisional licenses. (Survey respondents indicated that provisional licenses are already conferred, notwithstanding the Regulations' current silence on this);

k) Provision within the Regulations of a "disclosure declaration" to establish what data or information is deemed strictly confidential;

l) Adequate provision within the Regulations for the revocation or voluntary revocation of registration.



4. KEY CONSIDERATIONS TO BE TAKEN INTO ACCOUNT IN THE DEVELOPMENT OF HARMONISED BIOPESTICIDE GUIDELINES FOR PROJECT COUNTRIES

The participating project countries have widely divergent policy positions, with some devoid of any biopesticides policy. This review affirms this to be the case with most of the project countries: they do not possess a well-developed and established biopesticide regulatory framework through which to regulate the registration and application of biopesticides. Therefore, most of the project countries are reliant on processes better suited to conventional pesticides, despite the harmful impacts on human health and the environment due their excessive use.

4.1 Parameters proposed for harmonised biopesticide guidelines

a) Normative legislative framework for biopesticides
b) Minimal registration data requirements
c) Efficacy testing
d) Technical evaluation of registration data
e) Registration and licensing
f) Post-registration monitoring

4.2 Potential constraints to the integration of regional guidelines facilitating a harmonised biopesticides regulatory system

4.2.1 If the priorities of the respective project countries are not intentionally aligned, excessive divergence in levels of commitment may undermine collective efforts to integrate the regional guidelines facilitating a harmonised biopesticide regulatory system.

4.2.2 Harmonisation requires revising existing legislation to bring it in line with regional guidelines. This is likely to be a laborious process – the exact extent depends significantly on the legal system of the country in question. For instance, steps to domesticate the regional guidelines may include such processes as: legal drafting; technical consultation and validation at national and regional levels; approval by relevant policy organs; domestication at the national level. The speed and pace of domestication is contingent on many variables, including human and financial resources, available infrastructure, political will, etc.

4.2.3 Poor biopesticides demand within the agricultural sectors of the project countries may discourage the respective governments from investing in promotional activities to encourage biopesticides use or allocating adequate resources in support of the domestication of regional guidelines.

4.2.4 Divergent levels of technical capacity to evaluate data accompanying biopesticide registration applications has the potential to impede the efficient implementation of a harmonised regulatory system, even once regional guidelines are domesticated.

5. RECOMMENDATIONS

The following recommendations have been made to the project in order to facilitate the development and adoption of the regional guidelines, interventions necessary at country level, and effective harmonisation of biopesticide registration at country level. It is necessary to identify specific opportunities to use the STDF GRP guide[100] to support ongoing and future work on biopesticides regulation. This could include ongoing work to review existing regulations (regulatory stock-taking), engaging relevant private sector stakeholders (consultations), promoting transparency (sharing draft regulations, enabling feedback from all relevant stakeholders, etc.), and encouraging a coordinated approach across diverse agencies with an interest in biopesticides at the national/ regional level. As the recommendations provided in this section are related to the GRPs as outlined in the STDF GRP guide, footnotes are provided to indicate the specific GRPs that are related to each recommendation.

5.1 Recommendations for the development and adoption of regional guidelines for harmonised biopesticides regulatory systems in the project countries

5.1.1 Work closely with the Southern African Pesticide Regulators Forum (SAPReF) to ensure incorporation of the development of harmonised regional guidelines into its Strategic Plan.[101]

5.1.2 Establish a Technical Working Group comprising SAPReF focal points, legal drafters and technical government officials from the project countries to undertake preparation of the draft harmonised regional guidelines on biopesticides, along with timeframes for the domestication of guidelines into national legislation.[102]

[100] *Good regulatory practices to improve SPS measures: A practical guide*. Standards and Trade Development Facility (STDF), 2021. Available at https://www.standardsfacility.org/sites/default/files/STDF_GRP_Guide_EN.pdf

[101] Transparency; Stakeholder engagement; Coordination and cooperation mechanisms; Inter-agency cooperation.

[102] Transparency; Stakeholder engagement; Regulatory impact assessment.

5.1.3 Prioritise measures to avert duplication of efforts with SADC, which is currently revising the SADC Pesticide Guidelines that make provision for biopesticides.[103]

5.1.4 Convene broader consultations in project countries to garner increased political buy-in, ownership and support for the harmonised regional guidelines.[104]

5.1.5 Engage experts to facilitate the provision of technical support for the development of the regional harmonised biopesticides guidelines.[105]

5.1.6 Convene consultations to facilitate project countries' agreement on the following: the critical elements and priority areas for a normative biopesticides legal framework; harmonised data protection and sharing procedures; and unified lists of the minimum data required for the registration of different biopesticides categories.[106]

5.1.7 Provide financial support to facilitate the convening of planning and implementation meetings within project countries and at the regional level.[107]

5.2 Recommendations pertaining to the biopesticides legal framework at project country level

5.2.1 Undertake a review of existing legislation within the six participating project countries to ensure that it is in line with the regional guidelines, facilitating a harmonised biopesticides registration system.[108]

5.2.2 Provide technical assistance to the revision of existing legislation related to biopesticides.[109]

5.2.3 Clearly elaborate, within project countries' legal frameworks, of the registration process for biopesticides and conventional pesticides.[110]

5.2.4 Facilitate agreement among project countries on a follow-up action plan for the integration or domestication of the regional guidelines; with clearly stipulated timeframes, and assignation of lead persons/institutions mandated to implement each task. [111]

5.2.5 Take stock of regulatory measures to check to ensure that any new guidelines fit well in the overall regulatory framework, are not duplicative or contradict existing measures.[112]

5.2.6 Link new/revised regulatory measures to broader policy initiatives.[113]

---

[103] Ibid.
[104] Transparency; Stakeholder engagement; Coordination and cooperation mechanisms.
[105] Ibid.
[106] Taking stock of existing SPS measures based on international standards; Transparency; Stakeholder engagement; Coordination and cooperation mechanisms.
[107] Forward looking regulatory agendas.
[108] Taking stock of existing SPS measures based on international standards.
[109] Transparency and stakeholder engagement.
[110] Forward looking regulatory agendas.
[111] Inter-agency and international regulatory cooperation.
[112] Taking stock of existing SPS measures based on international standards.
[113] Forward-looking regulatory agendas.

5.3 Recommendations to ensure effective harmonisation of biopesticides registration in project countries

5.3.1 Implement a regional training programme to strengthen the capacities and upgrade the skills of staff tasked with performing efficacy evaluations as part of the biopesticides registration process.[114]

5.3.2 Provide support to project countries' development of awareness materials and strategies regarding the benefits of integrating biopesticides into GAP.[115]

[114] Transparency; Stakeholder engagement.
[115] Inter-agency and international cooperation.

6. REQUIREMENTS TO ENSURE THE ULTIMATE INTEGRATION OF HARMONISED GUIDELINES INTO NATIONAL REGULATORY PROCESSES

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

The following considerations should be made to ensure the integration of the harmonised regional guidelines into national regulatory processes:

6.1 Establishment of a regional-level Technical Working Group comprising at least three experts from the respective project countries, to support the formulation of harmonised guidelines and ensure ownership of the process. These credible experts would be expected to be consistent in attending and making substantive inputs to all the meetings and ensuring sound follow-up and implementation of actions emanating therefrom.

6.2 Consultative drafting of the harmonised regional guidelines by nominated experts from each project country.

6.3 Establishment of a National Review Team to oversee the domestication of regional harmonised regulations for the manufacture, use and trade of biopesticides in the project countries. This National Review Team would, during the implementation of the harmonised biopesticide regulations, strengthen the institutional, human and biopesticides infrastructure capacities and raise stakeholder awareness of the regulations in the respective project countries. The team could comprise expert consultants with the requisite biopesticides qualifications/skills and legal drafters of the respective project countries, to facilitate and expedite the legislative incorporation processes. Terms of reference for such a National Review Team may include, *inter alia*:

a) Identification of gaps and proposal of amendments to respective national legal instruments to ensure their alignment with the regional harmonised biopesticides regulations. Legal instruments may be constituted of principal and subsidiary legislation.

b) Submission of the final draft of regional harmonised biopesticides regulations to the ministry responsible for agriculture for onward transmission to the Attorney General's chambers/ Ministry of Justice for final approval.

