

GENOME EDITING IN ETHIOPIA

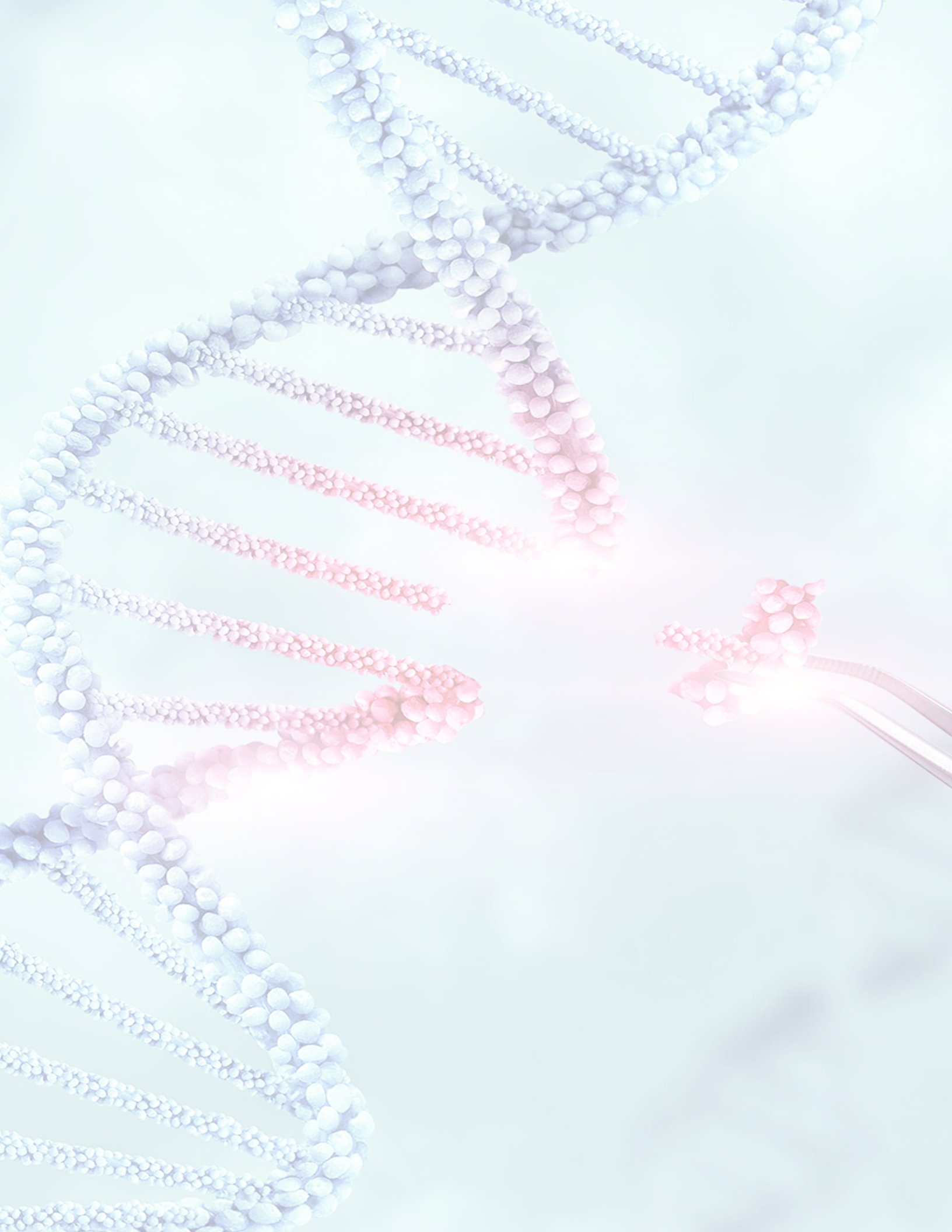
THE STATE OF GENOME EDITING IN ETHIOPIA

BETin BIO & EMERGING TECHNOLOGY INSTITUTE

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Acronyms

AAU	Addis Ababa University
AATF	African Agricultural Technology Foundation
ABE	Adenine Base Editor
ABS	Access and Benefit Sharing
ADLI	Agricultural Development–Led Industrialization
AfriSCI	African Science, Technology and Innovation Dialogue
AIA	Advance Informed Agreement
ALLEA	All European Academies
AUDA-NEPAD	African Union Development Agency – New Partnership for Africa's Development
BBNBT	Better Barley by New Breeding Techniques
BETin	Bio and Emerging Technology Institute
BL2 / BSL-2	Biosafety Level 2
Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
CBE	Cytosine Base Editor
CDA	Confidential Disclosure Agreement
CFT	Confined Field Trial
CGIAR	Consultative Group on International Agricultural Research
CPB	Cartagena Protocol on Biosafety
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRISPR-Cas9	CRISPR-associated protein 9
DNA	Deoxyribonucleic Acid
DSB	Double-Strand Break
DUS	Distinctness, Uniformity, and Stability
EAA	Ethiopian Agricultural Authority
EBI	Ethiopian Biodiversity Institute
EBW	Enset Bacterial Wilt
EFDA	Ethiopian Food and Drug Authority
EIAR	Ethiopian Institute of Agricultural Research

EIPA	Ethiopian Intellectual Property Authority
ELISA	Enzyme-Linked Immunosorbent Assay
EPA	Environmental Protection Authority (Ethiopia)
EPHI	Ethiopian Public Health Institute
EPO	European Patent Office
ES	Ethiopian Standard
FAO	Food and Agriculture Organization of the United Nations
FDRE	Federal Democratic Republic of Ethiopia
FGD	Focus Group Discussion
GE	Genetically Engineered
GEd	Genome Editing
GET-UP	Genome Editing in Tef for Uplifting Productivity
GMOs	Genetically Modified Organisms
HLIs	Higher Learning Institutions
ICGEB	International Centre for Genetic Engineering and Biotechnology
ILRI	International Livestock Research Institute
IoB	Institute of Biotechnology
IP	Intellectual Property
IPRs	Intellectual Property Rights
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LMO	Living Modified Organism
MAS	Marker-Assisted Selection
MinT	Ministry of Innovation and Technology
MoA	Ministry of Agriculture
MSc	Master of Science
MTA	Material Transfer Agreement
NAHDIC	National Animal Health Diagnostic and Investigation Center
NAIC	National Artificial Insemination Center
NABRC	National Agricultural Biotechnology Research Center
NBT	New Breeding Technique

NBAC	National Biosafety Advisory Committee
NGO	Non-Governmental Organization
NGT	New Genomic Technique
NPTCP	National Priority Technology Capability Program
NVI	National Veterinary Institute
OECD	Organization for Economic Co-operation and Development
PASDEP	Plan for Accelerated and Sustained Development to End Poverty
PCR	Polymerase Chain Reaction
PE	Prime Editing
PIP	Plant-Incorporated Protectant
PPP	Public–Private Partnership
QTL	Quantitative Trait Loci
RARIs	Regional Agricultural Research Institutes
SDN	Site-Directed Nuclease
SDN-1 / SDN-2 / SDN-3	Site-Directed Nuclease Categories 1, 2, and 3
SEQART	Sequencing Africa
SLU	Swedish University of Agricultural Sciences
SNP	Single Nucleotide Polymorphism
SPS	Sanitary and Phytosanitary
SSSfA	Striga Smart Sorghum for Africa
STI	Science, Technology and Innovation
TALEN	Transcription Activator-Like Effector Nuclease
TELA	Transgenic Enhanced Livelihoods in Africa
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WEMA	Water Efficient Maize for Africa
WIPO	World Intellectual Property Organization
ZFN	Zinc Finger Nuclease

Executive Summary

The State of Genome Editing in Ethiopia

Genome editing is emerging globally as a transformative technology capable of accelerating agricultural innovation while maintaining high standards of biosafety, environmental protection, and food safety. For Ethiopia, where agriculture underpins food security, livelihoods, export earnings, and industrial development, genome editing presents a timely and strategic opportunity to address persistent productivity constraints, climate-related stresses, and limited genetic improvement options for indigenous and orphan crops.

This report assesses Ethiopia's preparedness for genome editing across four interrelated dimensions: (i) policy, legal, and regulatory frameworks; (ii) institutional and human capacity; (iii) research and development status; and (iv) ethical, social, and public perception considerations. The assessment draws on desk reviews, stakeholder consultations, institutional surveys, and validation workshops involving key public agencies, research institutions, universities, and development partners.

The findings indicate that Ethiopia has established a credible and forward-looking policy and regulatory foundation for genome editing. The evolution of the national biosafety framework, particularly following the Biosafety (Amendment) Proclamation No. 896/201, has enabled the practical conduct of modern biotechnology research while maintaining alignment with international obligations under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

The recently developed guideline for the regulation of genome-edited plants adopts a case-by-case, risk-proportionate approach and positions Ethiopia among the leading African countries proactively preparing for genome editing applications. Institutionally, Ethiopia benefits from a multi-actor governance system involving the Environmental Protection Authority, sectoral ministries, specialized research institutes, and advisory bodies. The presence of the National Biosafety Advisory Committee and established permitting procedures provides a solid basis for science-based regulatory decision-making. However, the assessment identifies capacity gaps

related to staffing, specialized training, and operational experience with genome-edited products, particularly at the implementation and monitoring stages.

In terms of research and development, Ethiopia has made notable progress in building foundational genome editing capacity, especially within the Ethiopian Institute of Agricultural Research and selected universities. Ongoing research targets priority crops central to food security and industrialization, including tef, sorghum, wheat, barley, Ethiopian mustard, and enset. These initiatives demonstrate proof of concept and contribute to national learning-by-doing. Nonetheless, end-to-end genome editing pipelines remain incomplete, infrastructure is unevenly distributed, and advanced R&D activities continue to rely heavily on external funding and international partnerships.

Ethical, social, and public perception considerations emerge as critical determinants of successful genome editing deployment. While ethical risks associated with plant genome editing are broadly comparable to those of conventional breeding when no foreign DNA is introduced, public understanding of biotechnology remains limited. Experience from previous biotechnology introductions in Ethiopia suggests that acceptance depends on transparent regulation, demonstrated public benefit, and trust in public institutions. Strengthening science communication, stakeholder engagement, and ethical oversight mechanisms is therefore essential.

Overall, the assessment concludes that Ethiopia is moderately well prepared to advance genome editing from research toward responsible application, provided that targeted investments and institutional strengthening measures are implemented. Key priorities moving forward include reinforcing regulatory implementation capacity, investing in shared research infrastructure, integrating genome editing into national breeding programs, enhancing ethical and public engagement frameworks, and promoting regional and international collaboration.

With deliberate, phased, and well-governed action, genome editing can become a strategic tool supporting Ethiopia’s goals of food security, climate resilience, and sustainable bio-based industrial development.

Chapter 1. Introduction

1.1. Background and Significance

Agriculture is the backbone of the Ethiopian Economy and it contributes about 50% of the country's gross domestic product (GDP) and more than 80% of its exports. Furthermore, it is one of the main employment sectors with about 80% of the country's population depending on the agricultural sector for their livelihoods (Temesgen *et al*., **2009**). The agricultural sector of Ethiopia is dominated by smallholder farming. Smallholder farms are farmers that own less than two hectares of farmland and are mainly managed by family labor (Stellmacher and Kelboro, **2019**).

Endowed with its wide ranges of agro-ecological diversity, Ethiopia harbors huge floral, faunal and microbial diversities which resulted in diversified agricultural systems. In Ethiopia, about 95% of main crops (e.g., cereals, pulses, oilseeds, vegetables, root crops, fruits, and cash crops) are produced by smallholder farms (Stellmacher and Kelboro, **2019**). The major agricultural export crops are coffee, oil seeds (Niger seed, Linseed, and Sesame), pulses and cotton. In recent years, floriculture development has been significantly contributing to the economy of the country. Furthermore, semi- and fully-processed hides and skins are major traditional export goods derived from animals.

Ethiopia's agriculture is under mounting pressure from climate change (temperature rise, erratic rainfall, land degradation), major biotic constraints (parasitic weeds such as *Striga* and fungal rust diseases on wheat), and persistent low productivity of key staples crops. Other factors compounding the challenges include fast population growth, absence of formal seed system, lack of agricultural inputs such as quality seeds, fertilizers and pesticides; low income of the farmers coupled with lack of financial credit system (Njeru *et al*., **2016**; Stellmacher and Kelboro, **2019**; Imonikhe, **2024**). Smallholder farmers with limited resources have difficulties overcoming these challenges.

The severity of the challenges posed by few biotic stresses to Ethiopian agriculture are elaborated by the examples given below.

Striga commonly called Witchweed (*Striga hermonthica)* and related species are parasitic weeds affecting cereals (maize, sorghum, millet) across diverse Ethiopian regions. Surveys and studies

show widespread presence in sorghum- and maize-producing zones (Degbessa *et al*., **2022** and references therein). Striga infestations result in yield losses that vary widely, commonly 30-100% in heavily infested fields; reduced plant vigor, and competes with the crop for water and nutrients. Economic impact assessments in Ethiopia indicate serious threats to livelihoods in affected woredas. Striga poses management challenges as control is difficult because it forms long-lived seedbanks. The currently available control options require integrated application, and adoption is limited by knowledge, seed systems, and cost.

