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Regulatory Divergence and Genome Editing Governance in East African Crop Improvement Systems

Dr. Peter Mwangi Kihara[1*] *& Dr. Neema Asha Mwakalinga*[2]

[1]Department of Crop Biotechnology and Policy, Rift Valley Agricultural Innovation Centre, Nakuru, Kenya
[2]Institute for Plant Genetics and Food Security, Kilimanjaro Agricultural Research and Development Unit, Moshi, Tanzania

ABSTRACT

Genome editing offers a technically feasible route to addressing several intractable constraints in East African crop production, including banana Xanthomonas wilt, cassava viral disease, striga parasitism, and maize lethal necrosis. Regulatory treatment of genome edited organisms across the region has nevertheless diverged sharply within a single customs union that permits substantially free movement of agricultural goods. This narrative review synthesises the legal instruments, institutional arrangements, and political trajectories governing genome editing in Kenya, Uganda, Tanzania, Rwanda, and the newer East African Community partner states, with Ethiopia included as a regional comparator. The review draws on peer reviewed literature, national biosafety instruments, Biosafety Clearing House records, and regional economic community policy documents published up to the middle of 2026. Findings reveal a five-position gradient extending from the absence of any operative biosafety statute, through administrative moratoria, to published product-based exemption guidelines. Kenya and Ethiopia have issued genome editing guidelines that exempt products lacking foreign genetic material from full biosafety review, whereas Uganda has operated for more than a decade without an assented biosafety law, and Tanzania maintains a strict liability regime alongside an administrative suspension of field research. The review introduces the Tiered Biosafety Convergence Framework, which classifies national regimes across five tiers and specifies the legal, institutional, and political preconditions required for movement between them. The framework reframes regional harmonisation as sequential tier ascent culminating in mutual recognition, rather than as simultaneous statutory reform across all partner states. Practical implications include sequencing guideline development ahead of statutory amendment, establishing a regional technical working group, and integrating biosafety determinations with existing variety release and seed catalogue systems.

Keywords:
genome editing, biosafety regulation, East African Community, CRISPR, crop improvement, regulatory harmonisation

INTRODUCTION

Agricultural productivity across East Africa remains constrained by biotic pressures that conventional breeding has addressed only partially over several decades of sustained investment. Banana Xanthomonas wilt continues to devastate plantations across the Great Lakes region, cassava brown streak disease erodes root

*Corresponding Author: Department of Crop Biotechnology and Policy, Rift Valley Agricultural Innovation Centre (RVAIC), Nakuru, Kenya; Email: p.kihara@rvaic.ac.ke

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Pages: 52-70
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quality throughout the coastal and lakeside zones, and the parasitic weed striga suppresses cereal yields across large areas of rainfed farmland. Maize lethal necrosis, first reported in the region in 2011, has demonstrated how rapidly a novel pathogen complex can compromise the dominant staple of an entire subregion. Each of these constraints involves host susceptibility factors that are amenable to targeted modification through clustered regularly interspaced short palindromic repeat technologies. Assessments of breeding progress across African staple crops indicate that gains have been uneven and that several major crops have received limited sustained investment (Eriksson et al., 2018).

Genome editing differs from earlier transgenic approaches in one respect that carries substantial regulatory consequence, namely that many edited products contain no foreign genetic material in the final plant. This characteristic has prompted numerous jurisdictions to distinguish edited products from genetically modified organisms for regulatory purposes, generally exempting the former where no transgene is retained (Buchholzer and Frommer, 2023; Entine et al., 2021). African regulatory authorities have engaged with this distinction actively, and several have issued dedicated guidelines that establish separate pathways for edited products (Akinbo et al., 2025; Runo et al., 2024).

The East African Community presents an unusual configuration for examining this development. Its partner states operate a customs union and a common market that together permit substantially free movement of agricultural commodities and planting material across national borders. Yet biosafety governance remains an exclusively national competence, exercised through instruments that differ profoundly in legal form, institutional location, and operational status. One partner state has published a genome editing guideline and approved commercial cultivation of an insect resistant maize event, another has operated without an assented biosafety statute despite repeated parliamentary passage, and a third has suspended field research by administrative direction while retaining a strict liability regime.

This pattern of divergence has so far received limited systematic scholarly treatment. Existing scholarship has examined African biosafety systems at continental scale (Rabuma et al., 2024), through selected national case studies (Ongu et al., 2023), and through comparative legal treatment of the three original partner states (Mmbando, 2023), but has not analysed the specific problem posed by regulatory asymmetry inside an operating customs union. The present review addresses that gap by comparing national positions, identifying the determinants of divergence, and proposing a structured framework through which convergence might realistically proceed.

REVIEW APPROACH AND EVIDENCE BASE

This study is a narrative review employing structured comparative synthesis rather than systematic meta-analysis, a design appropriate where the object of study is a set of legal and institutional arrangements rather than a body of quantitative findings. The review assembled evidence from four categories of source material, each subject to distinct verification procedures before inclusion in the analysis.

The first category comprised peer reviewed journal articles addressing genome editing applications, biosafety governance, and regulatory comparison in African and global contexts. Searches were conducted across bibliographic databases using combinations of terms covering genome editing, biosafety, regulation, and the names of individual East African states. Articles were retained where they addressed regulatory arrangements substantively rather than in passing, and where full bibliographic details including digital object identifiers could be confirmed.

The second category comprised primary legal instruments, including national biosafety statutes, regulations, proclamations, and published guidelines. These were obtained from national

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

legislative repositories, national Biosafety Clearing House portals, and the central Biosafety Clearing House maintained under the Cartagena Protocol on Biosafety. The third category comprised regional and continental policy documents issued by the East African Community, the Common Market for Eastern and Southern Africa, and the African Union Development Agency. The fourth category comprised official statistical and regulatory databases used for contextual quantification of production and trade.