6.4 Provision of support by the SAPReF focal point to the coordination of activities of the National Review Team.

6.5 The focal point persons would be responsible for:

a) Establishing, in liaison with relevant national authorities, a follow-up action plan for the integration or domestication of the regional guidelines, with timeframes specified and designation of persons or institutions to lead each tasks' implementation.

b) Ensuring translation of the regional harmonised guidelines into local languages for distribution to traders, to optimise their commercial ventures within the region.

c) Development of documents providing simplified, lay-accessible articulations of the regional harmonised biopesticide guidelines - to be produced, published and disseminated to traders in the region to optimise their commercial biopesticides ventures.

6.6 Convening of national and regional validation meetings/workshops during the development of the regional harmonised guidelines, to ensure wider stakeholder buy-in and ownership. Since the project states are at different stages of development, these validation meetings/workshops would also assist project countries to benchmark their respective efforts.

7. THE REGULATORY CHANGES AND LEGAL STEPS PROJECT COUNTRIES WILL NEED TO TAKE TO INTEGRATE PROVISIONS OF THE HARMONISED REGULATORY GUIDELINES INTO RELEVANT NATIONAL LEGISLATION

7.1 Regulatory changes in the project countries

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

Domestication is the process whereby States incorporate – into domestic/national laws – provisions of regional 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 becomes legally applicable and enforceable within their State territory.

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 and relevant policies, as well as government priorities and resources. It is also important for the legislation to consider the economic and social situation and any relevant contextual circumstances of the country, such as for example, 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-up and considering these factors should help drafters to ensure a well-designed legal framework for the control of biopesticides that is tailored for, 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.

7.2 Factors to be considered prior to the revision or drafting of national biopesticide legislation

7.2.1 Analysis of the national legal and institutional frameworks relevant for biopesticide management

Analysis of national legislation should consider the national legal system and review all national legislation directly or indirectly affecting biopesticides management in all areas of the biopesticide lifecycle. As part of this analysis, it is important 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 legislation 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.

7.2.2 Identification of technical needs and regulatory failures through reference to:

a) field realities and experiences;
b) new biopesticide policy objectives;
c) existing legislation; and
d) international recommendations.

7.2.3 Drafting: Constituting a national team of legal drafters and technical experts

Drafters should identify the regulatory failures of existing legislation, 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 will have to decide whether to amend or repeal and replace existing legislation, or incorporate regional harmonised guidelines into their subsidiary legislation.

7.2.4 Key stakeholder review of drafts

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 the national circumstances and that takes account of local capacities. Stakeholder participation also facilitates heightened awareness and ownership, and more expansive dissemination and adherence.

7.3 The legislative process in Botswana

7.3.1 Introduction

Botswana is recognised as one of Africa's best examples of a vibrant Parliamentary democracy. The country's legislative process is modelled on the British Westminster system; however, it is also shaped and influenced by local realities, including, for example, the existence of *Ntlo ya Dikgosi* (House of Chiefs). While the *Ntlo ya Dikgosi* does not possess legislative powers, it is empowered by section 88(2) of the Constitution[116] to consider Bills referred to it. The *Ntlo ya Dikgosi* is permitted to submit any resolutions on said Bills to the National Assembly – its function is, therefore, exclusively advisory.

Consistent with most commonwealth countries, Botswana's legislative process is complex and comprises multiple sequential stages characterised by diverse considerations and constraints at different levels of government. Section 57 of the Constitution establishes that Parliament consists of the President and the National Assembly. The power to make laws[117], which is imbued in the National Assembly, is conferred by Section 86 of the Constitution. Section 87 provides that, subject to the provisions of Section 89(4) of the Constitution, the power of Parliament to make laws is exercised in respect of Bills passed by the National Assembly and assented to by the President. A Bill is a proposed law that acquires force of law after it is duly[118] passed by Parliament and assented to by the President who causes it to be published in the Gazette as law,[119] after which it becomes an Act of Parliament.[120] Legislative procedures are undertaken in accordance with the 2011 Standing Orders of the National Assembly of Botswana. Therefore, whereas the National Assembly passes laws in Botswana, the Government initiates new legislation in the form of Government Bills.

7.3.2 Types of bills

a) Government Bills: are brought to the National Assembly by Ministers.

b) Private Member's Bills: are brought to the National Assembly by Private Members (Members of Parliament without a Ministerial Portfolio).

A Bill can:

(i) propose a new law;
(ii) amend an existing law; or
(iii) repeal a law.

7.3.3 Pre-drafting stage

Botswana's legislative process is initiated by the Minister responsible for a specific legislative project, who tables a proposal for Cabinet's approval; which, if it succeeds, is forwarded to the Attorney General, who serves as Government's Principal Legal Advisor. The Attorney General, who is head of the Attorney General's Chambers, bears the responsibility to draft all Government legislation through the legislative drafting Division. The Attorney General's Chambers fall under the Ministry of Defence, Justice and Security, and comprises four main Divisions, namely: (i) Legislative

[116] Constitution of Botswana, 30 September 1966.
[117] Section 86 states that "*Parliament shall have power to make laws for the peace, order and good governance of Botswana*".
[118] For a Bill to be passed by Parliament, it must be agreed upon by a majority votes in the National Assembly.
[119] section 87(5) of the Constitution.
[120] section 87(7) of the Constitution requires "all laws made by Parliament to be styled "Acts."

Drafting Division, (ii) Civil Litigation Division, (iii) International and Commercial Division, (iv) and the Directorate Public Prosecutions.[121]

7.3.4 Drafting stage

The Drafting process commences when the Attorney General receives legislative proposals containing drafting instructions as well as a background to the proposal. The highly technical nature of legislative drafting can make it a time-intensive and laborious endeavour, depending on the focus of the Bill and expertise required to compile it. Once the Legislative Drafting Division has formulated a Bill, it is submitted for the approval of Cabinet, and thereafter tabled before Parliament by the responsible Minister. The Bill then undergoes various stages of Parliamentary enactment.

7.3.5 Stages of a bill

7.3.5.1 First Reading

The First Reading refers to a Minister's presentation of a Bill subsequent to its publication, for thirty days, in the Government Gazette. A certificate of urgency is used to expedite the introduction of Bills that have not exhausted the 30-day Gazette notice period. Urgent motion Bills are voted on immediately after they are tabled; and, if passed, are put on the Order Paper for the Second Reading.

7.3.5.2 Second Reading

The Second Reading of a Bill is characterised by a debate on the merits and any shortfalls or limitations of the Bill under discussion.

7.3.5.3 Committee Stage

During this stage, the Whole House is regarded as a Committee and tasked with evaluating the Bill in detail, clause by clause. Members can propose amendments to provisions of the Bill, after which each clause and amendment is voted on by members.

7.3.5.4 Third Reading

It is during the Third Reading that a Bill is either passed or rejected. If members vote in the affirmative, the Clerk will then read out the long and short titles of the Bill. During this stage it is permissible for members to debate the various provisions of the Bill; however, no amendments can be moved.

For a Bill to be passed by Parliament, it must be agreed upon by a majority vote in the House. A Bill may also be sent to a Parliamentary Committee for further investigation prior to being voted on by Parliament. If Members of Parliament agree on a Bill, it may pass through Parliament in a matter of days. However, the process more typically takes several weeks or even months if it is animated by a great deal of debate and/or disagreement, in which case the Bill may be deferred for further consultation.

7.3.5.5 Presidential Authentication and Assent

Once a Bill is passed by Parliament, it is authenticated by the Clerk before being sent to the President for consideration. The President may assent to the Bill or withhold assent. Once