Rust disease in wheat and barley, caused by *Puccinia* species is another threat that results in huge crop loss. Its outbreaks could cause sharp yield losses and threaten national-rehabilitation of wheat sectors. Overcoming this challenge requires effective rust management including routine surveillance, early warning, resistant cultivars, seed systems, and affordable fungicide to which smallholder farmers in Ethiopia have poor access.

Bacterial wilt disease caused by *Xanthomonas* spp is another economically important disease. It affects the multi-purpose crop enset (*Ensete ventricosum* ("false banana") which serves tens of thousands of people in the southern and southwestern parts of Ethiopia. Because enset is central to local food systems and drought resilience, Enset Bacterial Wilt (EBW) outbreaks erode a vital climate-resilient food source and require urgent integrated management (Negash *et al*., **2023**).

These combined threats reduce food security, increase vulnerability to shocks, and limit economic development unless addressed through coordinated adaptation, research, and extension measures (World Bank, **2021**). Therefore, appropriate management practices are urgently needed to resolve the constraints and to increase crop production without altering its potential for future generations. Biotechnology can be a key tool to meet the above and unleash the untapped biological resources in Ethiopia without affecting human and animal health and the environment. Therefore, the proper application of biotechnology offers sustainable solutions supporting almost all aspects of the nation's development agenda.

1.2. The role of Biotechnology for Food Security and Industrialization

In the past few decades, the Ethiopian government designed development strategies and policies such as Agriculture Development-Led-Industrialization (ADLI), Plan for Accelerated and

Sustained Development to End Poverty (PASDEP). Particularly, ADLI has been implemented since 1994 built on the development theories in which smallholder-agriculture needs to be advanced first to facilitate demand for industrial commodities and inputs for labor intensive industrialization (World Bank, **2016**).

Currently, the Government of Ethiopia has launched and is implementing a comprehensive and well-coordinated homegrown economic reform agenda with the goal to safeguard macro-financial stability and rebalance and sustain economic growth. The reform agenda builds on the achievements of the past decades in infrastructure and human capital developments. The primary objective of the agenda is to sustain economic growth through creating an environment supportive of accelerated private investment and structural transformation.

In line with the above development strategies, Biotechnology has long been recognized as one of the technologies in the forefront that could bring economic development in Ethiopia. Biotechnology is the manipulation of living organisms to create new products and/or processes. It has recorded tremendous success in various industries (Cheng, **2018**; Tavakoli *et al*., **2021**) and is expected to achieve a steady increase in research and development (R&D) worldwide in the years to come in agriculture, health, industry, and environmental sectors.

Genetic modification is widely utilized internationally as a significant frontier technology in agriculture and biosciences. In 2023, 206 million hectares of genetically modified (GM) crops were cultivated in 30 countries worldwide, and a total of 75 countries and territories have authorized the utilization of GM products (Liu, **2025**). Recently, one of the most-game changing innovations in biotechnology is genome (gene-) editing. Genome editing is a new breeding technique that allows scientists to improve the characteristics of living organisms, including plants, animals, and microbes (Chen and Gao, **2013**; Cheng, **2018**). Some of the salient benefits are mentioned below.

In agriculture, by manipulating the genetic makeup of crop plants, researchers have become capable of developing crop varieties that are resilient to environmental stresses such as drought (maize, sorghum, etc.), shattering (soybean), lodging (tef), soil acidity (wheat) and extreme temperature. This is very essential for meeting the food demand of a growing population. The technology also plays a role in the development of crops that are resistant to pests and diseases.

This gradually reduces the dependency on chemical pesticides, which have indirect effects on the environment. For example, crops like *Bt* cotton, *Bt* maize, *BtGt* maize, etc were developed to express proteins that are toxic to specific pests, leading to less crop losses and reduced pesticide usage.

Biofertilizers are currently produced from living organisms like nitrogen-fixing bacteria offering a more sustainable alternative as opposed to using chemical fertilizers that come with hefty environmental costs. Their application improves soil health and nutrient availability for plants.

In Ethiopia, while advances have been made in biotechnology and biosafety regulation, there has yet to be a comprehensive assessment of the country's readiness to move genome-edited products from research laboratories to commercialization following appropriate regulatory approvals. This study aims to fill that gap by generating an evidence-based assessment to guide policy, investment, and institutional strengthening.

1.3. Objectives

1.3.1. General objective

The main objective of this study was to assess Ethiopia's readiness for genome editing in terms of human resource, laboratory infrastructure, enabling policy environment and functional biosafety regulatory frameworks.

1.3.2. Specific objectives

- Conceptualize GEd in the Ethiopian Context
- Analyze the Policy and Regulatory Architecture for Genome Editing
- Map Academic and Research Capacity in Genome Editing
- Conduct Inventory and Evaluate current R&D Projects
- Assess Socio-Ethical Dimensions and Communication Strategies
- Develop IPR and Commercialization Framework
- Conduct Comprehensive Readiness Assessment
- Generate Strategic SWOT Analysis
- Formulate Actionable Recommendations for safe and effective use of GEd technology

Chapter 2: Concept and Rationale for Genome Editing

2.1 The Science of Genome Editing (GEd)

Genome Editing is a method of making specific changes to the DNA of a cell or organism. Conceptually, Genome Editing gives scientists the ability to change the genome of an organism. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome of an organism (Okita and Delseny, **2022**) and they have brought dramatic changes in many fields of research including plant sciences due to increased availability of nucleases in the public and commercial sources.

Genome editing relies on two aspects, the cutting phenomenon - performed artificially, and the repair mechanism, which is realized naturally. Various gene editing techniques exist, all of which are based on the use of enzymes called "nucleases" that directly interact with the DNA in a cell. Nucleases can be repurposed to specifically target a defined site within the genome. There are several approaches of site-directed nucleases including zinc finger nuclease (ZFN), transcription activator-like effector nuclease (TALEN) and clustered regularly interspaced short palindromic repeat (CRISPR)-associated proteins 9 (CRISPR-Cas9) (Wada *et al*., **2022;** Genetu et al., **2025**).

Precise genome editing was first demonstrated with the use of zinc finger nucleases (ZFN) in the 1980s. ZFNs contain a nuclease domain and specific zinc finger DNA-binding domains that recognize three-base pair sites on DNA. Multiple ZFNs can combine to form dimers. The dimerization process permits to recognize longer nucleotide sequences, amplify the specificity, and improve the adaptation to the target (Carroll, **2011**). While ZFNs had paved the way for precision genome editing, around 2011, transcription activator-like effector nucleases (TALENs) brought the recognition down to the single-nucleotide resolution. TALENs also contain a nuclease fused to a DNA-binding domain sequence but they are capable of single-nucleotide recognition, thereby increasing targeting capabilities and specificity compared to ZFNs. One of the main drawbacks of platforms such as ZFNs and TALENs is the requirement of designing and validating a new zinc-finger nuclease or TALEN protein for each new target editing site (Boch *et al*., **2009**).

An important step for genome engineering was achieved in 2012 with the discovery of the Clustered Regularly Interspaced Short Palindromic Repeats–CRISPR technology (Cong *et al*., **2013**). The technology is based on a guide RNA and the Cas9 endonuclease**;** the guide RNA recognizes target sites and the Cas9 endonuclease cuts and triggers the repair mechanism. The emergence of CRISPR-Cas9 and the relative ease, flexibility and efficiency of the technique has opened new avenues for precise genetic modifications enabling researchers to produce crops with desirable traits (Jinek *et al*., **2012**, ALLEA, **2020**; Thangaraj *et al*., **2025**).

The CRISPR-Cas-based technologies are currently evolving, Base-editing being the newest addition which is applied to directly install point-mutations in cellular DNA without inducing a double-strand DNA break (DSB). Two classes of DNA base-editors have been described thus far, cytosine base-editors (CBEs) and adenine base-editors (ABEs). Recently, prime-editing (PE) has further expanded the CRISPR-base-edit toolkit to all twelve possible transition and transversion mutations, as well as small insertion or deletion mutations (Kantor, 2020).

2.2 Advantages of Genome Editing Technologies

Unlike traditional genetic engineering techniques, which often involve the insertion of foreign DNA into an organism's genome, genome editing allows scientists to make precise modifications to the existing DNA sequence. The technology can be used to introduce desirable traits into crops without introducing unwanted traits or disrupting existing genes (Chen *et al*., **2019**; Abdelrahman, *et al*., **2021**).

Another advantage of genome editing is its efficiency. Traditional breeding methods can take many years to develop new crop varieties with desirable traits. In contrast, genome editing can produce changes in the DNA sequence in a matter of weeks or months. This speed and efficiency mean that genome editing can be used to rapidly develop new crop varieties that are better adapted to changing environmental conditions, such as drought or disease resistance.

Classical breeding often encounters the problem that a favorable trait is closely linked to a negative trait where in some cases they co-segregate and are inherited together. Genome editing can help to disable the unwanted genetic trait (ALLEA, **2020**). There is consensus among experts that GEd enhances agronomic performance and product quality of crops compared to those

developed through genetic modification and conventional breeding (Lassoued *et al*., **2019**). The majority of experts indicated that genome editing enables faster trait development, lower R&D costs, and trait innovation (Kalaitzandonakes, *et al*., **2019**).

2.3 Possible Risks of Genome Editing

Genome edited crops are becoming widely developed to address climate change, food security, nutrition and health, environmental sustainability and diversification of agriculture. However, there are also concerns about anticipated risks. Analysis of risks of genome edited crops indicates that the scientific risks are comparable to those of accepted, past and current breeding methods (Pixley *et al*., **2022**).

The risks of genome edited crop varieties should be considered alongside their benefits, and in the context of plant breeding. Traditional conventional breeding is not free of risks, such as unintended increased levels of toxic alkaloids in faba bean and potato, introduction of disease susceptibility, or the reduction of protein content when breeding for increased grain yield. Secondly, mutations occur spontaneously with every generational advance, giving rise both to favorable and unfavorable alleles that drive natural selection for fitness and enable farmer- and consumer-guided selection for preferred traits. These risks provide a baseline and context to assess the risks of genome-edited plants (Pixley *et al*., **2022**).

Continuous improvement in the bioinformatic tools and approaches used to design genome editing targets are also being employed to mitigate and reduce the likelihood of occurrence of non-target edits in crop plants. Much effort has been invested to develop robust assays for mutations, and to understand the frequency and nature of non-target site mutations resulting from CRISPR technology (Young *et al*., **2019**).

2.4 Product vs Process based Regulation of Genome Editing

Genome editing tools are generally characterized by site directed nucleases (SDNs), indicating the use of a DNA cutting nuclease for the generation of site-specific (or site directed) DNA break. There are three categories of SDN: SDN-1, SDN-2 and SDN-3, depending on the outcome of the DNA double-strand break repair (Friedrichs *et al*., **2019a**). Plants developed through SDN-1 and SDN-2 applications are comparable to plants generated by classical mutagenesis techniques which have a long history in production of improved crop varieties. The advantage of

SDN-1 and SDN-2 applications compared to classical mutagenesis is its precision to create a product with the desired variation. Once the product is identified, crossing and segregation is employed to select for plants that only contain the desired changes. The product then serves as donor material for elite plant variety development through classical breeding.

The SDN-3 is beneficial for stacking several traits (genes) together so that they are inherited as a single genetic locus. This helps avoid several years of trait introgression processes and enables efficient incorporation of traits into elite lines for the development of new varieties. The most likely application of SDN-3 would be the insertion of cisgenic, intragenic, or transgenic expression cassettes at a selected genome location offering reduced regulatory oversight compared to traditional transgenic products.

There are two main regulatory approaches to the governance of genome editing presented during the OECD 2018 Paris, process vs product triggered regulatory system (Friedrichs *et al*., **2019b**). This distinction represents a central debate in the governance of genome editing (Rios *et al*., **2025**). In a process-based regulatory system, oversight is typically triggered by the use of recombinant DNA technology, rather than by the properties of the resulting organism. A key assumption of a process-based approach is that products made using the regulated process are fundamentally different or more risky than similar products made using other methods (Breyer *et al*., **2009**). On the other hand, product-based regulation focuses on the characteristics of the final organism itself, regardless of the method used to generate it (Marchant and Stevens, **2015**).

Most scientific institutions in Canada, the US and some EU nations were prompted to advocate for product-based, evidence-driven governance to encourage innovations (Sprink *et al*., **2016;** Glenna, 2023; Rios et al., 2025). Since genome edited products (SDN1 and SDN2) are comparable to natural genetic changes occurring through mutations, recombination, or horizontal gene transfer. From a biosafety perspective, risk estimates genome edited products should thus align with those for naturally occurring variation or conventionally bred plants. This challenges the rationale for process-based regulation of genome edited products. Moreover, enforcement of process-based regulations becomes technically unworkable because it is not possible to determine the techniques by which a product was generated.