Analysis of the assembled material then proceeded through three sequential stages. National positions were first characterised across a common set of descriptors covering legal instrument, competent authority, liability regime, genome editing treatment, and operational status. Determinants of divergence were then identified inductively by examining which descriptors covaried across states. The framework presented subsequently was developed by ordering the observed national positions along a single dimension of regulatory operability, and by specifying the conditions associated with movement along that dimension. Because the underlying evidence is documentary and descriptive rather than experimental, the analysis employs associative language throughout and does not claim causal identification.

GENOME EDITING IN AFRICAN AGRICULTURE

Technical Foundations and Product Categories

Genome editing encompasses a family of techniques that introduce targeted changes at specified locations within a genome, using engineered nucleases to generate double strand breaks that the cell then repairs. Zinc finger nucleases and transcription activator like effector nucleases preceded the current dominant platform, which employs clustered regularly interspaced short palindromic repeats together with associated Cas proteins. The latter platform has displaced its predecessors largely because guide sequences can be designed and synthesised rapidly at modest cost, which lowers the technical barrier for laboratories operating with constrained budgets.

Regulatory analysis of edited products conventionally distinguishes three categories according to the nature of the repair outcome. Site directed nuclease category one outcomes involve small insertions or deletions arising from error prone repair, typically producing gene knockouts without any template supplied by the developer. Category two outcomes involve precise nucleotide substitutions guided by a supplied repair template, producing allele changes equivalent to those obtainable through mutation breeding. Category three outcomes involve the insertion of substantial sequences at a targeted location, which may include genes derived from unrelated species. The regulatory significance of this taxonomy lies in the fact that category three products typically retain foreign genetic material and are therefore treated as genetically modified organisms in most jurisdictions, whereas the first two categories frequently are not (Entine et al., 2021; Rabuma et al., 2024).

The practical difficulty for regulators is that the final product of a category one or category two edit may be indistinguishable, at the level of sequence, from a variant arising through spontaneous mutation or through chemical and radiation mutagenesis. Conventional mutagenesis has been practised for many decades without dedicated biosafety oversight in most countries, which creates an evident consistency problem for any framework that regulates edited products on the basis of process alone. Anticipation of this difficulty featured in early scenario analyses of how global regulatory positions on edited crops might subsequently diverge (Ishii and Araki, 2017). This consistency argument has featured prominently in the reasoning of authorities that have adopted product-based approaches.

The East African Research Pipeline

A substantial genome editing pipeline has developed within East African institutions over the past decade, concentrated in a small number of well-resourced laboratories and international

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

centres. Researchers at the International Institute of Tropical Agriculture in Nairobi established a robust editing platform for banana and plantain, initially validating the system through knockout of the phytoene desaturase gene as a visual marker (Ntui et al., 2020). Subsequent work applied the platform to susceptibility factors associated with banana Xanthomonas wilt, and to disruption of integrated banana streak virus sequences that had frustrated conventional improvement of the crop (Tripathi et al., 2024).

Cassava improvement has followed a parallel trajectory, building on earlier transgenic work that demonstrated resistance to brown streak disease under confined field conditions in Uganda and coastal Kenya. Editing approaches now target both viral susceptibility factors and agronomic traits including early flowering, which shortens breeding cycles in a crop with historically slow varietal turnover. Sorghum improvement has centred on resistance to striga, coordinated through a consortium that couples African agronomic knowledge with advanced editing capability held by overseas partners (Runo et al., 2024).

Maize occupies a distinct position because of its dominance in regional consumption and its exposure to both lethal necrosis and lepidopteran pests. Editing programmes targeting lethal necrosis susceptibility have advanced alongside conventional and transgenic approaches to the same constraint. Ethiopian institutions have pursued editing applications in teff, a crop of exceptional national importance that has attracted limited international breeding investment, and in Ethiopian mustard, alongside striga resistant sorghum (Akinbo et al., 2025).

The Kenyan competent authority has approved multiple editing projects for contained use, covering provitamin A enhancement in cassava, fusarium wilt and black sigatoka resistance in banana, early flowering in cassava, and striga resistance in sorghum (Ongu et al., 2023). Continental surveys published in late 2025 identified sixteen African countries with active genome editing projects, with Kenya, Nigeria, Ethiopia, Ghana, and Rwanda accounting for the largest national portfolios (Media for Environment, Science, Health and Agriculture, 2025). This pipeline indicates that the binding constraint on deployment in the region is now regulatory and institutional rather than scientific, a conclusion consistent with continental assessments of the field (Abkallo et al., 2024). Reviews of editing applications across the wider continent reach comparable conclusions concerning the balance between technical readiness and enabling environment (Amoah et al., 2024; Tripathi et al., 2022).

REGIONAL BIOSAFETY LEGAL ARCHITECTURE

International Obligations and Definitions

All East African Community partner states are parties to the Cartagena Protocol on Biosafety, which entered into force in 2003 as a supplementary instrument to the Convention on Biological Diversity. The Protocol establishes obligations concerning the transboundary movement of living modified organisms, defined as organisms possessing a novel combination of genetic material obtained through the application of modern biotechnology. National biosafety statutes across the region were drafted to give domestic effect to these obligations, and consequently reproduce the Protocol definition with limited variation.

This shared definitional inheritance is analytically important because it establishes the textual basis on which national authorities have subsequently reasoned about genome editing. Where an edited product retains no foreign genetic material and exhibits no novel combination of genetic material, an authority may conclude that the product falls outside the statutory definition of a living modified organism and therefore outside the scope of the biosafety statute. This is the reasoning that underpins the Kenyan guideline, and it is available in principle to any partner state whose statute reproduces the Protocol definition (Akinbo et al., 2025).

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

The Protocol does not, however, compel any particular treatment of edited products, and it explicitly preserves the right of parties to adopt more protective measures. The precautionary approach reflected in the Protocol preamble has been invoked by authorities and civil society organisations across the region in support of restrictive positions. International obligations therefore constrain the range of defensible national positions only weakly, which helps to explain the breadth of divergence observed.