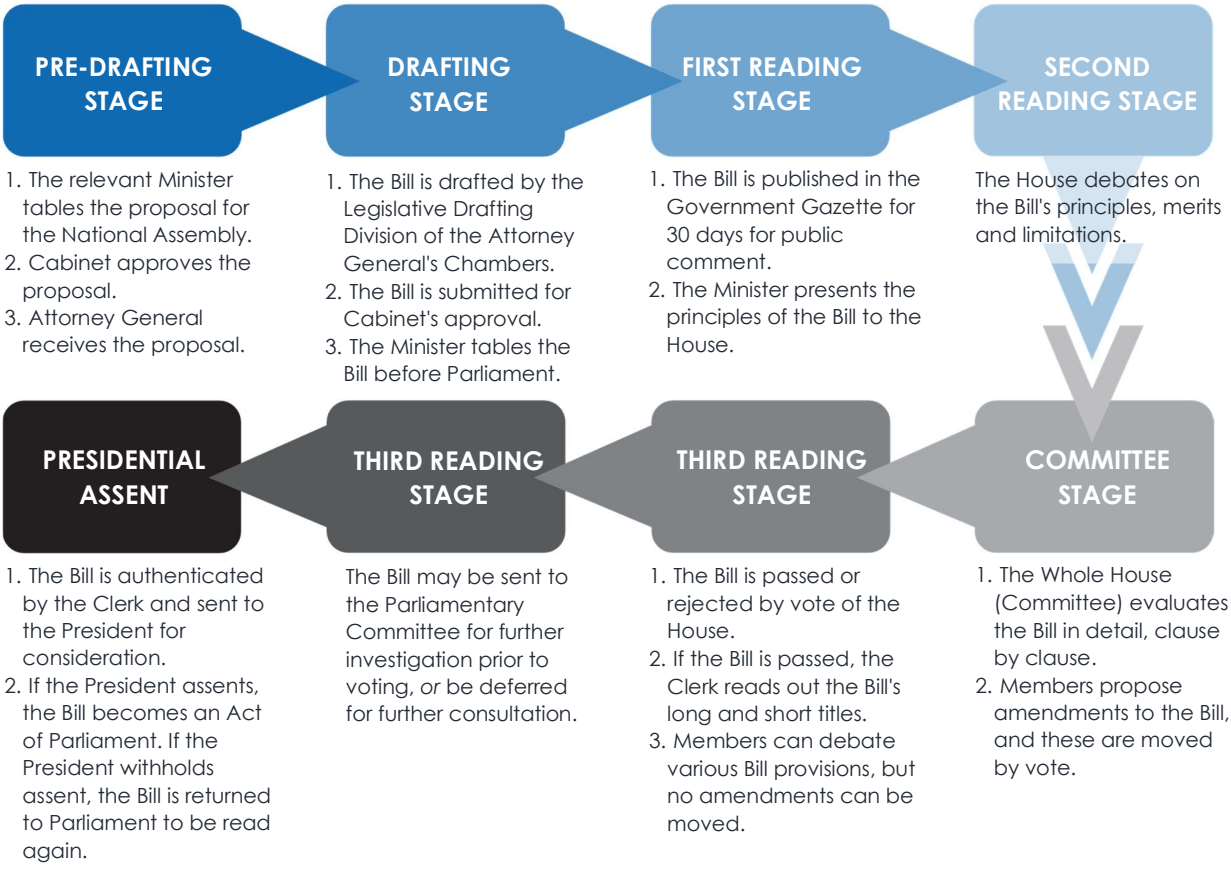
[121] It should be noted that the Directorate of Public Prosecutions is only subject to the administrative supervision of the Attorney General; however it is regarded as functionally independent, as provided by section 51A of the Constitution.

the President's assent is conferred, the Bill becomes an Act of Parliament; whereas if the President does not assent, the Bill is returned to Parliament to be read again.

7.3.6 Subsidiary legislation

Subsidiary legislation, which is intended to supplement an Act of Parliament, is subordinate as its legislative status is inferior to that of an Act of Parliament. Subsidiary legislation is also referred to as 'delegated legislation' because the enabling power it confers is delegated by Parliament to a person, institutional body or Authority. Subsidiary legislation includes, *inter alia*, Regulations, Rules, By-laws, Orders and Notices. Proposals to amend subsidiary legislation are submitted to the office of the Attorney General for legal drafting. The final copy is forwarded to the responsible Minister for signature before being sent for publication in the Gazette. The Regulations come into force on the day they appear in the Gazette.

Schematic to illustrate the legislative process in Botswana



7.4 The legislative process in Mozambique

7.4.1 Introduction

The Constitution is Mozambique's apex law, with the hierarchy of laws structured as follows: "the highest prevailing diploma is the Constitution, followed by the Laws produced by the Parliament, then the Decree-Laws issued by the Government, the Decrees of the Council of Ministers,[122] the Presidential Decrees, the Ministerial Diplomas, and the Ministerial Orders, all in this respective order".[123]

Parliament is Mozambique's legislative body, which has the power to approve all matters by a simple majority unless otherwise stipulated in the Constitution. The Executive proposes most of the legislation, although Members of Parliament, Parliamentary Groups, Parliament Committees, the President and Government Members may also propose legislation.

Article 179(2) of the Constitution specifies the matters in respect of which legislation Parliament may exclusively pass and the scope of issues in respect of how Parliament may delegate its legislative powers to the Government.[124] Legislative Acts of the Assembly of the Republic of Mozambique assume the form of laws; its other decisions shall take the form of resolutions to be published in the *Boletim da República*.

Legislation is initiated by the deputies, parliamentary benches and commissions of the Assembly of the Republic, the President and the Government. However, deputies and parliamentary benches may not propose Bills which directly or indirectly increase State expenditure.

7.4.2 Rules of debate and voting

Provision is made for debate on the text of legislative proposals and Bills, which consists of a general First Reading and a Second Reading. Three voting stages are envisaged, occurring on the First Reading, the Second Reading and an overall vote. Where the Assembly resolves, texts approved at the First Reading shall be put to the commissions for a vote on the Second Reading, without prejudice to the power of the Assembly to recall and put them to a final plenary vote for overall approval.

Bills passed by Parliament are forwarded to the President for assent. The President has the discretion, however, to veto a Bill by order with reasons adduced, which causes the Bill to be returned to the Assembly for re-examination. Bills are enacted into law within thirty days of receipt or after formal notification of the Constitutional Council's decision that none of the Bill's provisions are unconstitutional. Once the Bill fulfils all stipulated legal criteria, it is published in the *Boletim da República* on the order of the President, and becomes an Act of Parliament.

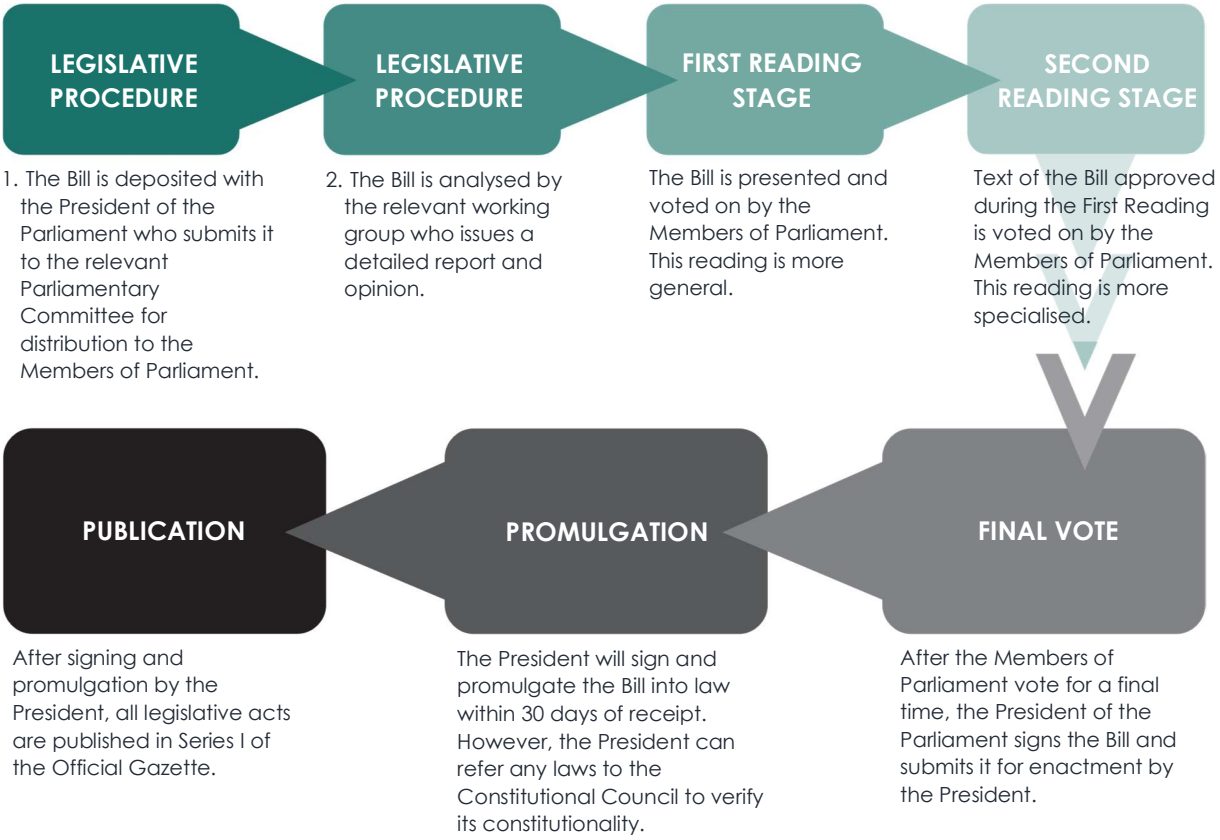
7.4.3 Delegated legislative authority

The Council of Ministers may pass decree-law under the authorisation of a specific piece of legislation. Such decree-laws are signed by the President who then orders their publication in the Official Gazette.[125] A decree-law passed by the Council of Ministers must be ratified by a minimum