Genome editing regulations vary considerably among regions, such as the European Union, Africa, Asia, and Latin America (Entine *et al*., **2021**). In the European Union, genome-edited organisms are classified as GMOs and patenting of New Genomic Techniques (NGTs) plants was banned by the European Parliament in 2024 (Jiang, **2025**). However, more flexible regulatory approaches have been adopted in Asian countries, such as China and India. China's framework prioritizes food safety and environmental impact assessments. India has adopted a flexible regulatory approach, excluding products developed through SDN1 and SDN2 being classified as GMOs, provided they do not contain foreign DNA. These products are exempt from biosafety assessments allowing them to be treated as conventional crops. On the other hand, regulations in some countries in Latin America establish prior consultation on whether a product derived from NBTs will be considered conventional or transgenic. The final product is classified as a conventional product if it does not contain foreign DNA or introduce a novel genetic combination (Rios *et al*., **2025**).

The lack of international harmonization between these two regulatory approaches creates a complex landscape for the development and international trade of gene-edited agricultural products. Many countries are now moving toward more adaptive, risk-proportional, case-by-case regulatory frameworks that combine elements of both approaches (Wolt et al., **2015**). A survey on expert opinion has concluded that product-based models or dual-product/process systems are viewed as potential appropriate frameworks to regulate outcomes of genome editing (Lassoued *et al*., 2020).

2.5 Rationale for Genome Editing Applications in Agriculture

Genome editing techniques are promising tools in plant and animal breeding. These techniques have applications in diverse plant and animal species to generate various site-specific genome modifications using targeted mutagenesis and editing for varied agricultural applications. Through these techniques, scientists can discover novel traits, expand the range of traits, preserve niche or orphan crops, and accelerate trait development in target crops and animals that are essential for food security. Globally, products developed using GEd tools involve various categories of traits including: increased plant yield and growth, increased food and feed quality, biotic and abiotic stress tolerance, industrial utilization, herbicide tolerance, product color/flavor and storage performance (Thangaraj *et al*., **2025**)

This sub-section highlights the existing opportunities towards harnessing these techniques to target traits that will boost crop and animal productivity and resilience to climate change and redesign the future of agriculture and food security. Notably, some of these crop improvements have been commercialized and others are at advanced stages of product development. CRISPR/Cas has been used to genetically edit many crops including rice, maize, wheat, soybean, barley, sorghum, potato, tomato, flax, rapeseed, Camelina, cotton, cucumber, lettuce, grapes, grapefruit, apple, oranges, and watermelon (Malzhan *et al*., **2017**; Zhang *et al*., **2018**; Menchaca *et al*., **2020**) where a few have already been commercialized.

Likewise, GEd techniques such as CRISPR/Cas9 have been used to efficiently and precisely develop genome-edited animals. Successful genome editing has been reported in cattle, sheep, goats, pigs, horses, and fish among others (Menchacaa *et al*., **2020**). However, animal welfare should be pursued when dealing with animals to promote ethical research when carefully choosing useful traits for economic advancement.

In the context of climate resilience, the strategic rationale for GEd is based on the urgent need to develop crops that can withstand the stresses induced due to climate change. This includes enhancing drought tolerance, heat tolerance, soil acidity tolerance, and improved nutrient use efficiency (Zhang *et al*., **2018**). GEd technology allows for targeted modifications of plant DNA, enabling the development of crops' capability to thrive in changing climates, ensuring food security and sustainable agriculture.

Over all, the strategic rationale for genome editing in enhancing economic competitiveness is multifaceted and it has the potential to:

- Enhance Economic Competitiveness by reducing reliance on imported seed/inputs and positioning Ethiopia in the global bio-economy.
- Accelerate the development of novel traits not possible through traditional crop improvement methods, leading to faster trait development and lower research and development time and costs.
- Increase productivity and broaden the scope of crop improvement, with potential outsized economic effects.

- Improve the efficiency of genetic engineering, which is crucial for the commercialization of gene edited organisms and their application in agriculture.
- Enhance the regulatory policy environment, which is still emerging in Ethiopia, to shape the innovation path of genome editing and its overall socioeconomic benefits.

Chapter 3. Methodology and Approach

The report was based on mixed-method approach, combining desk review, and stakeholder consultation, and capacity assessment.

3.1 Desk Review

A thorough review of the trends in biotechnology development at a global, regional and national level was made to get a good insight and identify gaps in the Ethiopian context. Emphasis was made on the status of Genome Editing (GEd) research and development at higher learning and research institutes in the country. In relation to the above, a systematic evaluation of Ethiopia's regulatory and policy frameworks was conducted in relation to international best practices.

The desk review was mainly focused on the following:

- Analyze national biotechnology and biosafety policies, institutional mandates, and relevant legislation.
- Review global best practices from countries advancing genome editing governance.
- Synthesize lessons applicable to Ethiopia.

3.2 Stakeholder Engagement Strategy

Stakeholders were categorized into:

- Policy and Regulatory Institutions: BETin, EPA, EFDA, Ministry of Agriculture, Ministry of Innovation & Technology.
- Research and Academic Institutions: EIAR, BETin, EPHI, major universities (AAU, JUCAVM, MU, HU, etc.).
- Private Sector and Industry: Seed companies, biotech startups, and laboratories.
- International Partners: AUDA-NEPAD, ICGEB, and FAO representations.

To collect data on stakeholder engagement tools employed included semi-structured interviews, focused group discussion (FGD), key informant interview and targeted surveys.

A 1–5 rating scale was used for each readiness dimension (Awareness, Institutional Role, Capacity, and Policy Preparedness)

3.3 Capacity Assessment

The overall "**Capacity Assessment**" was made through engagement with government institutions, regulatory authorities, research institutes, universities, and private sector actors. It also focused on collecting perspectives regarding institutional, technical, and regulatory readiness. Thus, the assessment was guided by a **Readiness Index**, covering three major pillars structures around:

1. **Institutional Capacity:** Mandates, coordination, experience, and strategy.
2. **Technical and Infrastructure Capacity:** Laboratory facilities, genome-editing tools, data management, and biosafety levels.
3. **Human Capacity:** Number and expertise of molecular biologists, genome editors, and regulatory specialists.

3.4 Regulatory and Policy Review

- Assess existing biosafety and biotechnology regulations vis-à-vis genome editing.
- Identify alignment gaps and areas requiring amendment or new guidance.
- Benchmark Ethiopia's regulatory readiness against international frameworks.

3.5 Data analysis

The data collated from desk review as well as the survey (self-administered questionnaires, interviews, Focused Group Discussions (FGD); visits to laboratory and greenhouse facilities and regulatory agencies) was carefully organized, analyzed and interpreted quantitatively and/or qualitatively, as appropriate for the report on "Assessment of Ethiopia's Readiness for Genome Editing/State of Genome Editing R&D in Ethiopia.

3.6 Validation

Preliminary findings were presented in a **stakeholder validation workshop** before final report preparation. Representatives were from universities, research institutions, competent regulatory authorities, and policy institutions.

Chapter 4. Results of the Assessment

4.1 Institutional Profile of Respondents

The study sample comprises respondents drawn from a wide range of institutions involved in policy, research, regulation, and development, reflecting the multidisciplinary nature of modern biotechnology including genome editing (**Figure1**).

The results show that research institutions constitute the largest share of respondents, accounting for 52.8% of the total sample. This is followed by respondents from academic and university institutions, who represent 30.2%. Together, these two groups account for more than four-fifths of the respondents, indicating a strong representation of knowledge-generation and research-oriented institutions. Smaller proportions of respondents were drawn from policy-making bodies, biosafety regulatory authorities, extension and development agencies, the private sector, non-governmental organizations (NGOs)/advocacy groups, media and communications, and other related institutions, each contributing a relatively modest share to the overall sample.

From a sampling and analytical perspective, the dominance of research and academic institutions suggests that the study primarily captures expert-driven perspectives grounded in scientific research, higher education, and evidence-based practice. This is particularly relevant for studies addressing complex issues such as agricultural innovation, technology adoption, and soil and water conservation, where technical knowledge and analytical capacity play a critical role. At the same time, the inclusion of respondents from policy, regulatory, extension, private sector, and civil society institutions enhances the diversity of viewpoints and allows the analysis to incorporate institutional roles related to governance, implementation, dissemination, and advocacy of the subject of this assessment - genome editing technology.

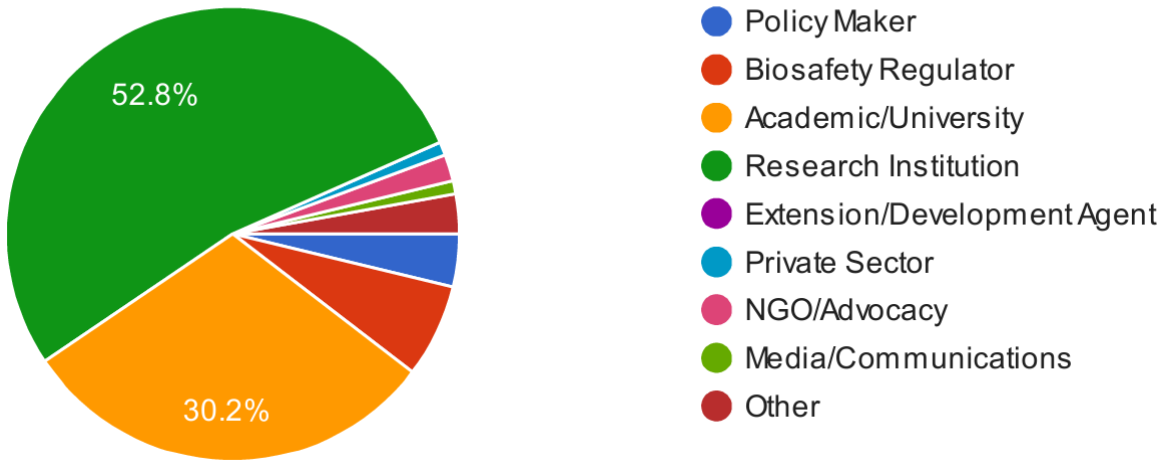


Figure 1. The institutional profile of respondents.

Overall, the institutional composition of the sample strengthens the credibility and analytical depth of the study by ensuring representation from both knowledge-producing and practice-oriented organizations. However, the relatively smaller representation of implementation-focused actors, such as extension agents and private sector stakeholders, should be considered when interpreting the findings, particularly with regard to on-the-ground adoption and scaling of technologies.

The survey respondents (**Figure 2**) were predominantly Researchers/Scientists**,** who constituted 63.2% of the total sample, indicating that the findings largely reflect perspectives from active research professionals. Lecturers/Faculty formed the second-largest group (11.3%), followed by Senior Leadership positions (7.5%). Technical Experts and Middle Management accounted for smaller but notable proportions, reflecting operational and managerial viewpoints within the respondent pool. The remaining categories Graduate Students, NBAC members, Senior Researchers, and Editors were represented at relatively low levels, each contributing marginal shares to the overall sample.

In general, the distribution suggests a strong research- and academia-oriented respondent base, with limited representation from regulatory, editorial, and senior research-only roles. This disparity in the composition of respondents was taken into account when determining the readiness index. .

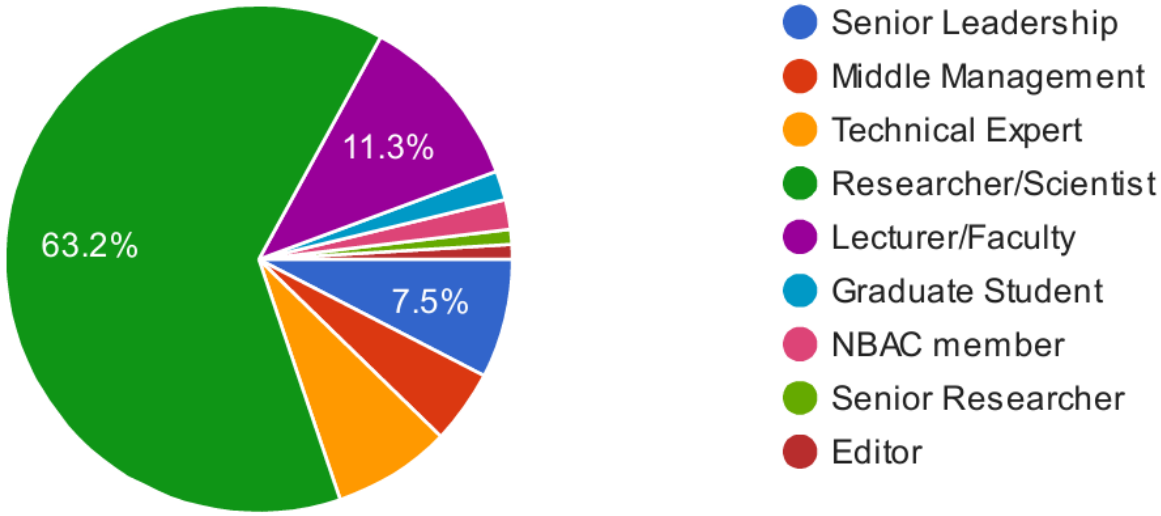


Figure 2. *Composition of respondents*

4.2 Policy, Legal, and Regulatory Landscape

4.2.1 National Biosafety Regulatory Framework

The Ethiopian Biosafety Law, Biosafety Proclamation No. 655/2009, was firmly based on the precautionary principle. However, the economic necessity to boost domestic production in high-demand sectors, such as cotton for the rapidly expanding textile industry, drove the adoption of the pivotal Biosafety (Amendment) Proclamation No. 896/2015. This amendment fundamentally altered the legal landscape by introducing a clear distinction between research and commercial release activities. To support the implementation of the revised proclamation, the Environmental Protection Authority has endorsed different directives, regulation and guidelines. Yet, with the coming of new breeding techniques such as Genome Editing, Synthetic Biology and Gene Drive, the biosafety framework has to evolve accordingly. This will ensure the country's preparedness for embracing new technologies that are highly valuable for sustainable economic development.