Regional Economic Community Instruments

The East African Community has developed institutional machinery for agricultural coordination without extending that machinery to biosafety in any operative sense. The Community operates a customs union established in 2005 and a common market established in 2010, both of which reduce internal barriers to the movement of goods including agricultural commodities and planting material. A Seed and Plant Varieties Bill was developed in 2019 to harmonise variety release and seed certification across partner states, but it remained in draft form awaiting adoption by the Council of Ministers for a considerable period thereafter.

The Common Market for Eastern and Southern Africa has advanced further on seed matters through the Seed Harmonisation Implementation Plan adopted by its Council of Ministers in 2014. That instrument established a regional variety catalogue permitting a variety registered in two member states to be listed regionally, together with regional seed certificates and labels intended to reduce duplicated testing. Implementation has proceeded unevenly, with a minority of member states having domesticated the harmonised regulations several years after adoption, and with institutional capacity differences among members constituting a recognised constraint (Common Market for Eastern and Southern Africa, 2018).

Neither instrument addresses biosafety directly, and neither provides a mechanism through which a biosafety determination made in one state acquires legal effect in another. The resulting structure permits an edited variety approved in one partner state to move physically across an internal border with limited practical impediment, while remaining formally unauthorised in the receiving jurisdiction. This structural mismatch between commercial integration and regulatory fragmentation constitutes the central problem examined in this review.

Continental Policy Guidance

The African Union Development Agency has assumed the principal coordinating role on biosafety capacity across the continent, initially through the African Biosafety Network of Expertise established in 2009. That programme has supported the development of functional biosafety systems in numerous member states through technical assistance, regulator training, and facilitation of peer exchange. Its work has been credited with accelerating the establishment of national frameworks following ratification of the Cartagena Protocol (Akinbo et al., 2021).

In 2022 the Agency, working through its High-Level Panel on Emerging Technologies, issued a policy framework addressed specifically to genome editing applications in African agriculture. That framework advocates a structured and scientifically grounded regulatory approach applied consistently across member states, and it has been invoked by national authorities in support of guideline development (African Union Development Agency, 2022). Continental guidance of this kind carries persuasive rather than binding force, and its influence depends on the willingness of national authorities to adopt its reasoning.

Continental coordination has produced observable convergence in the substance of national guidelines even in the absence of any binding instrument. The guidelines published by Nigeria, Kenya, Malawi, Ghana, Burkina Faso, and Ethiopia share a common architecture, under which products retaining no foreign genetic material are exempted from full biosafety review following a case-by-case determination (Runo et al., 2024). This substantive convergence is the most encouraging feature of the current

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

landscape, and it establishes a plausible foundation for eventual mutual recognition. Continental commentary has argued that consultative and collaborative coordination across biotechnology fields offers the most realistic route to coherent policy across African jurisdictions (Masehela and Barros, 2023).

COMPARATIVE NATIONAL REGULATORY POSITIONS

Kenya

Kenya operates the most fully articulated biosafety system in the region, established under the Biosafety Act of 2009 and administered by the National Biosafety Authority. The statute adopts the Cartagena Protocol definition of a genetically modified organism, requiring written approval from the Authority for any activity involving such organisms. Institutional arrangements include technical advisory committees, institutional biosafety committees at research organisations, and defined roles for the environment and plant health agencies.

In 2022 the Authority published guidelines determining the regulatory process applicable to genome edited organisms and products, becoming the second African jurisdiction to issue such an instrument (ISAAA, 2022). The guidelines establish an early consultation mechanism under which an applicant submits information on the experimental process and the resulting product before commencing regulated activity. The Authority then determines whether the product falls under the Biosafety Act or may proceed as a conventional variety. Products arising from deletions or knockouts that retain no foreign genetic material in the final plant, and products in which inserted foreign material cannot be detected, fall outside the Act. A revised version of the guidelines was subsequently issued, indicating that the Authority treats the instrument as a living document responsive to accumulated review experience (National Biosafety Authority, 2025).

Kenyan practice on transgenic products has been considerably more turbulent than its guideline architecture suggests. A prohibition on importation and cultivation imposed in 2012 remained in force for a decade, notwithstanding approval of insect resistant cotton for cultivation in 2019. A Cabinet decision of October 2022 lifted that prohibition and was gazetted later the same month, prompting sustained litigation. The Environment and Land Court dismissed an initial challenge in 2023, and the High Court dismissed consolidated petitions in November 2024 on the ground that the matter had already been determined. A Court of Appeal order issued in March 2025 restrained further implementation of the Cabinet decision, and a separate petition challenging the approval of an insect resistant maize event proceeded through the High Court at Kisumu into the middle of 2026.

The Kenyan case therefore demonstrates a pattern of considerable analytical interest. A jurisdiction may possess an advanced and internationally aligned guideline for edited products while simultaneously experiencing prolonged judicial contestation of its transgenic decisions. The guideline and the litigation address formally distinct categories of product, yet the reputational and political consequences of the latter plausibly affect the operating environment for the former.

Uganda

Uganda presents the most striking instance of regulatory incompleteness in the region, having conducted biotechnology research for approximately three decades without an operative biosafety statute. Legislative development commenced in the early 2000s, and a National Biotechnology and Biosafety Bill was tabled in Parliament in 2012 before lapsing at the dissolution of that Parliament. The Bill was reinstated and passed in October 2017 as the National Biosafety Act, whereupon the President declined assent and returned it with objections concerning the title, patent rights attaching to indigenous varieties, and sanctions for the mixing of engineered and indigenous material.

Parliament revised the instrument and passed it again in November 2018 as the Genetic Engineering Regulatory Bill. The President again declined assent in August 2019, requesting further provisions addressing the separation of

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

engineered and conventional material and the labelling of engineered products. The instrument has not entered into force, and administrative oversight of research activity has continued through the National Council for Science and Technology acting with its National Biosafety Committee (Ongu et al., 2023).

The consequences of this position extend beyond the absence of a commercial pathway. Confined field trials of engineered banana, cassava, and maize have proceeded under administrative authority, generating substantial technical results without any prospect of varietal release. Research investment therefore accumulates in a pipeline that has no legal outlet, and the absence of statutory authority creates uncertainty for international collaborators regarding the enforceability of material transfer and stewardship arrangements. Genome editing has been the subject of consultation among Ugandan stakeholders, but no dedicated instrument has been issued, and any such instrument would in any case lack a statutory foundation.