[122] For example, Mozambique's Pesticide Management Regulation is a decree passed by the Council of Ministers.
[123] Investment and Exports Promotion Agency (APIEX), *Laws and Regulations Related to Foreign Direct Investment in Mozambique August,* 2017, 8. Available at https://www.jica.go.jp/project/english/mozambique/010/materials/c8h0vm0000e4zyeu-att/materials_03.pdf
[124] Articles 179, No. 3, 180, 181 and 204 No. 1 [d] of the Constitution.
[125] Article 144 of the Constitution of the Republic of Mozambique.

of fifteen deputies during the session of the Assembly held immediately following its publication. The Assembly may wholly or partially suspend the legal force of a decree-law subject to conclusion of its evaluation. The suspension expires if no pronouncement is made on the matter by the end of the Assembly session. Refusal to ratify results in revocation of the decree-law.[126]

Schematic to illustrate the legislative process in Mozambique



[126] Article 181 of the Constitution of the Republic of Mozambique.

7.5 The legislative process in South Africa

7.5.1 Introduction

The Constitution of the Republic of South Africa[127] is the supreme law of the country. Chapter 4 of the Constitution sets out the national legislative process and provides that Parliament is the national legislature. Parliament, as the law-making body of the country, comprises two Houses: the National Assembly and the National Council of Provinces (NCOP).

South Africa's Parliament has the power to pass new-, amend existing-, and repeal old laws. Schedules 4 and 5 of the Constitution provide a list of functional areas in which Parliament and the provincial legislatures are competent to make laws. Parliament has legislative authority (the right to make laws) in the national sphere of government, provincial legislatures in the provincial sphere of government, and municipal councils in the local sphere of government. Schedule 4 provides the functional areas in which Parliament and the provincial legislatures jointly have the right to make laws; this includes matters such as agriculture, health, housing, the environment and education (with the exception of tertiary education).

7.5.2 Law-making process: Principal legislation

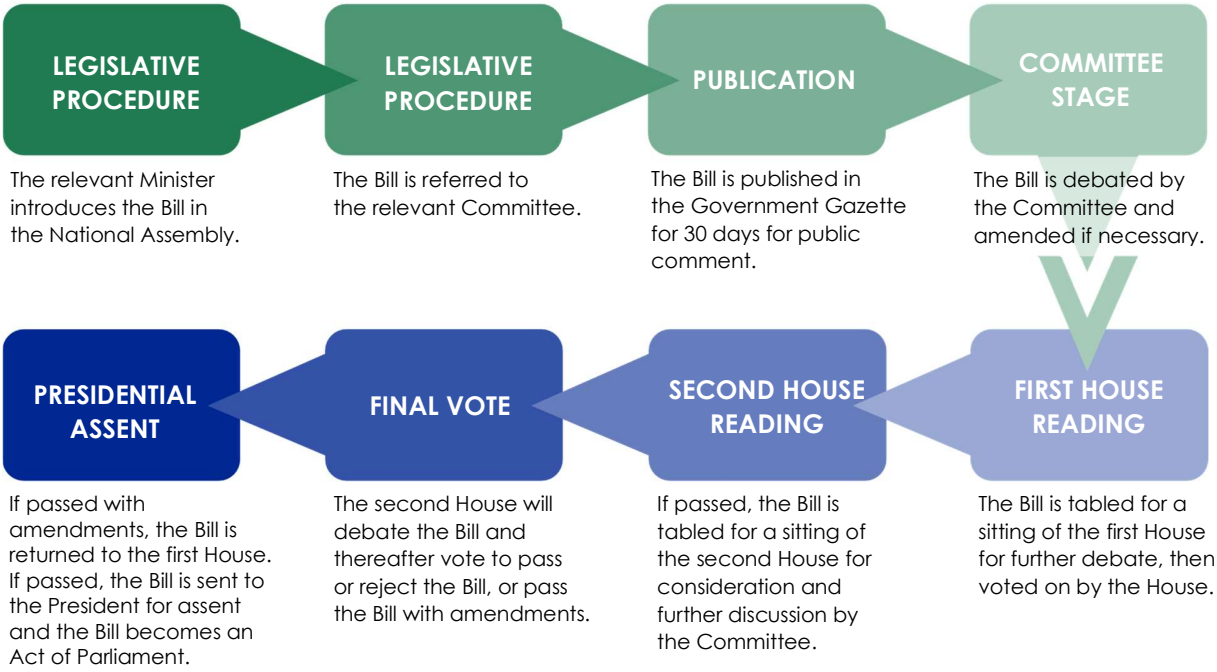
As the legislative body of government, Parliament considers draft legislation in the course of exercising its power to make laws. The draft legislation, or Bill, is formally submitted to Parliament for consideration prior to its transformation into law. Only a Minister, Deputy Minister, Parliamentary Committee or an individual Member of Parliament is empowered to introduce a Bill in Parliament.

Most Bills are prepared by Government departments, under the direction of their respective Minister or Deputy Minister; this generally follows widespread consultation of the proposals contained in the Bill to obtain input and comments from stakeholders. Bills of this nature must be approved by Cabinet before being submitted to Parliament.

A Bill must be considered by the Houses of Parliament before it can become a law. When it is introduced in Parliament, it is referred to the relevant Committee for scrutiny. The Bill is published in the Government Gazette to allow for public comment unless it is very urgent. It is then debated in the Committee and amended as deemed necessary. If there is great public interest in the Bill, the Committee may organise public hearing. Once there is support for the substance of a Bill, the Committee submits it to a sitting of the House for further debate and a vote. A Bill is then referred to the other House for its consideration. A Bill passed through the National Assembly and the NCOP is then submitted to the President for assent. Once signed by the President, the Bill becomes an Act of Parliament.

[127] Act 108 of 1996.

Schematic to illustrate the legislative process in South Africa



7.6 The legislative process in Tanzania

7.6.1 Introduction

Article 64(1) of the Constitution of the Republic of Tanzania vests legislative powers in all matters concerning mainland Tanzania in Parliament. Article 64(2) vests all legislative powers relating to all matters concerning the island of Zanzibar in the House of Representatives.

A draft of a proposed Act of Parliament, or Bill, may be introduced in the House by a Government Minister or a Private Member. Once passed by the National Assembly and assented to by the President, the Bill becomes an Act of Parliament.

Tanzania recognises two types of Bills, namely:

(i) Government Bills, which are introduced in the Assembly by a Minister or Attorney-General; and

(ii) Private Member's Bills, which are introduced in the Assembly by a Member of Parliament who is not a Minister or the Attorney-General.

7.6.2 Government bill

Before a Government Bill is introduced in the Assembly, it goes through a lengthy process of consultation and decision-making at Ministerial level, Permanent Secretaries level and finally the Cabinet.

After the Bill has been approved by the Cabinet, it is signed by the Minister responsible for introducing it in the National Assembly and published in the official Gazette together with a statement of its objects and reasons. It must be published in at least two issues of the Gazette at intervals of no less than seven days. The first publication must contain the Bill's full text and be published at least twenty-one days prior to its introduced in the National Assembly for first reading. The second publication of the Bill is by the insertion of a notice in the Gazette naming the title of the Bill, with the number and date of the Gazette in which it was first published.

7.6.3 Bill under certificate of urgency

The above-mentioned procedure for publication may be dispensed with if a certificate under the hand of the President is laid on the table of the Assembly by a Minister or Attorney-General, stating that the relevant Bill is of such an unusually urgent nature that time does not permit compliance with the prescribed procedure.

7.6.4 Private member's bill

As already mentioned, any Member of Parliament who is not a Minister may introduce a Bill in the Assembly. Such a Bill is known as a Private Member's Bill. A member who desires to do so will notify the Clerk of the National Assembly of his intention by submitting the name of his Bill and fully describing the objects and reasons of the Bill. As far as printing and publication is concerned, the procedure is the same as for Government Bills.