Figure 3 presents respondents' perceptions regarding whether Ethiopia currently has a legal framework that adequately governs genome editing. The results reveal mixed views among respondents, indicating uncertainty and divergence in stakeholder assessments of the existing regulatory environment.

A plurality of respondents **(**37.7%**)** indicated that Ethiopia does have a legal framework that adequately governs genome editing. However, a substantial proportion **(**30.2%**)** reported that the framework exists only partially, suggesting that while some regulatory elements may be in place, they are perceived as incomplete or insufficient. In contrast, 21.7% of respondents stated that Ethiopia does not have an adequate legal framework for genome editing, while 10.4% reported that they were not sure.

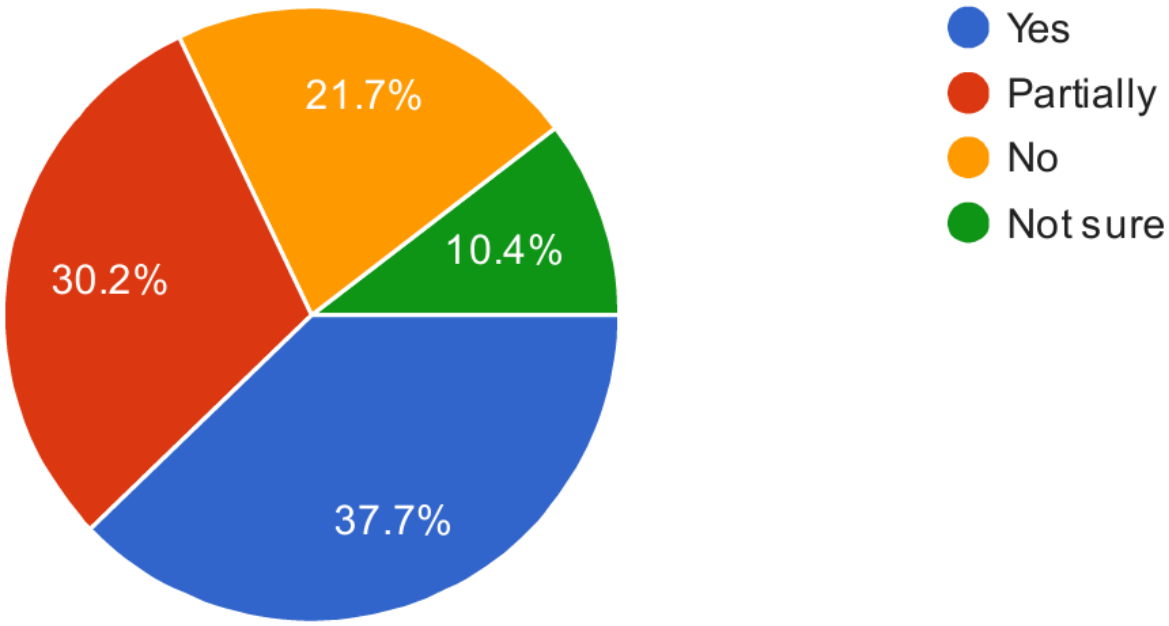


Figure 3. Adequacy of Ethiopia's current legal framework that governs genome editing.

The distribution of responses highlights a lack of consensus among stakeholders regarding the adequacy and clarity of the current legal and regulatory framework. Overall, the findings underscore the need for clearer, more comprehensive, and more widely communicated legal and regulatory frameworks to effectively govern genome editing in Ethiopia and to build confidence among stakeholders involved in research, policy, and implementation.

4.2.2 Institutional Governance of Genome Editing

Effective governance of genome editing requires clearly defined institutional roles, coordination mechanisms, and accountability across policy, regulatory, research, and legislative bodies. In countries where genome editing technologies are emerging, governance frameworks are often multi-layered and distributed across several institutions rather than centralized within a single

authority. Understanding stakeholder perceptions of institutional responsibility is therefore essential for identifying governance gaps, overlaps, and coordination challenges.

In this context, the study assessed respondents' views on which institutions are responsible for genome editing governance in Ethiopia. The results provide insight into how governance responsibilities are currently perceived and offer an empirical basis for developing an integrated genome editing governance framework.

Figure 4 presents respondents' perceptions of institutional responsibility for genome editing governance. The Environmental Protection Authority (EPA) was the most frequently identified institution, cited by 58.5% of respondents. This was followed by the Biotechnology Institute (BETin) (53.8%) and the Ethiopian Institute of Agricultural Research (EIAR) (48.1%). The Ministry of Agriculture (MoA) and the Ministry of Innovation and Technology (MinT) were identified by 31.1% and 28.3% of respondents, respectively. In contrast, Parliament or relevant standing committees and the Ethiopian Food and Drug Authority (EFDA) were each mentioned by only 16.0% of respondents.

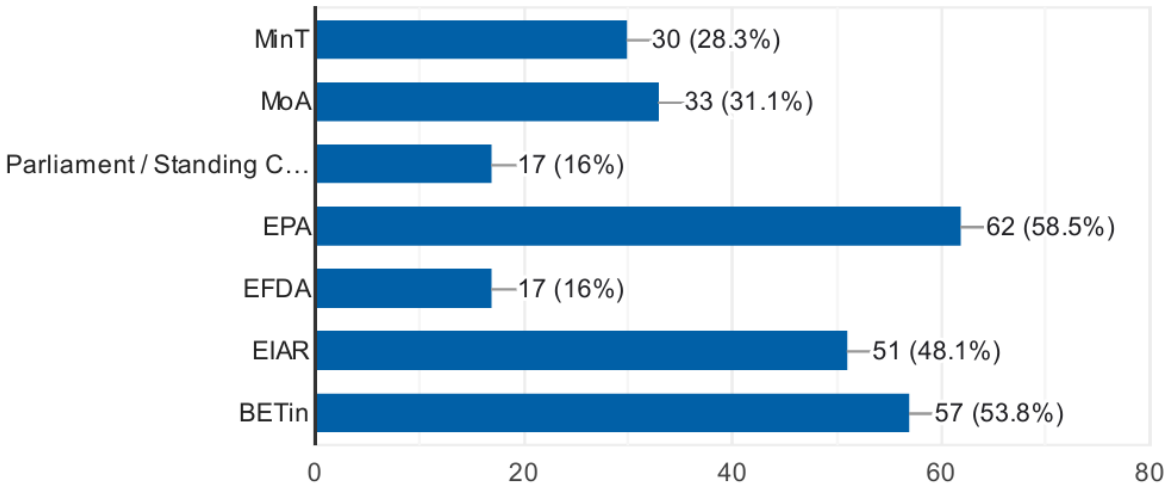


Figure 4. Respondents view of responsible institution(s) for genome editing governance

These results indicate that respondents largely associate genome editing governance with environmental regulation, biotechnology oversight, and agricultural research institutions, while legislative and food and drug regulatory bodies are perceived as playing a more limited role. However, the mandate of the regulation of Genome Editing is given to EPA according to

Biosafety (Amendment) Proclamation 968/2015 and this clearly indicates the level of awareness of the respondents. Yet, institutions like EFDA and MoA will have their own regulatory roles to play on aspects related to GEd-derived foods and Sanitary and Phytosanitary, respectively, after being permitted for environmental release by EPA.

4.2.3 International Obligations and Domestic Legal Overrides

Ethiopia is a party to the international instruments governing LMOs, having ratified the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB) in 2003. The domestic biosafety framework is structured to be in line with the CPB.

Furthermore, domestic legal safeguards are established through the Plant Breeder's Right Proclamation (No. 1068/2017). This law contains provisions that prevent the unrestricted commercialization of new varieties, including GE crops, by allowing the restriction of a Plant Breeder's Right if its exercise is likely to adversely affect public health, food security, biological diversity, the environment, or other matters of public interest.

While the 2024 Agricultural Policy guarantees Intellectual Property (IP) protection for agricultural innovators, the Plant Breeder's Right Proclamation ensures that this protection is not absolute. This mechanism confirms that biosafety and national public interest-concerns rooted in the original precautionary framework—are maintained as a higher legal priority than commercial IP rights in cases of conflict, reflecting a balanced regulatory approach designed to maintain national food sovereignty.

International R&D partnerships supporting genome editing in Ethiopia are present but largely underdeveloped (**Figure 5**). The predominance of weak-to-moderate collaborations suggests missed opportunities for technology transfer, advanced training, shared infrastructure, and co-funded research programs.

Respondents generally perceived international research and development partnerships in genome editing as limited in strength. Half of the respondents (50.0%) characterized partnerships as moderate, while a substantial proportion (41.2%) rated them as weak. Only a small minority reported strong or very strong partnerships, and very few indicated having no partnerships at all.

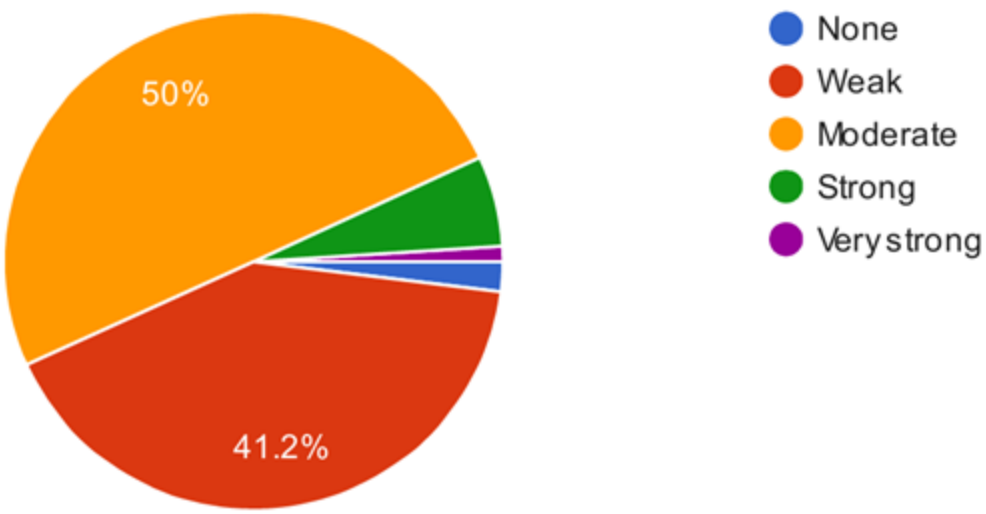


Figure 5. Status of international R&D partnerships

4.3 Institutional Role and Responsibilities

Regulatory readiness is supported by a multi-institutional framework with clearly defined roles spanning environmental protection, scientific advice, agricultural research, and market control.

4.3.1 Competent National Authority for Biosafety (EPA)

Proclamation No.362/2003 (A proclamation to ratify the Cartagena protocol on biosafety to the convention on biological diversity), the Ethiopian Environmental Protection Authority (EPA) is mandated to take actions necessary to implement the Cartagena protocol, in coordination with appropriate governmental organs. The EPA is the operational Competent National Authority for biosafety. Its core functions include facilitating the conditions for the “Special Permit” process for both contained research and confined field trials; and grants permit through Advance Informed Agreement (AIA) for environmental release based on the amended Biosafety Proclamation and directives. It is responsible for monitoring these experiments, developing and implementing risk management plans, and controlling the transboundary movement, distribution, transport, and positioning of genetically modified organisms (GMOs).

The Biosafety Law of Ethiopia also requires the establishment of a National Biosafety Advisory Committee (NBAC). Accordingly, the NBAC was established with specialists nominated from various public institutions. The NBAC serves as Ethiopia’s highest technical advisory body on

biosafety, providing science-based guidance to the government on the safe use of modern biotechnology, including GMOs and Genome Edited products. It plays a critical role in risk assessment review, policy advice, and alignment with international biosafety obligations such as the Cartagena Protocol.

4.3.2 Research, Development, and Technology Promotion (MoA, EIAR, BETin)

The Ministry of Agriculture (MoA) is the primary institution responsible for agricultural development, food security, and natural resource management. It oversees the introduction and scaling of agricultural biotechnologies related to crops, livestock, fisheries, and plant protection, in coordination with biosafety and regulatory bodies. The recently published Agricultural and Rural Development Policy of 2024 is driven by the need to transition the sector into a technology and science-led system by strengthening the private sector's role in research and extension and establishing a robust public-private partnership with clear regulatory oversight. The Ethiopian Agricultural Authority (EAA), which is accountable to MoA is mandated by Regulation no. 509/2022 to ensure agricultural inputs, products and services are standardized and registered.

The Ethiopian Institute of Agricultural Research (EIAR) serves as the applicant for contained laboratory research and environmental release related to GMOs. Furthermore, EIAR as an applicant is expected to take the lead in conducting safety assessments and confined field trials (CFTs) associated with the commercialization pathway of a biotech product, thereby organizing the technical data required for regulatory compliance.