Tanzania

Tanzania regulates biotechnology through the Environmental Management Biosafety Regulations of 2009, made under the Environmental Management Act and administered through the National Biosafety Focal Point located within the environment portfolio. The regulations require prior authorisation for importation, transit, contained use, confined use, deliberate release, and commercial placement of engineered organisms. Their most consequential provision imposes strict liability on any person conducting such activities, extending to personal injury, property damage, financial loss, and harm to biological diversity, and taking account of socioeconomic, cultural, and ethical considerations (United Republic of Tanzania, 2009).

The breadth of this liability provision effectively precluded field research for several years, since no research institution or commercial partner was willing to accept open ended exposure of this kind. A relaxation adopted in 2015 permitted confined field trials to proceed, and the first such trial in the country was established at Makutupora in 2016 under a regional drought tolerant maize initiative. That regulatory opening subsequently proved to be temporary rather than durable. In 2018 the Permanent Secretary of the agriculture ministry directed that field trials cease, and in January 2021 the incoming minister announced cancellation of research trials involving engineered organisms together with additional scrutiny of imported engineered seed (United States Department of Agriculture Foreign Agricultural Service, 2024a).

Tanzania has issued no instrument addressing genome editing, and its statutory definition of a regulated organism has not been interpreted publicly in relation to edited products. The combination of a strict liability regime, an administrative suspension of research, and an absence of interpretive guidance places the jurisdiction in a distinctive position. It possesses an operative legal framework that is comprehensive in scope yet effectively dormant in application, which differs materially from the Ugandan situation of statutory absence.

Rwanda

Rwanda completed its biosafety legislative process considerably later than its neighbours, having relied for many years on framework strategy documents rather than a binding statute. Cabinet approved a draft biosafety law in July 2023, and the law was promulgated on 21 February 2024 as Law number 025 of 2024 governing biosafety. The instrument establishes requirements for the safe transfer, handling, and use of living modified organisms, designates the Rwanda Environment Management Authority as competent authority, and provides for a national biosafety committee to review applications and advise that authority (ISAAA AfriCenter, 2023; United States Department of Agriculture Foreign Agricultural Service, 2024b).

Implementation has proceeded through subsidiary regulation development and regulator training supported by continental and international partners. Confined field trials of cassava resistant

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

to brown streak disease had been conducted prior to promulgation, and continental surveys have identified Rwanda as hosting several active genome editing projects. The jurisdiction has not issued a genome editing specific instrument, with the consequence that edited products presently default to the general authorisation pathway established by the new law.

Rwanda therefore occupies an intermediate position of particular analytical value for this review. It possesses a recent statute drafted with awareness of contemporary technological developments, a functioning competent authority, and an active research portfolio, yet lacks the interpretive instrument that would distinguish edited products from transgenic ones. Its position therefore illustrates that statutory modernity alone does not deliver a differentiated pathway for edited products.

Newer Partner States

The East African Community expanded substantially during the 2020s to include the Democratic Republic of the Congo, South Sudan, and Somalia alongside the earlier accession of Burundi. Biosafety development across these states is uneven and in several cases minimal. Continental surveys have recorded authorisation of research and confined field trial activity in the Democratic Republic of the Congo, indicating the presence of at least a rudimentary administrative framework. Burundi has domesticated harmonised seed regulations under the Common Market instrument, though its biosafety arrangements remain limited in operational terms.

South Sudan and Somalia have functioned under conditions of prolonged instability that have constrained the development of specialised regulatory institutions across many sectors. Neither state possesses a documented biosafety framework capable of assessing applications involving engineered or edited organisms. Their accession nonetheless extends the customs union territory across which agricultural commodities circulate, which enlarges the practical scope of the regulatory asymmetry problem.

The inclusion of these states carries an implication that regional policy discussion has not yet addressed adequately. Any mutual recognition arrangement predicated on equivalent regulatory capacity would exclude several partner states for a considerable period, whereas any arrangement predicated on the lowest prevailing capacity would forgo most of the benefit sought. Framework design must therefore accommodate substantial and persistent heterogeneity rather than assume eventual uniformity.

Ethiopia as Regional Comparator

Ethiopia is not a member of the East African Community, but its inclusion as a comparator is analytically warranted on three grounds. It shares agroecological conditions and crop constraints with the northern portion of the region, it participates alongside several partner states in the Common Market for Eastern and Southern Africa, and it has completed the guideline development trajectory that several partner states have not.

Ethiopian biosafety law originated in Proclamation number 655 of 2009, which proved restrictive in application because it did not adequately accommodate contained use, continued research, and environmental release (Federal Democratic Republic of Ethiopia, 2009). Parliament amended the framework through Proclamation number 896 of 2015, which expanded definitions, clarified regulatory responsibilities, and established permit procedures for activities involving modified organisms (Federal Democratic Republic of Ethiopia, 2015). Subordinate instruments followed, including directives addressing risk assessment parameters, transport and storage, contained use applications, and deliberate release. Institutional arrangements include a national biosafety advisory committee and institutional biosafety committees at research organisations.

In December 2024 the Environmental Protection Authority published guidelines for the regulation of genome edited plant products together with guidance on stacked gene products (Environmental Protection Authority, 2024). The instrument adopts a product oriented approach

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

under which the presence or absence of transgenes in the final product determines the applicable pathway. Ethiopian editing projects positioned to benefit include teff, Ethiopian mustard, and striga resistant sorghum (ISAAA AfriCenter, 2025; United States Department of Agriculture Foreign Agricultural Service, 2025). The Ethiopian sequence, moving from a restrictive original statute through legislative amendment to subordinate directives and finally to a dedicated guideline, offers a documented trajectory of direct relevance to partner states currently positioned at earlier stages.