7.6.5 Stages of a bill

7.6.5.1 First Reading

The First Reading of a Bill is performed by the Clerk who reads only the Bill's long title to the Assembly (no substantive discussion is permitted during this stage) before referring the Bill to the appropriate Standing Committee for consideration. The appropriate Standing

Committee has no power to amend a Bill referred to it, but may request the Minister responsible for the Bill to introduce amendments in the Assembly.

7.6.5.2 Second Reading

After the Chairman of the appropriate Standing Committee has reported to the Speaker that the Committee has concluded its consideration of the Bill, the Speaker orders the Bill to be entered on the Order Paper for the Second Reading. At this stage, the responsible Minister proposes a motion for the Bill to be read for a second time, providing detailed explanations to the Assembly. The Minister's speech is followed by a statement from the Chairman of the Standing Committee that considered the Bill, who outlines the views of the Committee regarding the Bill. The spokesman for the opposition then delivers the official Opposition's views regarding the Bill. This is followed by a general debate among Members on the merits or otherwise of the Bill.

7.6.5.3 Committee of the Whole House

Following the debate, the Assembly immediately resolves itself into a Committee of the whole House. The Clerk calls the number of each clause in succession together with any amendments made by the Minister in charge of the Bill.

7.6.5.4 Third Reading and Passing of the Bill

Once the clauses of the Bill have been dealt with, the Assembly resumes. The Minister in charge of the Bill then reports to the Assembly that the Committee has considered the Bill, clause by clause, and approved the same. Thereafter, the Minister requests the Assembly to concur with the findings of the Committee, which sets in motion the Assembly vote: if the majority of the Members of Parliament endorse the Bill, it is passed by the House; conversely, if the majority oppose the Bill then it is deemed to be rejected by the Assembly.

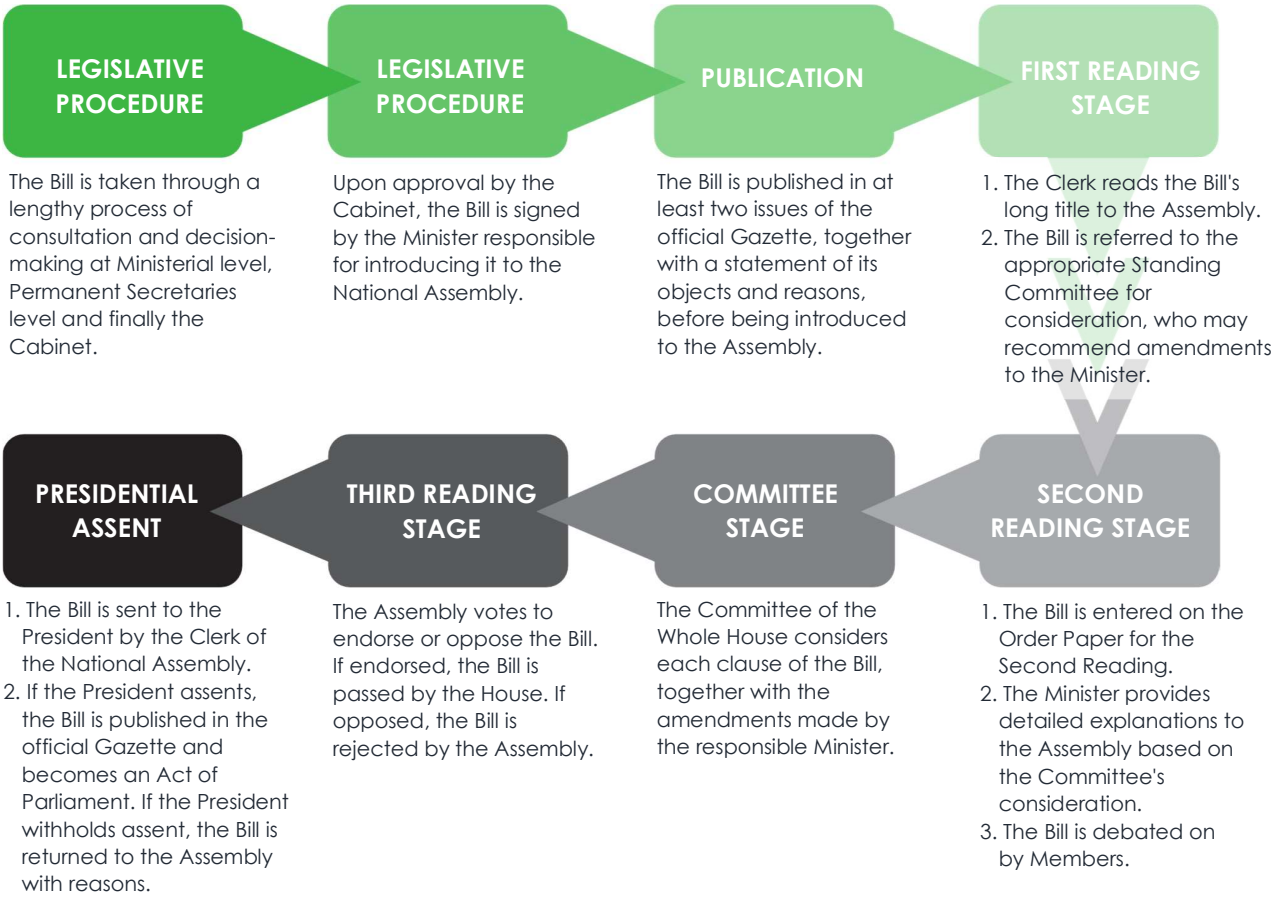
7.6.5.5 Presidential Assent

When a Bill has been passed by the Assembly, a printed copy of the Bill is submitted by the Clerk of the National Assembly to the President for assent. If the Bill is assented to, it becomes an Act of Parliament. Where the President withholds assent, the Bill is returned to the Assembly, together with a statement of reasons for the withholding of assent. After the Bill is returned to the Assembly, it shall not be presented again to the President for assent before the expiration of six months. For the Bill to be presented again to the President, it must be supported by the votes of not less than two-thirds of the Assembly. Upon presentation of the Bill to the President for the second time, the President is obliged to assent within twenty-one days; failing which, Parliament must be resolved, and new general elections called for. Once assented to, the Bill is sent to the official Gazette for publication and printing after which it becomes law.

7.6.6 Subsidiary legislation

The power to make subsidiary legislation emanates from article 97(5) of the Constitution, which provides that provisions of this article, or article 64 of the Constitution, shall not prevent Parliament from enacting laws making provisions conferring any person or department of Government the power to make regulations, or conferring the force of law on any regulations made by any person or government department. An enabling Act provides a person or a government body responsible to make subsidiary legislation. In practice, subsidiary legislation is made by Ministers, Local Governments, Authorities, Directors, Commissions, Boards, or the Chief Justice. Regulations need not be laid in Parliament unless expressly stated in the principal Act.

Schematic to illustrate the legislative process in Tanzania



7.7 The legislative process in Zambia

7.7.1 Introduction

Zambia has constitutional supremacy, meaning that the Constitution of Zambia is the supreme law of the country; therefore, any other law that is inconsistent with the Constitution is, to the extent of its inconsistency, void.

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 legislation brought to Parliament must be scrutinised by the National Assembly before its submission to the President for assent. Parliament comprises one House, namely the National Assembly. Laws made by the National Assembly and assented to by the President are styled "Acts", which contain the words of enactment: "Enacted by the Parliament of Zambia".

Section 97(1) of the Standing Orders provides that a Member, a Minister or the Vice-President may introduce a Bill in the Assembly. Before a Bill is drafted, principles for drafting must first be approved by Cabinet; these proposals for legislation are contained in a Cabinet memorandum that must first be approved by the responsible Minister. Drafting instructions are submitted to the Attorney General who is charged with drafting and signing all Bills presented before Parliament under Article 54(2)(a). The Attorney General may, however, delegate this function to the Solicitor General.

7.7.2 Stages of a bill

7.7.2.1 First Reading

During this stage, the Bill is 'read' for the first time by the Clerk reading the short title and number only. The Bill may then be referred to an appropriate Committee for scrutiny and examination unless the Speaker excludes such a referral for a stated reason. A Bill's referral to a Committee is dealt with as expeditiously as the Speaker or House Business Committee determines. Where a Committee requires more time to consider the Bill, the Speaker has the discretion to grant additional time.

7.7.2.2 Second Reading: Consideration of Bill

When a Bill is reported by a Standing Committee, the House deliberates on and considers the report of the Committee pertaining to the Bill in question. When a Bill is read a second time, it is then committed to a Committee of the Whole House.