The Bio and Emerging Technology Institute (BETin) is another institution which coordinates national projects and provides capacity building in biotechnology and emerging technologies and ensures that technology promotion is integrated with biodiversity, biosafety matters in cooperation with other concerned bodies including EPA. BETin is accountable to the Ministry of Innovation and Technology (MinT).

4.3.3 Ethiopian Institute of Biodiversity (EBI)

The Ethiopian Biodiversity Institute (EBI) is mandated to ensure that the country's biodiversity and the associated community knowledge are properly conserved and sustainably utilized, and the country and its communities get fair and equitable share of the benefits arising from their utilization. The Institute regulates access to genetic resources and requires MTAs for domestic

and international research collaborations. With regard to Biotechnology R&D, MTAs govern access to plant germplasm and microbial collections, ownership of biotechnology products and derivatives, and rights over downstream inventions, patents, and commercialization (Tawari and Agnihotri, **2023**).

4.3.4 Ethiopian Food and Drug Authority (EFDA)

The Ethiopian Food and Drug Authority (EFDA) is the primary regulatory agency for processed food products. Proclamation No. 1112/2019 grants EFDA legal authority to enforce food safety, quality regulations, and product standards, aligning directly with the MoA's 2024 policy commitment to strengthening the control system for agricultural inputs and product quality, health, and safety.

Proclamation 1112/2019, Article 12, specifies that every infant formula and follow-up formula shall comply with applicable Ethiopian quality and safety standards; its component shall not contain GM products and exposed to any radiation during manufacturing, and its packaging is made from a non-plastic material, and contains a label bearing the source of its protein. Article 54(c) also stipulates that any food containing a GM element may only be placed on the market if it is packaged and its label clearly contains the phrase "genetically modified," "genetically modified organism," or a comparable description.

The labelling issue is further empowered by the Ethiopian standards (ES 6793:2021), which specifies that operators must ensure that labeling information is transmitted at all stages of the production and distribution chain, extending to bulk, non-packaged products via accompanying documents when a physical label is impossible. This is an example of regulatory complementarity between institutions.

4.3.5 National Science, Technology and Innovation Policy (STIs)

This policy is developed to build a strong national science and technology foundation and coordinate capacity building efforts to boost economic competitiveness and reduce technological dependence. Crucially, the policy identifies intellectual property rights (IPRs) as critical issues, and it specifies key focus areas—known as National Priority Technology Capability Programs (NPTCPs)—which include agricultural productivity through improvement of crops and livestock

exploiting the country's rich genetic diversity with the application of biotechnological tools. National Research Institutes (NARs) are directed to focus their major activities on adaptive research, technology adaptation, practical training, and consultancy services.

National science and technology (S&T) policies play a critical role in shaping the development, regulation, and responsible use of emerging technologies such as genome editing. Clear policy recognition provides strategic direction, guides investment and research priorities, and supports the establishment of appropriate regulatory frameworks. Assessing the extent to which genome editing is addressed in existing national S&T policies therefore offers important insights into a country's readiness to govern and harness these technologies.

The perceptions of respondents regarding how well genome editing is addressed in Ethiopia's national science and technology policies is also assessed. The results indicate that genome editing is widely perceived as insufficiently covered within the current policy framework (**Figure 6**). The largest share of respondents (37.7%) reported that genome editing is slightly addressed, while 34.9% indicated that it is not addressed at all. Collectively, these responses account for 72.6% of the sample, suggesting a substantial policy gap. However, this is well understood taking into account that Genome Editing is a recent technology while most of the policies were formulated a few years ago.

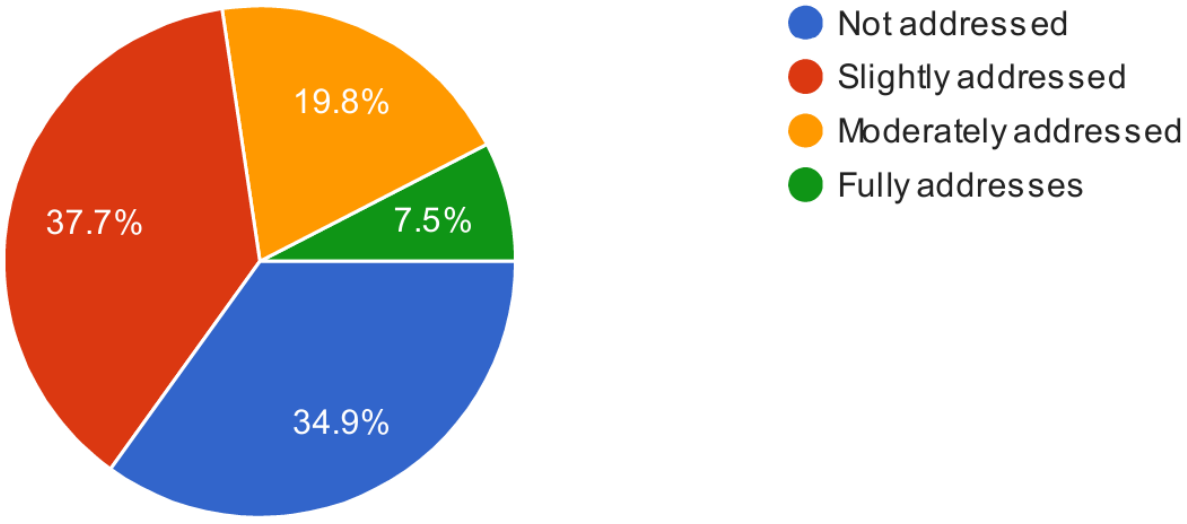


Figure 6. How Ethiopia's national science and technology policies addressed genome editing?

A smaller proportion of respondents (19.8%) perceived genome editing as being moderately addressed, indicating that some policy elements may indirectly relate to genome editing without explicitly recognizing or regulating it. Only 7.5% of respondents reported that genome editing is fully addressed in national S&T policies, underscoring the limited extent of comprehensive policy integration.

These findings suggest that Ethiopia's national S&T policies may not yet have fully adapted to the rapid advancement of genome editing technologies. Existing policy instruments are likely to emphasize broader themes such as biotechnology, innovation, or agricultural transformation, without clearly distinguishing genome editing from conventional genetic modification or addressing its specific governance, ethical, and regulatory implications. The limited explicit policy coverage may contribute to uncertainty among researchers, regulators, and other stakeholders regarding strategic priorities and regulatory expectations.

Overall, the results highlight the need for policy revision and modernization to explicitly incorporate genome editing within national S&T frameworks. Doing so would enhance policy coherence, support responsible innovation, and complement existing biosafety and institutional governance arrangements. Explicit policy recognition of genome editing would also strengthen Ethiopia's capacity to leverage emerging biotechnologies while ensuring appropriate oversight and public trust.

4.3.6 Environmental Protection Policy

The Environmental Policy of Ethiopia was approved in April 1997 by the Council of Ministers as the overarching policy document of environmental management in the country. The policy sets an overall goal of improving and enhancing the health and quality of life of the citizenry and the promotion of sustainable social and economic development. This is done through the sound management and use of natural, human-made and cultural resources and the environment as a whole so as to meet the needs of the present generation without compromising the ability of future generations to meet their own needs.

The policy constitutes ten sectoral and ten cross-sectoral policy elements amongst which the Control of hazardous materials and pollution from industrial waste is included. The need to adhere to the precautionary principle is emphasized under this policy section. The Polluter pays

principle is recognized as a key guiding principle under the policy. It underlines that all biological material which is self-regenerative and impossible to control once allowed to get out of control may result in the most insidious and damaging form of pollution which is biological pollution, thus the importation and use of biological material including those genetically engineered should be under stringent regulations.

4.3.7 Ethiopia's Guideline for Regulating Genome Edited plants

Ethiopia is strategically advancing in the adoption of GMOs and genome-edited plants as vital components of its national policy imperative to transform agriculture into a science- and technology-led system, primarily aimed at ensuring food security, boosting productivity, and increasing exports. This forward-looking approach, which prioritizes the use of "bio and emerging technologies," is supported by ongoing efforts to establish a comprehensive legal framework, institutional structure, and control system for the safety of agricultural technology and quality (MoA, **2024**).

The FDRE Environmental Protection Authority (EPA) Guideline for the Regulation of Genome Edited Plants in Ethiopia represents a critical regulatory response to the rapid advancement of modern biotechnology. This guideline uses a case-by-case approach, exempting certain New Breeding Techniques (NBTs) products from strict regulations. Ethiopia is ahead of many African countries in publishing its guideline for Genome Editing and creating an enabling environment for GEd R & D and commercialization. Ethiopia takes a scientifically robust, risk-proportionate approach, positioning it to safely harness GEd for agricultural innovations.

Assessing national readiness to develop a genome editing policy, strategy, or roadmap is essential for understanding a country's institutional capacity, strategic vision, and preparedness to govern emerging biotechnologies. Readiness reflects not only the existence of regulatory and scientific capabilities but also policy awareness, coordination mechanisms, and stakeholder confidence. This study therefore examined stakeholder perceptions of Ethiopia's readiness to formulate a dedicated national framework for genome editing.

Ethiopia's readiness to develop a national genome editing policy, strategy, or roadmap beyond the existing Genome Editing guideline was assessed. The results indicate a moderate but uneven

level of preparedness, with perceptions distributed across all readiness categories (**Figure 7**). The largest proportion of respondents **(**26.7%**)** perceived Ethiopia as slightly ready, followed by 24.8% who considered the country moderately ready. A further 23.8% of respondents indicated that Ethiopia is read**y**, while 16.2% perceived the country as not ready. Only 8.6% of respondents considered Ethiopia to be fully ready.

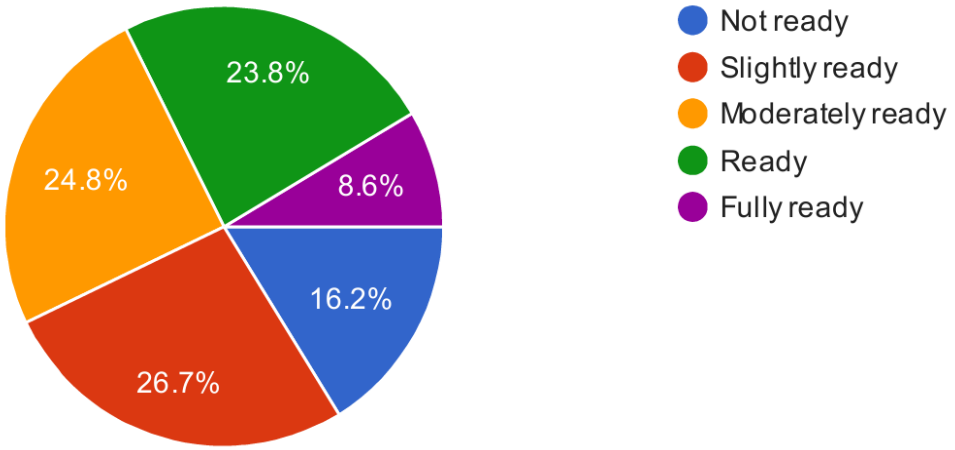


Figure 7. Respondent's view on Ethiopia's readiness for Genome Editing

Overall, nearly half of the respondents (**51.5%**) rated Ethiopia's readiness as slight or moderate, suggesting that foundational elements for developing a genome editing policy may exist but remain insufficiently developed or coordinated. The relatively small proportion of respondents who perceive full readiness points to gaps in institutional capacity, policy clarity, or strategic alignment.

The findings suggest that while Ethiopia has made progress in areas such as biotechnology research, regulatory awareness, and institutional engagement, these efforts may not yet be consolidated into a coherent national strategy for genome editing. The presence of a notable share of respondents who view the country as not ready further highlights concerns related to limited policy experience with genome editing, uncertainty about regulatory mandates, and the need for stronger inter-institutional coordination.

4.4 International Experience in Genome Editing Governance

Biotechnology advancements are rapidly shaping the future of food and agriculture with genetic engineering tools utilizing both classical transgenic methods and cutting-edge genome editing techniques such as CRISPR. At the same time, the regulatory system and assessment processes have struggled to keep pace with these rapid innovations and techniques. Notably, this can be an issue when investigating the potential environmental impacts in the development and production of these crops due to the complexity and temporal nature of potential risks. As GE technologies and applications continue to evolve and expand, governance of GEd crops should consider strengthening environmental assessment and oversight practices (Ríos *et al*., **2025**). This can be achieved by making regulatory frameworks keep pace with advances in biotechnology, strengthening oversight of GE crops by expanding assessment parameters and ensuring transparency and stakeholder engagement in the oversight processes.

Organisms developed through new breeding techniques, including genome editing, may contain nucleic acids from a foreign source. The regulatory status of Genome Edited organisms has been discussed in various countries, and the regulatory approaches differ across countries.