INSTITUTIONAL AND CAPACITY DETERMINANTS

Instrument Type and Amendment Cost

The single most consistent determinant of regulatory adaptability across the region is the legal form in which biosafety rules are expressed. Jurisdictions that regulate through primary legislation face a high cost of adaptation, because any change to statutory scope requires parliamentary passage and executive assent. Jurisdictions that retain discretion to issue subordinate guidance can respond to technological developments through administrative instruments that require neither legislative time nor political capital.

The Kenyan experience illustrates the advantage of the latter approach with unusual clarity. Rather than seeking amendment of its Biosafety Act to accommodate edited products, the competent authority developed a guideline interpreting the existing statutory definition, a route considered suitable because it preserved flexibility in a rapidly evolving field and permitted consultation with scientific and regulatory communities (Komen et al., 2020). Nigeria pursued the alternative route of statutory amendment, inserting an express provision on gene editing, gene drives, and synthetic biology into its principal Act before developing operational guidance. Both routes produced published guidelines, but the guideline route consumed substantially less institutional and political resource.

The Ugandan experience demonstrates the cost of dependence on primary legislation in an environment of contested executive support. Two parliamentary passages across a period exceeding five years failed to produce an operative statute, and no subordinate instrument could remedy the deficiency because none had a statutory foundation on which to rest. Instrument type therefore functions less as a technical detail than as a structural determinant of whether a jurisdiction can respond to technological change at all.

Liability Regimes

Liability design exerts an influence on research activity that is disproportionate to the attention it typically receives in regulatory analysis. Strict liability regimes, under which any person conducting a regulated activity bears responsibility for resulting harm irrespective of fault, transfer an open ended and unquantifiable risk to research institutions and their partners. Where the definition of compensable harm extends to socioeconomic, cultural, and ethical dimensions, as it does in the Tanzanian regulations, insurability becomes effectively impossible and rational institutions decline participation.

The Tanzanian sequence provides direct evidence of this mechanism operating in practice. No confined field trial occurred in the country while the original liability provision applied without qualification, the first such trial followed within approximately one year of its relaxation, and activity ceased again when administrative direction intervened. Liability provisions of this kind function as de facto prohibitions even where the formal legal position permits authorised activity to proceed.

Liability considerations acquire additional weight for edited products because the causal attribution of any alleged harm becomes considerably more difficult where the modification is indistinguishable from natural variation. A liability regime designed around detectable transgenic events transfers poorly to products that carry no distinctive molecular signature. Regional

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

framework design should therefore address liability explicitly rather than treating it as a residual matter for national determination.

Technical Review Capacity

Regulatory operability depends upon the availability of personnel capable of evaluating molecular characterisation data, assessing potential off target effects, and interpreting comparative compositional evidence. Capacity of this kind is concentrated in a small number of institutions across the region, and continental assessments have identified limited access to laboratories, equipment, and reagents as persistent constraints on the broader development of the field (Abkallo et al., 2024). Where a competent authority cannot convene qualified reviewers, procedural requirements function as barriers regardless of their substantive reasonableness.

An early consultation mechanism of the kind adopted in Kenya reduces the reviewing burden considerably, because a determination that a product falls outside statutory scope terminates the regulatory process at an early stage. This design feature has practical value for capacity constrained authorities that exceeds its apparent procedural modesty. It concentrates scarce technical attention on products that genuinely warrant assessment while allowing conventional equivalents to proceed through variety release channels.

Capacity considerations also encompass the interface between biosafety authorities and variety release systems, which operate under separate legislation and separate institutional authority in every regional jurisdiction. A product may satisfy biosafety requirements and yet remain unavailable to farmers because national performance trials, distinctness testing, and variety release committee approval have not been completed. Analysis of African commercial release experience has identified this interface as a recurrent source of delay requiring deliberate coordination between the two regulatory systems (Akinbo et al., 2021).

Judicial and Political Exposure

Biotechnology decisions across the region have proved unusually susceptible to judicial challenge and to political reversal. The Kenyan sequence of petitions, dismissals, appellate orders, and continuing proceedings has extended across more than three years without producing settled legal certainty. Judicial exposure of this magnitude affects investment decisions by seed companies and research funders, since the expected duration between regulatory approval and commercial availability becomes indeterminate.

Political exposure operates through different channels but produces comparable effects. Executive intervention prevented statutory completion in Uganda and terminated field research in Tanzania, in both cases through mechanisms outside the formal regulatory process. Analyses of African biotechnology adoption have consistently identified political contestation and organised opposition as constraints operating alongside, and frequently overriding, technical regulatory considerations (Komen et al., 2020; Mmbando, 2024). Ethical scholarship has argued further that the terms on which biotechnology is introduced, rather than the technology itself, frequently drive contestation in African settings (Komparic, 2015).

Public perception constitutes the substrate on which both forms of exposure operate. Evidence from consumer and stakeholder studies indicates that edited products are generally evaluated more favourably than transgenic ones, and that information provision shapes attitudes substantially (Atimango et al., 2024). This differential offers a communication opportunity that regional authorities have not yet exploited systematically, since public discourse across the region continues to conflate the two categories. Reviews of adoption and acceptance across African markets have similarly identified public unawareness as a principal constraint requiring sustained educational investment (Gbadegesin et al., 2022).

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
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THE TIERED BIOSAFETY CONVERGENCE FRAMEWORK

Framework Structure

The comparative analysis presented above indicates that national positions across the region do not distribute randomly across independent dimensions, but instead arrange themselves along a single ordered gradient of regulatory operability. This observation supports the construction of a tiered classification in which each tier represents a qualitatively distinct configuration of legal authority, institutional capability, and operational status. The Tiered Biosafety Convergence Framework proposed here (Figure 1) formalises that classification and specifies the conditions associated with movement between adjacent tiers.

Tier zero denotes the absence of an operative biosafety statute, whether because no instrument has been enacted or because an enacted instrument has not entered into force. Research may proceed under administrative arrangements, but no lawful pathway exists to commercial release, and no interpretive question concerning edited products can be resolved authoritatively. Tier one denotes the presence of an operative statute accompanied by conditions that suspend its practical application, whether through prohibitive liability provisions or through administrative moratoria on regulated activity.