7.7.2.3 Third Reading and Assent Motion for recommittal

At the Third Reading stage, no amendments are made to a Bill. Section 119 of the Constitution states that when the order of the day for the Third Reading of a Bill is read, a motion may be made to recommit the Bill, either wholly or in part, to the Committee of the Whole House.

7.7.2.4 Printing of Bill and Certification

After a Bill has been passed, it is printed and the copies thereof are signed by the Speaker or the First Deputy Speaker or, in the absence of both the Speaker and First Deputy Speaker, the Second Deputy Speaker or – if they are all unable to act – the Clerk, before being presented to the President for assent.

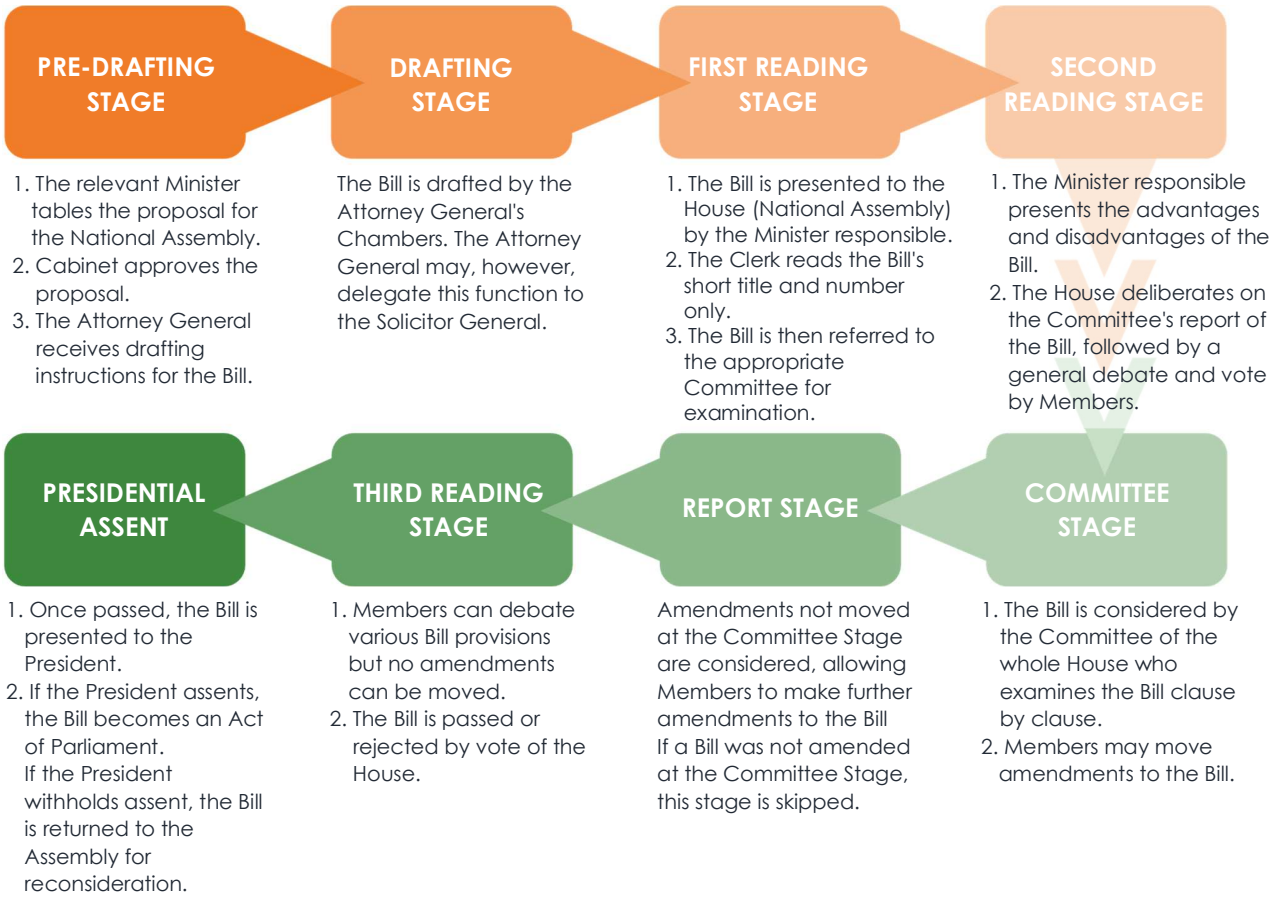
The Bill presented to the President is accompanied by a certificate attesting that the version before the President has been compared with the Bill passed through the Assembly and found to be a correct printed copy. The President is conferred twenty-one days from

receipt of the Bill to make a determination regarding assent. If assented to, the Bill becomes an Act of Parliament; if assent is withheld, the Bill is returned to the Assembly for reconsideration.

7.7.3 Subsidiary legislation

The Constitution of Zambia empowers Parliament to delegate its functions to other bodies with legislative powers by means of an Act of Parliament. Subsidiary legislation, which may assume the form of Regulations, Rules or Orders, enter into force upon signature of the responsible Minister and publication in the Gazette.

Schematic to illustrate the legislative process in Zambia



7.8 The legislative process in Zimbabwe

7.8.1 Introduction

The Constitution of Zimbabwe is the supreme law of the land. This implies that for any law in the country to be deemed valid, it must be in accordance with the Constitution; and any law which is inconsistent with the Constitution will be void to the extent of that inconsistency. Zimbabwe therefore has constitutional, rather than parliamentary, supremacy. The Constitution dictates, among other things, how the legislatures (Parliament, provincial legislatures and municipal councils) are to conduct their legislative processes. Other relevant Rules of Parliament and the conventions of the other legislatures with a bearing on law-making are also provided.

Zimbabwe's legislative authority vests in the President and Parliament. Section 118 of the Constitution states that Parliament consists of the Senate and the National Assembly. Parliament has the power to pass new laws, amend existing laws and repeal old laws in the "national sphere" of Government.

The Parliament of Zimbabwe's law-making mandate is conferred by Section 117 of the Constitution (Amendment no. 20) of 2013:

> "(1) The legislative authority of Zimbabwe is derived from the people and is vested in and exercised in accordance with this Constitution by the Legislature.
>
> (2) The legislative authority confers on the Legislature the power -
>
> a) to amend this Constitution in accordance with Section 328;
>
> b) to make laws for the peace, order and good governance of Zimbabwe; and
>
> c) to confer subordinate legislative powers upon another body or authority in accordance with Section 134".

Parliament, therefore, bears legislative, oversight and representative responsibility in respect of the Executive's areas of operations. The fifth Schedule to the Constitution read together with the Standing Orders 133 - 35 provides a detailed elaboration of the country's legislative processes and procedures.

Legislation is divided into the following categories:

i) Principal (Primary) legislation: the Bills passed by Parliament that enter into force of law as Acts; and

ii) Subsidiary legislation: the legislation supplementing the principal legislation, created by bodies or individuals under powers delegated to them by Parliament. The powers to make subsidiary legislation are usually stipulated in the principal legislation.

7.8.2 Types of bills

Two types of Bills can be brought before Parliament:

7.8.2.1 Public Bills

Public Bills relate to matters of general public interest and are introduced upon notice by a Member of Parliament. Public Bills are divided into Government Bills and Private Member's Bills. Government Bills are channelled through Parliament by government ministers while Private Members Bills are tabled in Parliament by Private Members or backbenchers.

7.8.2.2 Private Bills

Private Bills address matters of particular interest or benefit to a specified person or group of persons, for instance, juristic persons (such as public companies), corporations or a local authority. These Bills can only be introduced in Parliament after a petition and a copy of the proposed Bill has been presented and adopted.

7.8.3 Preliminary process

Public Bills undergo various preliminaries well before they are tabled in Parliament. A sponsoring Minister first tables his proposal for a Bill to Cabinet, which scrutinises the proposal to ensure it in line with Government policy. Where accepted by Cabinet, the Minister responsible is directed to issue drafting instructions to the Legal Drafting Department of the Attorney General's Chambers to undertake the substantive preparation of the Bill. This Bill is then prepared and printed for presentation and consideration by the Cabinet Commission on Legislation, chaired by the Minister of Justice, Legal and Parliamentary Affairs.

Once approved by Cabinet, the Bill is published in the Government Gazette at least two weeks prior to its introduction in Parliament.