Ríos *et al*. (**2025**) propose that regulatory harmonization strategies are necessary to enhance transparency, mitigate trade barriers, and fully leverage the potential of these technologies in addressing global issues, including food security and climate change. The governance of Genome Editing technology should be strengthened through a policy recommendation for a hybrid model that integrates precautionary measures with principle-based flexibility (Vengadesen *et al*., **2025**). Countries across the world continue to adapt their own regulations and oversight with novel biotechnology innovations (Loschin *et al*., **2025**). The regulatory experience of Genome Editing in the US and Japan is briefly discussed below and **Table 1** summarizes the regulatory status of a few more countries.

US Genome Editing regulatory system

U.S. regulatory oversight of genetically engineered (GE) crops is managed by three federal agencies under the Coordinated Framework for the Regulation of Biotechnology. The U.S. Department of Agriculture (USDA) APHIS is responsible for preventing agricultural risks and regulating the release of GE organisms as potential plant pests. Concurrently, the Food and Drug

Administration (FDA) ensures the safety of GE-derived human and animal food. The Environmental Protection Agency (EPA) regulates the environmental and health safety of pesticidal substances - known as plant-incorporated protectants (PIPs) - engineered into the crops. This product-based, multi-agency system ensures comprehensive safety coverage for biotechnology products (Zarate *et al*., **2023**).

Some Latin America and the Caribbean countries (e.g., Argentina) interpret existing legislation to promulgate regulations for biotechnology and Genetically Modified Organisms (GMOs), while others (e.g., Brazil and Honduras) have specific legislation for GMOs. In both cases, often a case-by-case approach is chosen to determine whether a Gene Editing organism is subject to GMO regulations or not. Other countries such as Peru have opted to ban the technology due to its perceived resemblance to GMOs (Zarate *et al*., **2023**)

Japan

In February 2019, the Japanese government defined genome-edited end products derived by modifications of SDN-1 type (directed mutation without using a DNA sequence template) as not representing "living modified organisms" according to the Japanese Cartagena Act, as they are considered similar to those produced by conventional breeding technologies. (Tsuda *et al*., **2019**).

Table 1. Comparative overview of genome editing regulatory policies across countries and regions (Source: Rios et al., 2025)

Region/ Country	Regulatory approach	Reference
Argentina, Brazil, Chile, Colombia, Costa Rica, El-Salvador, Guatemala, Honduras, Paraguay, Ecuador, And Uruguay	Case-by-case assessment of products obtained through Genome editing. If the final product does not have a new Combination of genetic material, it is considered conventional.	Ríos *et al*. (2024), Gobernaetal (2024), Hernández-Sotoand Gatica-Arias (2024), Sánchez (2024)
Australia	Has revised its regulations to exclude SDN1 from oversight. Modifications without the introduction of foreign DNA are not interpreted as additional risks.	Thygesen (2019), Jones *et al.* (2024)
Bangladesh	Case-by-case approach. Products obtained through SDN1/SDN2, with no foreign DNA, are excluded from strict regulations.	Groover *et al*. (2024)

Burkina Faso, Ghana, Kenya, Malawi, and Nigeria	Guidelines using a case-by-case approach, excluding certain genome-edited products without foreign DNA from strict regulations.	Adegbaju *et al*. (2024), Groover *et al*. (2024)
Canada	Applies product-based approach. Assesses final traits of the organism, not the technique used to develop it. Plants without foreign DNA are exempt from strict regulations	Lassoued et al. (2024)
China	Regulation prioritizes food safety and environmental risk assessment. Pre-market requirements include risk assessment processes similar to those applied to GMOs, while post-market provisions provide mandatory labeling, thus ensuring transparency and traceability of products on the market.	USDA (2023)
European Union	Genome-edited organisms are considered as GMOs. There are proposals to categorize certain edited products, with a limited and pre-defined number of genetic changes in a differentiated manner. Pre-market requirements not yet fully defined, likely to include labeling, segregation, and specific provisions for handling	Purnhagen *et al*.(2023), Molitorisová *et al*. (2024)
India	ProductsobtainedthroughSDN1/SDN2, with no foreign DNA, not considered GMO Ministry of Environment Forest and Climate Change	Groover *et al*. (2024)
Japan	Case-by-case approach, excluding certain genome-edited products that do not contain foreign DNA from strict regulations	Tomita (2024)
Philippines and Singapore	Case-by-case approach, excluding products without Foreign DNA from strict regulations	Groover *et al*. (2024)
Russia	It implemented a decision for a research and development Program that classifies genome-edited products as similar as conventional products	Dobrovidova (2019)
South Africa	Considers NBT, including genome editing, such as GMOs	Berger (2022); ACB (2024)
South Korea	Currently updating regulatory frameworks for NBTs. Currently, these techniques are regulated under the law on Living Modified Organisms (LMOs)	Yang and Zhou (2024)
Thailand	ExemptsproductsobtainedthroughSDN1fromstrict regulations; forSDN2andSDN3, without foreign DNA, assessment performed case by case to determine applicable regulation	Groover *et al*. (2024)

United Kingdom	Measures were implemented to allow field trials of genome-edited plants, requiring only one registration	Groover *et al*. (2024)
United States	Case-by-case approach, Department of Agriculture and Environmental Protection Agency assesses products	Hoffman (2021), Groover *et al*. (2024)

Chapter 5. Academic, Research Capacity and Institutional Readiness

5.1. University Education and Training in HLIs

Biotechnology education and research at HLIs in Ethiopia was initiated during the 1980s in collaboration with European universities (e.g. Swedish universities). Faculty members at Addis Ababa University (AAU), Haramaya University (HU), University of Gondar (UoG) were trained in the area of agricultural, health and industrial biotechnology through these joint programs, and limited facilities were acquired allowing the establishment of modest biotechnology teaching and research programs.

In the 2006/2007 Academic year, AAU and UoG launched the first MSc and BSc programs in biotechnology, respectively. In response to the growing need and demand for high level trained manpower in biotechnology, AAU upgraded its Biotechnology Program Unit to the Institute of Biotechnology (IoB) in June 2012, with concurrent launching of the first PhD program in four specializations, i.e., agricultural, industrial, environmental and health biotechnology. Subsequently several universities have launched BSc and MSc programs in biotechnology to contribute towards manpower development in the sector.

Currently about 13 HLIs are offering biotechnology undergraduate training using a harmonized curriculum. The average enrolment ranges from 40 to 60 students per year per university with increasing trends from year to year. Seven universities (including AAU, UoG, JU, Haramaya University, Hawassa University, Dilla University and Arba Minch University) are also offering a two-year MSc program in biotechnology with an average enrolment range from 8 to 10 per year per university. Currently, several universities are running PhD programs in Agricultural, Health, Industrial and environmental biotechnology, including AAU, UoG, Haramaya, Jimma, and Hawassa to meet the demand for highly skilled manpower. However, the graduate programs are challenged by the availability of laboratory facilities, consumables, budget for hands-on training and skilled teaching staff to offer proper advice in their thesis research. This is rectified by sending students abroad to do part of their research in advanced laboratories of international collaborators.

In recent years, we have witnessed encouraging progress in the upgrading of laboratory facilities using funds obtained from the government or international research funds. The curricula are also being revised from time to time to include practical skills due to the fast growth of the field of biotechnology, especially in molecular biology, genomics and bioinformatics

University curricula play a central role in building the human capital required for the development, regulation, and responsible application of emerging technologies such as genome editing. Most recently, some universities are updating their courses to integrate Genome Editing. In majority of the courses, Genome editing is offered as a component of other courses such as Genomics and Bioinformatics, Plant Molecular Breeding, Genetic Engineering, Molecular Approaches in Entomology. In Addis Ababa University, it is given more attention and a course is designed entitled "Genetic Engineering and Genome Editing".

The extent to which genome editing is incorporated into higher education curricula reflects national preparedness in terms of skills development, research capacity, and long-term innovation potential. This study therefore assessed stakeholders' perceptions of the level of genome editing content currently included in university curricula in Ethiopia (**Figure 8).** The results indicate that genome editing is largely underrepresented in higher education programs. A majority of respondents (61.9%) reported that genome editing content is minimal**,** while 11.4% indicated that there is no content at all. Together, these responses account for 73.3% of the sample, suggesting substantial gaps in formal training on genome editing at the university level.

Approximately, 24.8% of respondents perceived the level of genome editing content as moderate, indicating that some universities may be introducing relevant concepts, possibly within broader biotechnology or molecular biology courses. However, only a very small proportion of respondents reported advanced coverage, and virtually none indicated the presence of comprehensive genome editing curricula. These findings also align with the assessment of the current genome editing curriculum that GEd is taught not as a standalone but rather integrated with other courses in major universities **(Table 3)**.

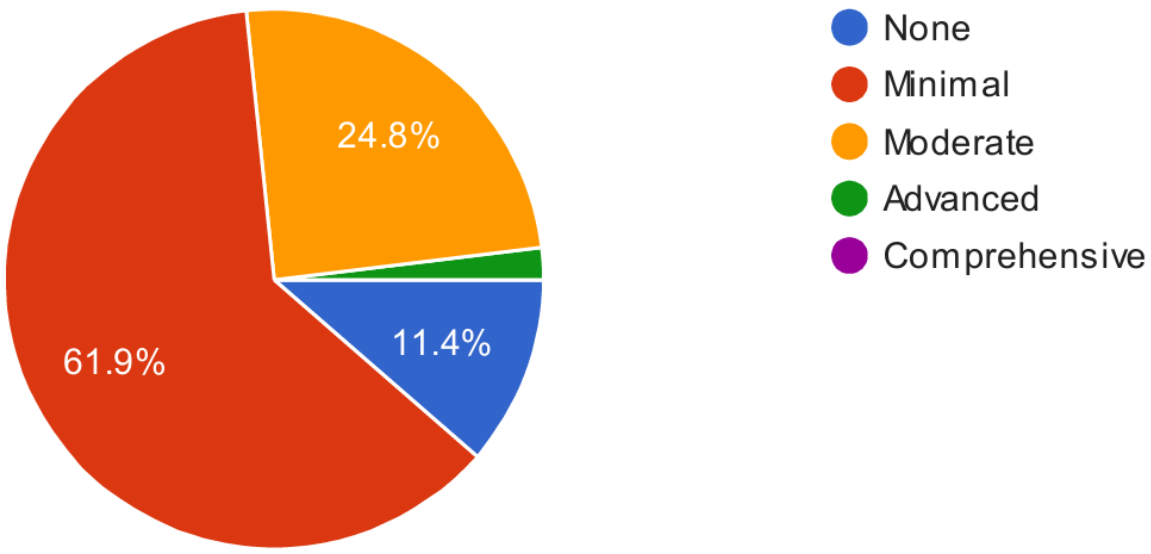


Figure 8. Level of Genome Editing content in university curricula

These findings suggest that, despite growing global importance of genome editing technologies, Ethiopian university curricula have not yet systematically integrated this field into teaching and training programs. The dominance of "minimal" responses implies that genome editing may be treated as a peripheral or emerging topic rather than a core area of instruction. This limited curricular exposure may constrain the development of skilled professionals capable of conducting research, informing policy, and supporting regulation of genome editing technologies.

The low levels of advanced and comprehensive coverage also point to broader challenges, including limited faculty expertise, insufficient laboratory infrastructure, and the absence of clear national policy signals prioritizing genome editing education. Without strengthening curricular content, efforts to develop national genome editing policies, regulatory frameworks, and innovation strategies may face human capacity constraints.

5.2 Human Resources Capacity in Genome Editing Technology

Human capacity is a critical pillar for the effective development, regulation, and application of genome editing technologies. Adequate numbers of trained professionals with appropriate technical, regulatory, and ethical expertise are essential to support research, policy formulation,

and governance. This study therefore assessed stakeholders' perceptions of the sufficiency of human capacity in genome editing (GEd) education in Ethiopia.

Figure 9 presents respondents' assessments of the status of human capacity in genome editing education. The results reveal a strong consensus that current capacity is largely inadequate. A majority of respondents (60.8%) rated human capacity as insufficient in research institutions and universities (**Figure 14**), while a further 25.5% considered it very insufficient. Together, these responses account for 86.3% of the sample, indicating widespread concern regarding the shortage of adequately trained personnel in genome editing.

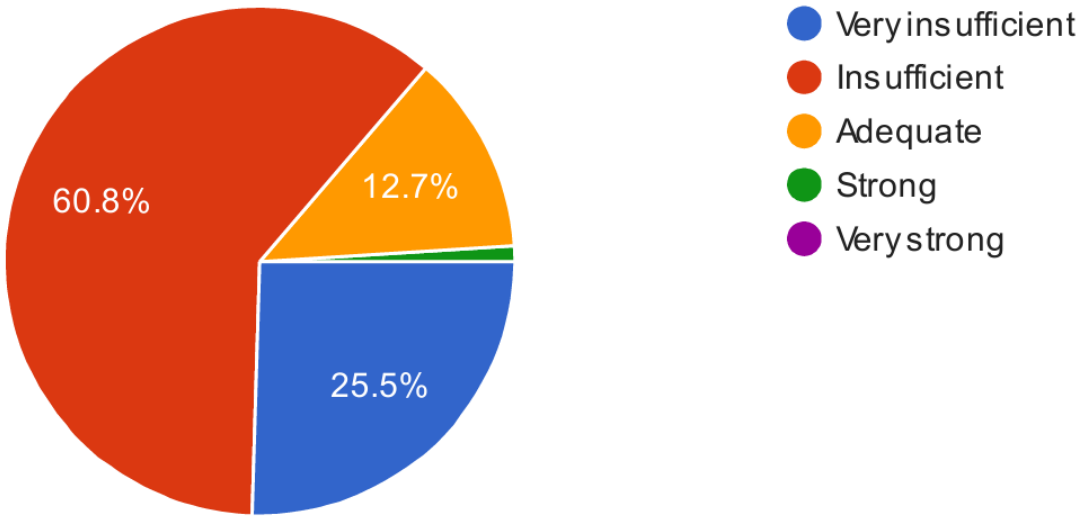


Figure 9. The status of trained human capacity in genome editing technology

Only 12.7% of respondents perceived human capacity as adequate, while a negligible proportion rated it as strong, and virtually none considered it very strong. This distribution highlights the limited availability of advanced expertise and specialized training in genome editing within the country.