Tier two denotes a functioning authorisation pathway applied uniformly to all products of modern biotechnology, without differentiation of edited products. Applications can be submitted, reviewed, and determined, but edited products bear the full evidentiary burden associated with transgenic ones. Tier three denotes the presence of a published instrument establishing a differentiated pathway for edited products, typically through an early consultation mechanism that determines applicability on a case-by-case basis. Tier four denotes regional mutual recognition, under which a determination made by one national authority is accorded effect by others and edited varieties enter a shared regional catalogue.

Transition Preconditions

Movement between tiers is not a matter of political declaration but requires the joint satisfaction of three categories of precondition. Legal preconditions concern the existence of an instrument of appropriate form, together with an amendment pathway proportionate to the change required. Institutional preconditions concern the availability of technical review capacity, laboratory infrastructure, and functional coordination with variety release authorities. Political preconditions concern the legitimacy of the decision process, the degree of judicial exposure, and the state of public understanding. Table 2 summarises the specific legal, institutional, and political preconditions associated with each transition.

The framework holds that these preconditions are conjunctive rather than substitutable at each transition. A jurisdiction that satisfies legal and institutional preconditions while lacking political legitimacy will experience the pattern observed in Kenya, where an advanced instrument coexists with sustained litigation. A jurisdiction that satisfies institutional and political preconditions while lacking a suitable legal instrument will experience the pattern observed in Uganda, where technical activity accumulates without any lawful outlet.

Transition between tier two and tier three is the least demanding in resource terms and offers the largest immediate return, because it requires only an interpretive instrument issued under existing statutory authority. Transition between tier three and tier four is qualitatively different, since it requires coordinated action by multiple sovereign authorities and therefore depends upon regional rather than national decision processes. The framework consequently predicts that national ascent to tier three will substantially precede any regional achievement of tier four.

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

Figure 1: Structure of the Tiered Biosafety Convergence Framework showing ascending tiers and associated transition preconditions.

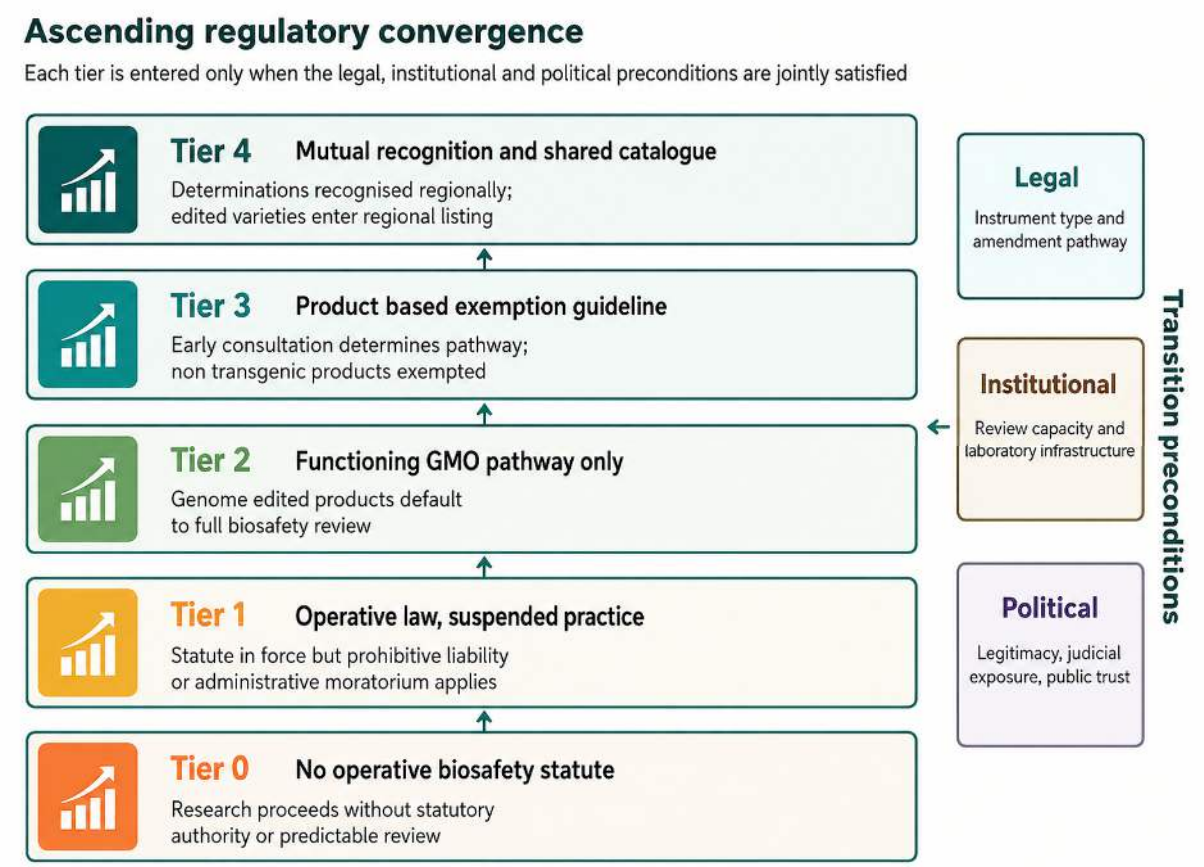


Table 1: Comparative regulatory positions across East African jurisdictions and the regional comparator

Jurisdiction	Principal instrument	Competent authority	Genome editing treatment	Framework tier
Kenya	Biosafety Act 2009	National Biosafety Authority	Published guideline with early consultation	Tier 3
Ethiopia	Proclamation 896 of 2015	Environmental Protection Authority	Published guideline issued December 2024	Tier 3
Rwanda	Law 025 of 2024	Rwanda Environment Management Authority	No dedicated instrument, general pathway applies	Tier 2
Democratic Republic of the Congo	Administrative framework	National biosafety structures	No dedicated instrument	Tier 2
Tanzania	Biosafety Regulations 2009	National Biosafety Focal Point	No instrument, activity administratively suspended	Tier 1
Uganda	Bill not assented	Council for Science and Technology	No statutory basis for any instrument	Tier 0
Burundi	Limited framework	Environment authority	No dedicated instrument	Tier 0
South Sudan	No documented framework	Not established	No dedicated instrument	Tier 0
Somalia	No documented framework	Not established	No dedicated instrument	Tier 0