7.8.4 Stages of a bill

After being Gazetted, the Bill is referred to a Parliamentary Portfolio Committee for scrutiny alongside the functions of the sponsoring ministry. The Portfolio Committee conducts public hearings and wide consultations with members of the public to allow them the opportunity to make inputs and provide comments on the Bill.

7.8.4.1 First Reading

Before the Bill is tabled in Parliament, the sponsoring Minster will notify either of the Houses of the intent to present the Bill. On the appointed day, the Minister presents the Bill by reading the long title to formally introduce the Bill before the House. No debate on the contents of the Bill is permitted at this stage. The Bill is then referred to the Parliamentary Legal Committee in accordance with the Constitution and Standing Orders to determine the constitutional conformity of the proposed Bill.

7.8.4.2 Second Reading

During this stage, the Minister explains the principles of the Bill. The Parliamentary Legal Committee presents its report containing findings on constitutionality and advancing recommendations. The Bill is then read for a second time. If any amendments to the proposed Bill are advised, the House may refer the Bill to the Committee to undertake the necessary amendments.

7.8.4.3 Committee Stage

At this stage, the whole House forms a Committee for the purpose of considering the Bill in detail, clause by clause. The guiding principle is that the Committee should make such amendments in the Bill as may seem likely to render it more acceptable. The Committee ensures that amendments to the Bill are effected in a manner consistent with the principles of the Bill approved by Cabinet. It also considers the recommendations of the relevant portfolio committee.

7.8.4.4 Report Stage

The Chairman of the Committee of the whole House reports the recommendations on the Bill, which are either accepted or rejected by the majority of the House.

7.8.4.5 Third Reading

At this stage, debate may occur; however, no new principles may be introduced or raised. The Third Reading is the final stage, and the Bill can now be said to have been passed by the House to which it was introduced. The Bill is then forwarded to the lower or upper house, whichever is the case.

7.8.4.6 Presidential Assent

Where a Bill has been duly passed by Parliament in accordance with the Constitution and Standing Orders and duly signed by the Clerk to Parliament, the Clerk will forward a copy of the Bill to the President for assent within twenty-one days. The President will then authenticate the copy by means of signature and public seal. The Bill then becomes an Act of Parliament and enforceable by law. Where assent is withheld by the President, the Bill is returned to Parliament for reconsideration.

7.8.4.7 Enrolment of an Act

The Clerk of Parliament causes the authenticated copy of the Act to be enrolled on record in the office of the Registrar of the High Court. It is this copy which is recognised as providing conclusive evidence of the provisions of the Act concerned. The Act will generally come into operation on the date of publication in the Government Gazette or alternatively on a date stipulated in a Statutory Instrument by the responsible Minister.

7.8.5 Subsidiary legislation

Section 134 of the Constitution provides that:

"Parliament may, in an Act of Parliament, delegate power to make statutory instruments within the scope of and for purposes laid out in that particular Act, but –

a) Parliament's primary law-making power must not be delegated;

b) statutory instruments must not infringe or limit any of the rights and freedoms set out in the Declaration of Rights;

c) statutory instruments must be consistent with the Act of Parliament under which they are made;

d) the Act must specify the limits of the power, the nature and scope of the statutory instrument that may be made, and the principles and standards applicable to the statutory instrument;

e) statutory instruments do not have the force of law unless they have been published in the Gazette; and

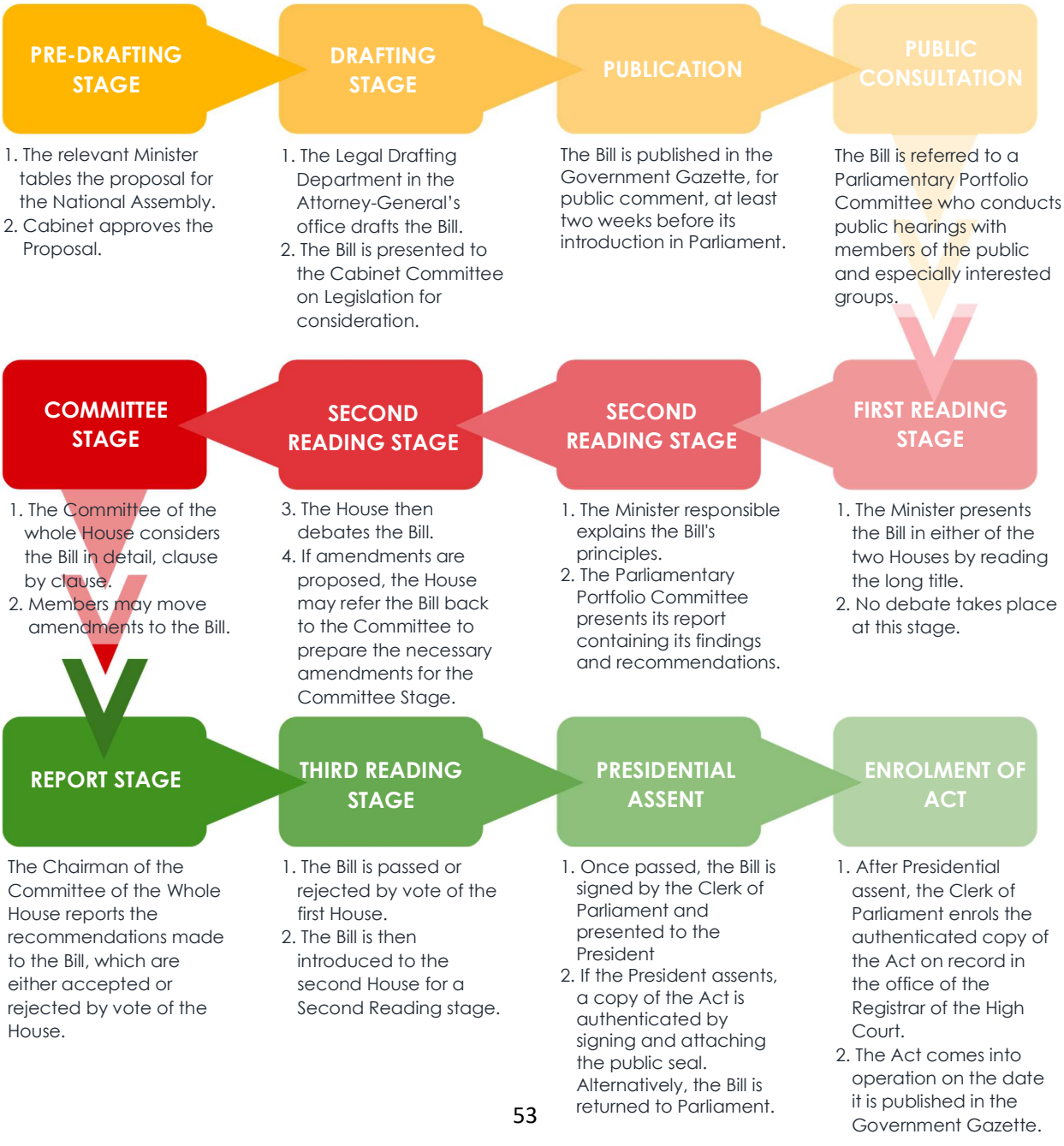
f) statutory instruments must be laid before the National Assembly in accordance with its standing orders and submitted to the Parliamentary Legal Committee for scrutiny".

Subsidiary legislation is contained in Statutory Instruments. A Statutory Instrument is defined in Section 3 of the Interpretation Act, Chapter 1:01 as -

"Any proclamation, rule, regulation, by-law, order, notice or other instrument having the force of law, made by the President or any other person or body under any enactment".

The responsible ministry submits proposals for subsidiary legislation to the Attorney General's Chambers for legal drafting. This may involve various meetings between the officials of the Ministry and the office of the Attorney General, as well as wide stakeholder consultations for the input of members of society. Regulations are then submitted for the signature of the responsible Minister; after which they are sent to the Gazette for publication and laid before the National Assembly for scrutiny and approval.