These findings are consistent with earlier results showing minimal genome editing content in university curricula and limited integration of genome editing into national science and technology policies. The perceived insufficiency of human capacity likely reflects multiple structural constraints, including limited curricular coverage, shortages of specialized faculty,

inadequate laboratory infrastructure, and restricted opportunities for advanced training and professional development. As shown in **Figure 10**, respondents identified multiple capacity gaps constraining genome editing education in Ethiopia. The most frequently reported gaps were shortages of skilled laboratory technicians (88.5%), reagents and consumables (86.5%), and laboratory equipment (84.6%). In addition, a lack of bioinformatics specialists (76.9%) was highlighted as a major constraint. Fewer respondents (32.7%) identified shortages of molecular biology lecturers. Overall, the results indicate that capacity gaps in genome editing education are primarily related to technical support, infrastructure, and computational expertise, rather than the availability of basic teaching staff.

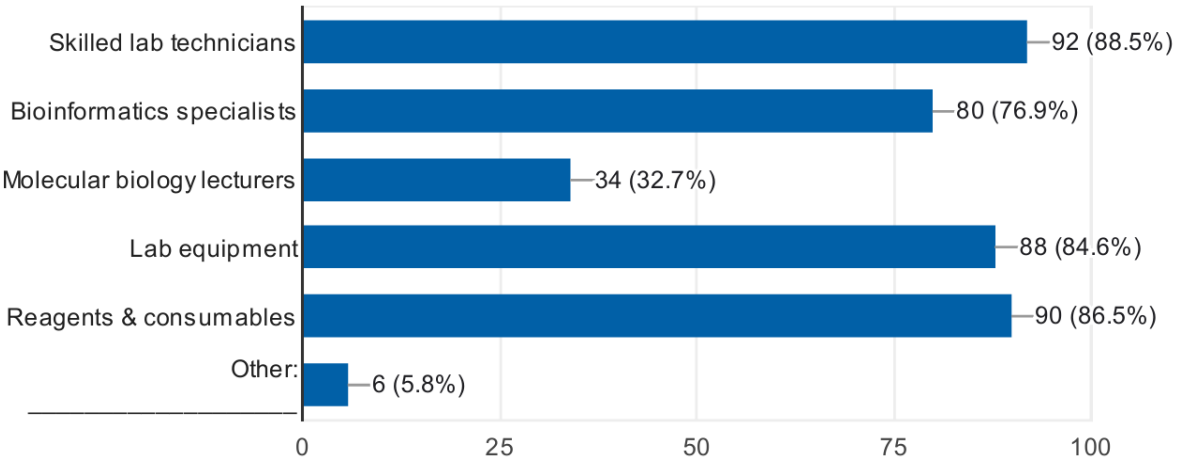


Figure 10. Capacity gaps constraining genome editing education

Regarding the strength of university/research - industry collaboration in Genome Editing in Ethiopia, **Figure 11** presents respondents' perceptions. The results indicate that collaboration is predominantly weak, with limited evidence of strong or institutionalized partnerships. A majority of respondents rated collaboration as weak (43.7%) or very weak (37.9%), accounting for 81.6% of responses. This overwhelmingly negative assessment suggests that linkages between academic institutions, research organizations, and industry remain poorly developed, fragmented, or largely informal. Such weak collaboration limits knowledge transfer, applied research, and the translation of genome editing research into practical or commercial outcomes.

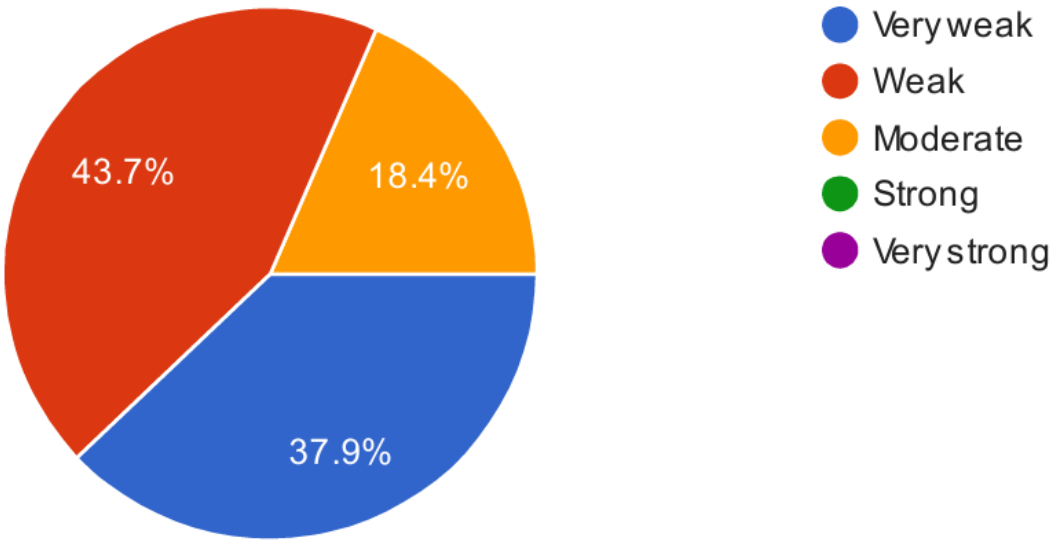


Figure 11. Strength of University/Research -Industry Linkage

Only 18.4% of respondents perceived collaboration as moderate, while virtually none rated it as strong or very strong. The absence of high-strength ratings highlights the lack of structured mechanisms such as joint research programs, industry-funded projects, shared infrastructure, or innovation platforms.

Overall, the findings demonstrate that weak university/research - industry linkage represents a significant bottleneck in the genome editing ecosystem in Ethiopia. This limitation slows innovation, reduces opportunities for commercialization, and undermines the development of demand-driven research and training. Strengthening collaborative frameworks will be essential to link genome editing education and research with national development priorities and emerging biotechnology markets.

Academic preparedness to contribute to genome editing R&D is shown in **Figure 12**. The response indicated generally low to moderate levels of academic preparedness to contribute to genome editing research and development. The largest proportions rated their preparedness as level 2 (34.3%) or level 3 (34.3%), indicating that nearly two-thirds of participants perceived themselves as having limited to moderate readiness. A further 16.7% reported very low preparedness (level 1). In contrast, fewer respondents indicated higher levels of preparedness, with 12.7% rating themselves at level 4 and only a small minority at level 5 (very high). Overall,

these findings suggest that most respondents do not yet feel highly prepared to engage in genome editing R&D.

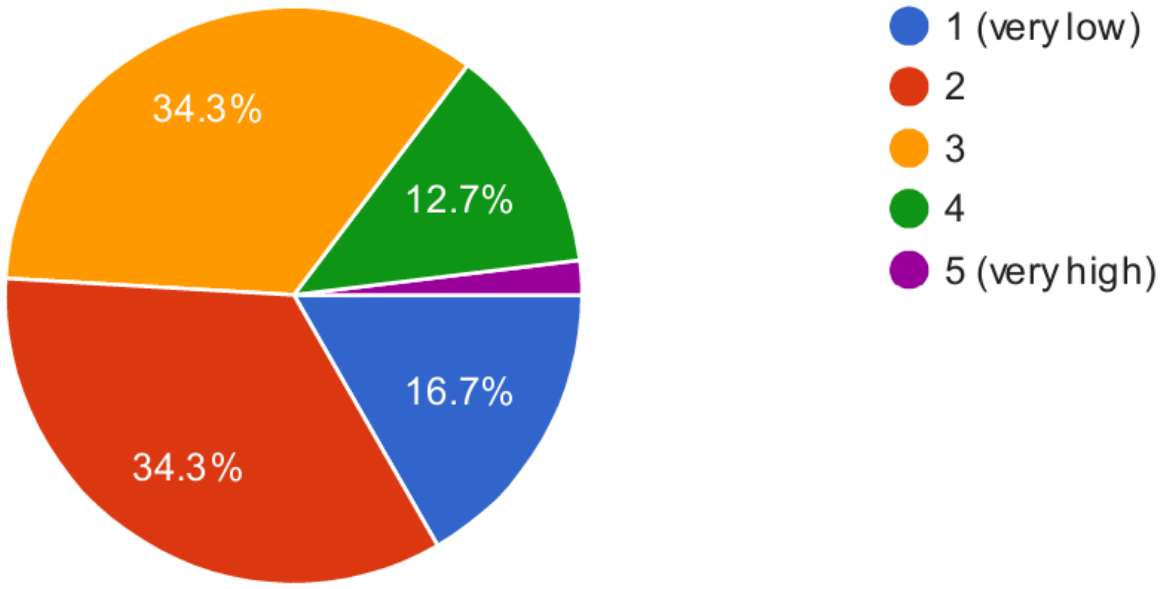


Figure 12. Academic preparedness to contribute to genome editing R&D

5.3. Research Infrastructure

In Ethiopia, there are developments in different research institutes and universities with regard to research activities in agricultural biotechnology. The institutes involved in agricultural biotechnology research activities include: Ethiopian Institute of Agricultural Research (EIAR), Bio and Emerging Technology Institute (BETin), National Veterinary Institute (NVI), National Animal Health Diagnostic and Investigation Center (NAHDIC), International Livestock Research Institute (ILRI) and the Regional Agricultural Research Institutes (RARIs). Higher learning institutions engaged in research and training in agricultural biotechnology include Addis Ababa, Jimma, Gondar, Bahir Dar, Mekele, Hawassa and Haramaya Universities. A number of other universities are also engaged in research and offer biotechnology degrees at undergraduate and graduate levels in agricultural biotechnology.

EIAR in particular, has been building capacity on molecular biology with government and donor funding at a center specialized on biotechnology, the National Agricultural Biotechnology

Research Center (NABRC). Furthermore, the institute has been working to make NABRC a center of excellence in genome editing research to support its crops and livestock improvement agenda. Thus far, the institute has established well organized molecular biology and plant tissue culture laboratories which are required for genome editing R&D. Ethiopian expats working in overseas research institutions have been playing very crucial roles in supporting home research institutions through collaborative projects.

Comprehensive analysis of molecular biology infrastructure, plant tissue culture facilities, bacterial handling and biosafety systems, and human resources across seven Ethiopian institutions (EIAR, BETin, AAU, Haramaya, Jimma, Hawassa and Mekelle Universities) demonstrates that Ethiopia's genome-editing ecosystem is structurally fragmented, with critical transformation, imaging, regeneration and biosafety components unevenly distributed among institutions (**Figure 13**).

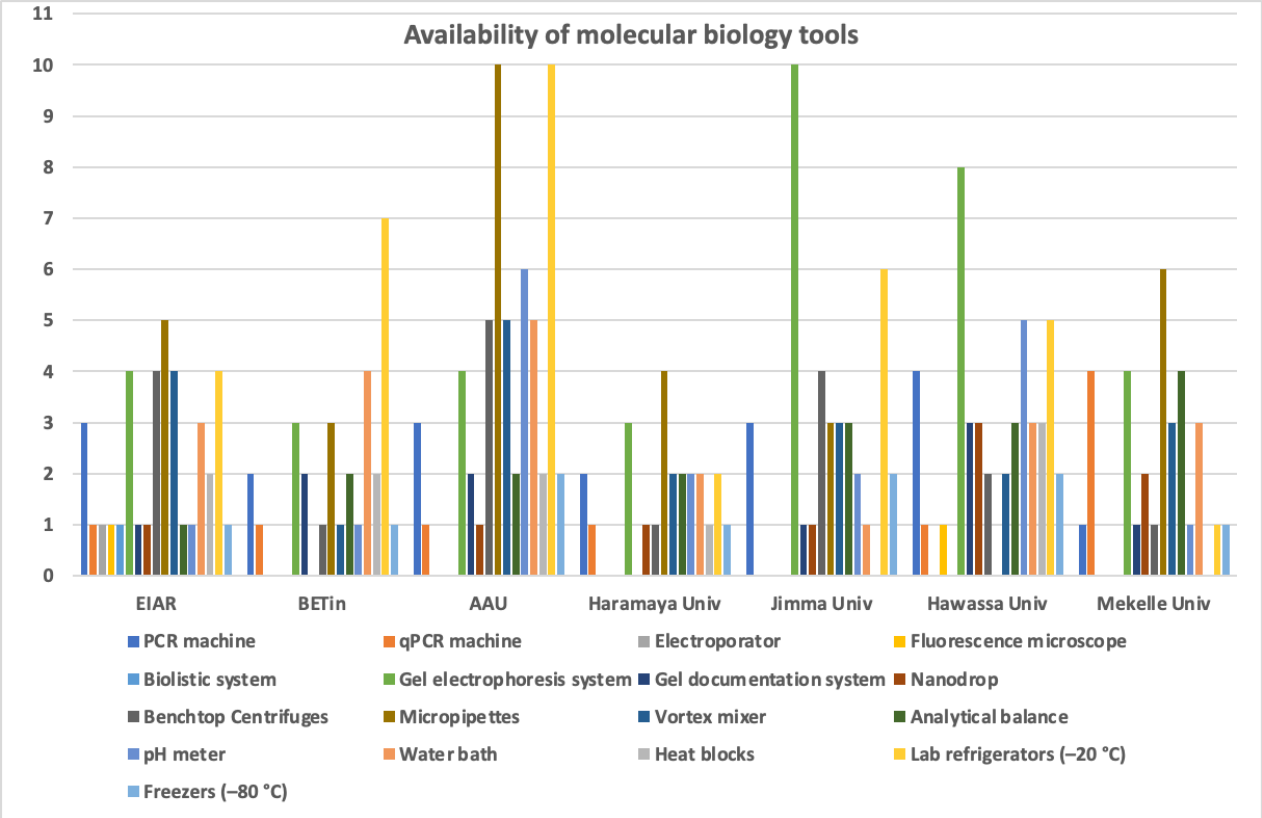


Figure 13. Availability of molecular biology tools for genome editing across institutions

Although all universities possess at least basic molecular biology equipment, no single university except EIAR possesses the complete suite of physical and human resources required to independently execute full genome-editing pipelines. Results were summarized in the charts (**Figures 12-14**).