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

Positioning East African States

Application of the framework to current regional positions produces a distribution weighted towards the lower tiers. Only Kenya among East African Community partner states occupies tier three, joined by Ethiopia among regional comparators. Rwanda and the Democratic Republic of the Congo occupy tier two, possessing operative frameworks without differentiated treatment of edited products. Tanzania occupies tier one, and four partner states occupy tier zero. No jurisdiction occupies tier four, and no regional instrument presently contemplates the mutual recognition that tier four requires. Table 1 summarises the principal instrument, competent authority, and framework tier for each jurisdiction reviewed.

This distribution carries an important implication for the sequencing of reform effort. Efforts directed towards immediate regional harmonisation would require simultaneous progress across four tiers in some jurisdictions, which is neither administratively feasible nor politically realistic within any short horizon. A sequenced strategy would instead prioritise transitions that are individually achievable, beginning with movement from tier two to tier three in Rwanda, which requires only an interpretive guideline issued under an existing and recently enacted statute.

The framework also clarifies why continental guidance has produced substantive convergence in guideline content without producing regional integration. Guidance operates on the transition from tier two to tier three, which is a national decision requiring national capability (African Union Development Agency, 2022). It does not operate on the transition to tier four, which requires an intergovernmental instrument that no continental body can supply on behalf of member states.

Table 2: Transition preconditions associated with movement between adjacent framework tiers

Transition	Legal precondition	Institutional precondition	Political precondition
Tier 0 to Tier 1	Enactment and entry into force of a biosafety statute	Designation of a competent authority with defined powers	Executive assent and parliamentary consensus
Tier 1 to Tier 2	Revision of liability provisions or withdrawal of moratorium	Functioning application and review procedure	Ministerial willingness to permit regulated activity
Tier 2 to Tier 3	Authority to issue interpretive guidance under existing statute	Early consultation mechanism and reviewer availability	Absence of active litigation on scope of the statute
Tier 3 to Tier 4	Intergovernmental instrument providing for mutual recognition	Comparable review standards and shared dossier repository	Reciprocal confidence among partner state authorities

TRADE AND SEED SYSTEM IMPLICATIONS

Asynchronous Approval Within a Customs Union

Asynchronous regulatory approval has been documented globally as a source of trade disruption, sustained alteration of trade patterns, and economic loss for both exporting and importing parties. The East African configuration intensifies this general problem because internal barriers to the movement of goods have been deliberately reduced through customs union and common market arrangements. An edited variety lawfully cultivated in one partner state may therefore enter the territory of a partner state in which it holds no authorisation, through ordinary commercial channels operating exactly as regional integration policy intends.

Informal movement of seed across national borders compounds this exposure considerably. Smallholder seed systems across the region rely substantially on farmer saved seed, local exchange, and informal markets that operate outside formal certification channels. Regulatory divergence expressed through formal authorisation decisions does not readily translate into differential outcomes on the ground where the material in question moves through these

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

channels. The practical effect is that restrictive jurisdictions may bear the costs of restriction without securing its intended benefits.

Seed catalogue arrangements offer a partial mechanism for managing this exposure, since regional variety listing under the Common Market instrument provides a formal channel through which varieties acquire recognition across multiple jurisdictions. That mechanism presently addresses conventional varieties and has not been extended to products of modern biotechnology in any operational sense. Extension of catalogue arrangements to edited varieties determined to fall outside biosafety scope would represent a modest and administratively tractable step towards the mutual recognition contemplated at tier four.

Detection and Enforcement Constraints

Enforcement of divergent national positions presupposes an analytical capability to distinguish regulated from unregulated material, and that presupposition fails for most edited products. Conventional screening for genetically modified organisms relies on detection of introduced elements such as promoters, terminators, and marker genes that are common across many transgenic events. Products of category one and category two editing carry no such elements, and the sequence changes they carry are frequently indistinguishable from natural or induced variation.

Detection is technically achievable where the specific target sequence is known in advance and validated methods have been developed for that particular event. Identification, meaning the attribution of a detected variant to a specific edited product and a specific developer, is considerably more difficult and in many cases not achievable through analytical means alone. Proposals for anticipatory frameworks based on voluntary disclosure and collated developer information have been advanced precisely because analytical detection alone cannot support enforcement of authorisation requirements (Entine et al., 2021).

The consequence of this analytical limitation for regional policy design is substantial. A partner state maintaining a restrictive position on edited products cannot enforce that position at its borders using currently available analytical infrastructure, still less at internal borders across which formal customs controls have been reduced. Restrictive positions therefore impose costs on domestic researchers and seed suppliers, who face authorisation requirements, without imposing corresponding constraints on material entering through commercial or informal channels. This asymmetry between regulatory burden and regulatory effect strengthens the practical case for convergence.

External Market Signals

Regional policy development occurs against a shifting external regulatory environment that affects the calculus of East African exporters. The European Union, historically the most restrictive major jurisdiction and an important destination for regional horticultural and legume exports, completed a substantial reform of its treatment of products obtained through new genomic techniques during 2025 and 2026. The resulting regulation establishes two categories, under which plants considered equivalent to conventionally bred varieties follow a simplified pathway while others remain subject to the existing framework for genetically modified organisms. The regulation was adopted by the Council in April 2026 and approved by the Parliament in June 2026, with application anticipated from the middle of 2028 (Council of the European Union, 2026; European Parliament, 2026).