Schematic to illustrate the legislative process in Zimbabwe



8. REFERENCES

1. Agrochemicals Act and the Agrochemicals Regulations (Chapter 35:09) of Botswana
2. African Agricultural Technology Foundation (AATF). 2013. *A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa.* Nairobi: African Agricultural Technology Foundation
3. Constitution of Botswana (Cap. 01:00)
4. Constitution of the Republic of Tanzania, 1977
5. Constitution of the Republic of Mozambique, 2018
6. Constitution of the Republic of South Africa, 1996 (Act 108)
7. Constitution of the Republic of Zambia, 1996
8. Department of Agriculture, Forestry and Fisheries (DAFF). 2015. *Guideline on the Data and Documents required for Registration of Agricultural Remedies in South Africa*. Pretoria: Department of Agriculture, Forestry and Fisheries. https://www.nda.agric.za/doaDev/sideMenu/ActNo36_1947/AIC/Guidelines%20on%20Data%20Requirements%20for%20Agricultural%20Remedies%202015%20AVCASA.pdf
9. Department of Agriculture, Forestry and Fisheries (DAFF). 2015. *Guidelines on the Data Required for Registration of Biological/Biopesticides Remedies in South Africa.* Pretoria: Department of Agriculture, Forestry and Fisheries. https://www.nda.agric.za/doaDev/sideMenu/ActNo36_1947/AIC/Guidelines%20for%20Registration%20of%20Biological%20Remedies%202015%20Registrar%20of%20Act%2036%20of%201947.pdf

10. Environment Act No. 20 of 1997 and the Pesticides Management Regulations Decree No. 6 of 2009 of Mozambique

11. Environmental Management Act No. 12 of 2011 and the Environmental Management (Licensing) Regulations Statutory Instrument No. 112 of 2013 of Zambia

12. Fertilisers, Farm Feeds and Remedies Act [Chapter 18:12] and the Pesticide Regulations Statutory Instrument No. 144 of 2012 of Zimbabwe

13. Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947) of South Africa

14. Investment and Exports Promotion Agency (APIEX). 2017. *Laws and Regulations Related to Foreign Direct Investment in Mozambique*. https://www.jica.go.jp/project/english/mozambique/010/materials/c8h0vm0000e4zyeu-att/materials_03.pdf

15. Ministry of Agriculture and Rural Development, (MADER). 2020. *Mozambique Conservation Areas for Biodiversity and Development - Phase II. Updated Pest Management Plan*. https://www.biofund.org.mz/wp-content/uploads/2018/07/PMP-MozBio-Phase-2.pdf

16. National Biotechnology Authority (Agricultural Biotechnology Products) Regulations, Statutory Instrument No. 160 of 2018 of Zimbabwe. http://www.livestockzimbabwe.com/Updates/SI%20160%20of%202018%20a%20NBA%20%20Agricultural%20Biotech%20Products%20Regs.pdf

17. Plant Health Act No. 4 of 2020 and the Plant Protection Regulations of 1998 of Tanzania

18. Parliamentary Standing Orders of Tanzania, 2021

19. The Standing Orders of the National Assembly of Botswana, 2011

20. The Official Secrets Act [Chapter 11:09] of Zimbabwe

21. Standards and Trade Development Facility (STDF). 2021. *Good regulatory practices to improve SPS measures: A practical guide*. https://www.standardsfacility.org/sites/default/files/STDF_GRP_Guide_EN.pdf

22. Standing Orders of Zambia, 2005

ANNEXES

Annex 1

SURVEY OF THE BIOPESTICIDES REGULATORY SYSTEMS

Full Name:	
Designation:	
Organisation:	
Country:	

1. Do you have a primary law related to biopesticides enacted?
   ☐ Yes
   ☐ No
   If so, please provide the precise title of the legislation together with a web link, if any: _____
2. Has this law been amended, and if so, when?
   _____
3. Does the definition of 'pesticide', 'plant protection product', etc. encompass biopesticides?
   ☐ Yes
   ☐ No
4. Do definitions distinguish 'active ingredients', 'active substances' and 'formulated products'?
   ☐ Yes
   ☐ No
5. Is there a definition of 'biopesticides'?
   ☐ Yes
   ☐ No

6. Is there provision for a Register of pesticides?
   ☐ Yes
   ☐ No
7. Is there provision for a Registration Committee and secondment of experts to perform specific risk assessments as required?
   ☐ Yes
   ☐ No
8. What categories of registration are provided for? (*Please tick all appropriate options*)
   ☐ Provisional
   ☐ Full
   ☐ Other (*Please specify*):_____
9. Are businesses who are importing, distributing, manufacturing, selling and otherwise handling pesticides commercially required to register and be subject to inspection?
   ☐ Yes
   ☐ No
10. Is there a Schedule or Annex with detailed data requirements for the registration dossier(s) and/or an application form?
    ☐ Yes
    ☐ No
11. What provisions are made to distinguish public and confidential data?
    _____
12. Do data requirements include plans or models for labelling and advertising?
    ☐ Yes
    ☐ No
13. Does your law have provisions for the following post-registration/authorisation controls? (*Please tick all appropriate options*)
    ☐ Ensuring only registered pesticides are available
    ☐ Monitoring for expired, poor quality and fraudulent products
    ☐ Monitoring efficacy, toxicity and residues
14. Are applicants for registration required to provide details of post-registration controls?
    ☐ Yes
    ☐ No
15. Is there provision for revocation of registration by the authorities and/or voluntary withdrawal by the applicant?
    ☐ Yes
    ☐ No
16. Is there provision for using non-registered biopesticides in an emergency?
    ☐ Yes
    ☐ No
17. Is there reference to policies to promote integrated pest management or biopesticide use?
    ☐ Yes

☐ No

If so, please provide the citation of the policy and link if available:

_____

18. Are fees fixed by statute or reviewable without reference to parliament? _____
19. How might the absence of a relevant primary law governing pesticides be rectified? *(Please tick all appropriate options)*

    ☐ Drafting a new law – taking a long time before enactment

    ☐ Drafting regulations under another, existing law

    ☐ Ignoring absence of primary law by drafting Presidential or Ministerial

    ☐ Decree or other 'stand-alone' legal instrument

    ☐ Preparing code of practice or administrative guidance document
20. What are the major challenges affecting due process in biopesticides registration?

    (Please tick all appropriate options)

    ☐ Lack of transparency in application process, data requirements and evaluation

    ☐ No certainty in the time limit for evaluation and decision-making

    ☐ Not giving reasons for refusal

    ☐ Lack of complaints and appeals procedures

    ☐ Other (*Please specify*): _____
21. In some Jurisdictions, registrants do not have to prove that a product is safe and efficacious if an identical product has already been registered in another jurisdiction (i.e. parallel registration). Does the current registration framework provide for **parallel registration**?

    ☐ Yes

    ☐ No
22. Where two or more pesticides are 'identical' to the extent that data dossiers may be shared, does the registration framework provide for **"equivalent pesticides"** in the registration of identical generic pesticides?

    ☐ Yes

    ☐ No
23. Would the country consider adopting the use of biopesticides?

    ☐ Yes

    ☐ No

    If no, please explain: _____
24. What factors may contribute adoption of biopesticides? (*Please tick all appropriate options*)

    ☐ Legislative review

    ☐ Developing technical capacity

    ☐ Political will and change in policy direction

    ☐ Demand for the product in the agricultural sector

    ☐ Other (*Please explain*): _____
25. What are the challenges of integrating biopesticides into GAP?_____
26. Would the country consider a regionally harmonised regulatory system for biopesticides?

    ☐ Yes

    ☐ No

    If no, please explain: _____

Annex 2

REVIEW OF THE LEGAL LANDSCAPE IN EACH OF THE PROJECT COUNTRIES

Item	Primary Law Provision	Zambia	Zimbabwe	Mozambique	Botswana	South Africa	Tanzania
1	Is there a primary law related to pesticides and biopesticides?						
2	Has this law been amended (in the last 5 years)?						
3	Does the definition of 'pesticide', 'plant protection product', etc. encompass biopesticides?						
4	Do definitions distinguish 'active ingredients', 'active substances' and 'formulated products'?						
5	Is there a stand-alone definition of 'biopesticides'?						
6	Is there provision for a Register of pesticides?						
7	Is there provision for a Registration Committee and secondment of experts to perform specific risk assessments as required?						
8	Is provisional registration possible?						
9	Is business dealing with pesticides/biopesticides required to register and be subject to inspection?						
10	Is there a Schedule or Annex with detailed data requirements for the registration dossier(s)?						
11	Are provisions made to distinguish public and confidential data?						
12	Do data requirements include plans or models for labelling and advertising?						
13	Does the law have provisions for post-registration/ authorisation controls?						
14	Is there provision for revocation of registration by the authorities?						
15	Is there provision for using non-registered biopesticides in an emergency?						
16	Are fees fixed by statute, or reviewable without reference to Parliament?						
17	Does the current registration framework provide for parallel registration?						
18	Does the current registration framework provide for 'equivalent pesticides'?						

Key:

None
Not certain
Certain

www.sabiop.co.za