This development materially alters the export risk calculation that has historically supported restrictive positions in several regional jurisdictions. Concern that edited products might jeopardise access to European markets constituted a substantial and defensible argument while the destination market treated all such products as genetically modified organisms. That argument weakens considerably once the principal destination market adopts a differentiated approach that broadly resembles the approach already taken by Kenya and Ethiopia.

The regulatory approaches adopted across major agricultural producing and consuming

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

jurisdictions have converged appreciably over the past several years, with an increasing number of countries exempting edited products that retain no transgene (Buchholzer and Frommer, 2023). East African jurisdictions that retain undifferentiated treatment therefore occupy an increasingly unusual global position, and one that is progressively harder to justify on export protection grounds. The external environment consequently favours regional convergence at a level of stringency close to that already adopted by the region's two guideline issuing jurisdictions.

POLICY PATHWAYS AND RESEARCH PRIORITIES

Five policy pathways follow from the analysis, ordered by the ratio of expected benefit to institutional cost. The first is guideline development ahead of statutory amendment in jurisdictions holding operative statutes. Rwanda occupies the most favourable position for this step, since its statute is recent, its competent authority is functioning, and its research portfolio is active (Rwanda Environment Management Authority, 2025). An interpretive guideline modelled on existing regional instruments could be developed within an ordinary administrative cycle without recourse to parliamentary process.

The second pathway is the establishment of a technical working group under the auspices of the East African Community, convening national biosafety authorities together with technical experts from regional research institutions. Such a body would provide the institutional venue that regional biosafety coordination presently lacks entirely, and its initial mandate could be limited to information exchange and the development of common terminology. Modest early mandates of this kind have historically proved more durable than ambitious ones in regional integration contexts.

The third pathway is the development of a shared dossier repository holding molecular characterisation data, risk assessment documentation, and determination records for products considered anywhere in the region. Such a repository would reduce duplicated technical effort substantially, which matters particularly for authorities operating with constrained reviewer availability. It would also generate the accumulated familiarity on which any subsequent mutual recognition arrangement would necessarily depend.

The fourth pathway is deliberate integration of biosafety determinations with variety release procedures. A determination that a product falls outside biosafety scope should trigger entry into national performance trials rather than initiating a separate administrative sequence, and regional catalogue listing should follow release on the same terms applicable to conventional varieties. The fifth pathway is sustained public engagement organised around the specific crops and constraints that regional editing programmes address, since evidence indicates that concrete benefit framing shapes attitudes more effectively than abstract technology advocacy (Atimango et al., 2024; Gbadegesin et al., 2022).

Four corresponding research priorities follow from the pathways identified above. Ex ante economic assessment of edited products addressing regionally significant constraints would supply the benefit estimates that policy deliberation presently lacks. Farmer and consumer evaluation studies conducted within the region would replace inference from studies conducted predominantly in high income settings. Assessment of national analytical capability for detection would establish whether enforcement of any authorisation requirement is feasible in practice. Comparative analysis of liability design would identify provisions that allocate risk defensibly without extinguishing research activity altogether.

Limitations

Three principal limitations qualify the conclusions presented in this review. The first concerns the currency of documentary evidence in a domain where positions change rapidly and where administrative decisions are not always published promptly or in accessible form. Regulatory positions described here reflect the documentary record available to the middle of

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Vol. 2, Iss. 1 (2026)
Pages: 52-70
Doi: 10.65965/sentam.202608.jaxro3PQ

2026, and subsequent developments may have altered the position of individual jurisdictions.

The second limitation concerns pronounced evidential asymmetry across the jurisdictions examined. Kenya, Uganda, Tanzania, and Ethiopia are represented substantially in the peer reviewed literature, whereas Burundi, South Sudan, Somalia, and to a lesser extent the Democratic Republic of the Congo are documented principally through continental survey instruments and administrative reporting. Characterisation of the latter group therefore rests on a thinner evidential base and should be treated as provisional.

The third limitation concerns the properties of the proposed framework itself. Tier assignment reflects documented legal and institutional characteristics rather than measured regulatory performance, and no attempt has been made to validate the ordering empirically against outcomes such as approval duration or research investment. The framework is offered as an organising structure for comparative analysis and policy sequencing, not as a validated measurement instrument, and its propositions concerning transition preconditions remain open to empirical testing.

CONCLUSION

Genome editing has advanced across East African research institutions to a point at which the principal constraint on deployment is regulatory rather than scientific. Laboratories in the region have developed editing platforms for banana, cassava, sorghum, maize, and teff, addressing constraints that have resisted conventional improvement across several decades of effort. The translation of that capability into varieties available to farmers depends upon regulatory arrangements that differ profoundly across a set of states committed to substantially free internal movement of agricultural goods.

This review has documented a five-position gradient across the region, extending from the absence of any operative biosafety statute through administrative suspension to published product-based exemption guidelines. Kenya and Ethiopia have issued instruments that exempt products retaining no foreign genetic material from full biosafety review. Rwanda possesses a recent statute without differentiated treatment of edited products. Tanzania maintains an operative but dormant framework, and Uganda has conducted biotechnology research for approximately three decades without an assented statute.

The Tiered Biosafety Convergence Framework organises these positions into an ordered classification and specifies the legal, institutional, and political preconditions associated with movement between adjacent tiers. Its central proposition is that these preconditions operate conjunctively, so that progress requires joint rather than partial satisfaction. Its central practical implication is that regional convergence should be pursued as sequential national ascent culminating in mutual recognition, rather than as simultaneous statutory reform across all partner states.

Two features of the current policy environment nevertheless favour continued progress. Continental guidance has produced substantive convergence in the content of national guidelines even without any binding instrument, which establishes a foundation for eventual recognition arrangements. The principal external export market has adopted a differentiated approach to products obtained through new genomic techniques, which weakens the export protection argument that has historically supported restrictive regional positions. Whether these favourable conditions are converted into regulatory progress will depend upon decisions taken within national authorities, and upon the willingness of the regional institutions to supply the coordinating venue that biosafety governance in East Africa presently lacks.

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Pages: 52-70
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rwandas-biosafety-regulatory-system-and-advances-regulations

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