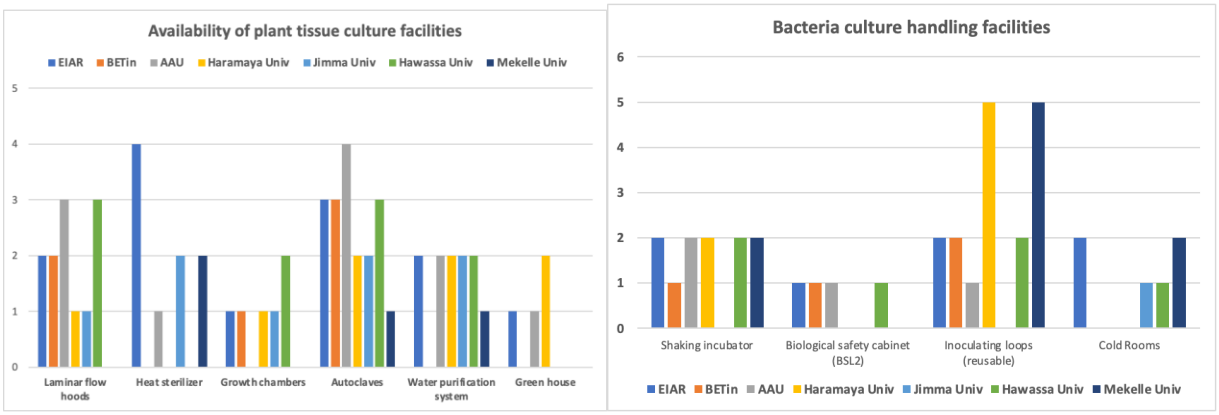


Figure 14. Plant tissue culture and bacteria culture handling facilities in research and universities

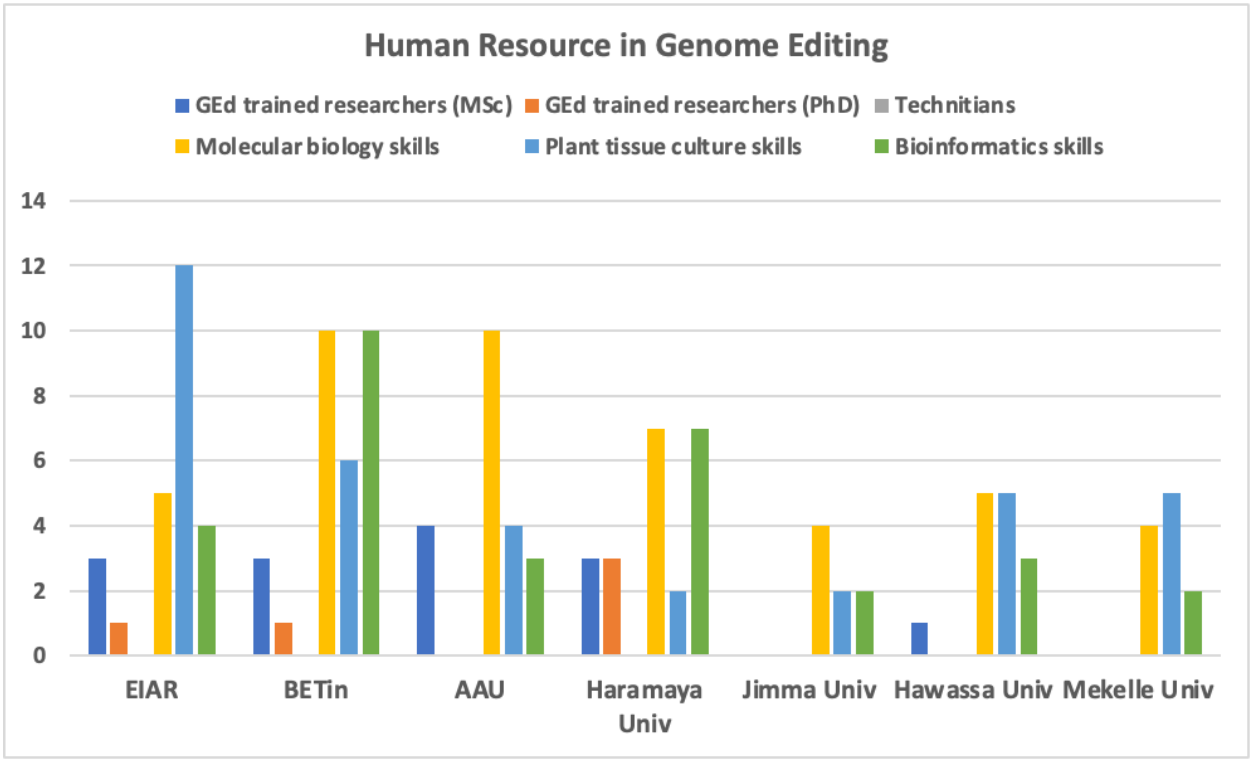


Figure 15. Human resource with respect to GEd in research and universities

Based on the assessment of institutions presented above, their readiness for genome editing R&D in terms of infrastructure and human resource was summarized in the following table.

Table 2. Institutional Preparedness for Genome Editing

Institution	True Functional Genome-Editing Capacity Profile
EIAR	EIAR possessing transformation platforms (electroporation + biolistic system), fluorescence microscopy, qPCR, tissue-culture pipeline (laminar hoods, growth chambers, autoclaves, greenhouse), cold rooms, BSL-2 cabinet, and strong MSc/PhD genome-editing experts. Can perform complete end-to-end plant genome-editing workflows independently.
AAU	Strongest molecular laboratory density, largest cold-chain capacity, strongest molecular & bioinformatics human resources. Lacks transformation platforms, fl. scence microscopy, growth chambers, greenhouse, and cold rooms. Gaps should be filled to run transformation-to-regeneration workflows independently.
BETin	BETin has very strong molecular & bioinformatics skills but extremely limited laboratory infrastructure; not capable of genome editing without major equipment investment.
Hawassa Univ.	The university has good molecular labs, tissue-culture capacity and skilled personnel. Lacks transformation platforms and cold rooms, limiting full genome-editing autonomy.
Haramaya Univ.	Strong MSc/PhD genome-editing workforce and bioinformatics skills but fragmented lab systems, no transformation platforms, no fluorescence microscopy, no cold rooms.
Jimma Univ.	Jimma is a moderate molecular teaching and pilot-research node. Strong electrophoresis and reasonable molecular base but lacks imaging, transformation platforms, biosafety redundancy and advanced tissue culture.
Mekelle Univ.	Emerging but incomplete node. Reasonable molecular base and some tissue culture & biosafety elements, but lacks transformation systems, fluorescence microscopy, growth chambers, greenhouse and genome-editing PhD staff.

There have been considerable research achievements on Ethiopian crops with efforts from researchers both within the country and with partner institutions in Africa, Europe and North America. Different research centers in Ethiopia such as those in EIAR are involved in the following research activities: tissue culture of potato, Enset, grapevine and other medicinal and ornamental plants; marker-assisted selection in Teff, wheat, millet, barley and sorghum; confined field trial of Bt cotton, water efficient maize for Africa (WEMA) and insect resistant maize. Ambo Agricultural Research Center (previously Ambo Plant Protection Research Center) of the EIAR is working on disease diagnosis of plants using both traditional and modern biotechnological tools.

Micropropagation and *in vitro* regeneration protocols have been developed and optimized for some economically important plants by research and higher learning Institutes as well as a few private sectors. By using tissue culture applications, disease-free, high quality planting materials such as ginger, garlic, potato and apple were produced and disseminated to farmers in various parts of the country (Abraham, **2009**; Dugassa and Feyissa, **2011**). Furthermore, haploid and double haploid production protocols have been developed for some crops to speed up conventional breeding. Recently BETin has started to work on plant tissue culture, molecular breeding, plant and animal disease diagnosis. In addition, the institute has collaborations with local and international research institutes.

Collaborative research projects on developing bacterial wilt resistant enset have been underway between EIAR and International Institute of Tropical Agriculture (IITA) and are currently under confined field trial (CFT). Research activities in molecular genetic diversity, Quantitative Trait Loci (QTL) mapping, association mapping and marker assisted selection (MAS) that potentially could contribute to molecular breeding have also been conducted in higher learning institutions. However, the results of these studies are not used so far for practical applications

In Animal biotechnology, the production, preservation and distribution of cattle semen mainly from selected exotic and local sires have been carried out by the National Artificial Insemination Center (NAIC). Research on embryo transfer technology was conducted by ILRI on zebu cattle (Tegene, **2016**). EIAR has also been working on application of multiple ovulation and embryo

transfer of indigenous breeds. Synchronization in dairy animals has been carried out in smallholder farmers in the different parts of the country.

Animal vaccines have also been produced at large scale by NVI at Debre Zeit for 17 types of viral and bacterial diseases of ruminants and chicken. In addition to local supply, the institute also exports to some African and Middle East countries. There are also vaccines that are produced through recombinant DNA technology against rinderpest in collaboration with overseas laboratories. For livestock disease diagnosis, ELISA, PCR and cDNA probe-based techniques have been used at National Animal Health Diagnostic and Investigation Center (NAHDIC), Sebeta.

The above institutions lack fully functional sequencing facilities. However, some of the sequence activities are conducted abroad either through the funds obtained for collaborative research or by outsourcing. For example, AAU has good relations with SEQART AFRICA located at International Livestock Research Institute (ILRI) in Nairobi Kenya, for sequencing services. The payment for the service in local currency at ILRI, Addis Ababa, when foreign currency from external funding is unavailable.

Table 3. Courses in Genome Editing (Standalone or as part of other courses)

University	Courses with Genome Editing Content	Education Level	Remark
AAU	GeBT8232 Genetic Engineering and Genome Editing	**PhD**	
Jimma Univ	PLBR722 Molecular Plant Breeding	**PhD**	
Jimma Univ	PLBT562 Molecular Plant Breeding	**MSc**	
Jimma Univ	PLBT512 Genetic Engineering	**MSc**	
Haramaya Univ	PLBR742 Genomics and Bioinformatics	**PhD**	
Haramaya Univ	PLPA721 Molecular concepts and methods in Plant Pathology	**PhD**	
Haramaya Univ	PLEN741 Molecular approach in Agricultural Entomology	**PhD**	
Haramaya Univ	PLPB562 Biotechnology for Crop Improvement	**MSc**	
Haramaya Univ	PlSc2022 Introduction to Biotechnology	**BSc**	
Hawassa Univ	PtBt514 Plant Molecular biology	**MSc**	

Chapter 6. Research and Development (R&D) Landscape

6.1. Current GEd Research Projects in Ethiopia

In the last few decades, Ethiopia has made great strides in increasing the productivity of its main staple crops such as maize, sorghum, tef, wheat, Enset, and barley through conventional breeding efforts and use of modern inputs. However, compared to the global average, the yield of staple food crops is still low due to minimal use of improved technologies and loss to abiotic and biotic stresses.

Biotechnology is emerging as an important research approach to bring about new prospects with viable potential of overcoming the challenges in agriculture. Accordingly, Ethiopia has adopted modern biotechnology through its public research and higher learning institutes. Addis Ababa University (AAU) has pioneered in graduate education and research in Ethiopia. It runs various biotechnology research projects funded by the government and international collaborators for attaining environmentally safe and sustainable food security and green development of the country.

Particularly, Ethiopian Institute of Agricultural Research (EIAR) and Biotechnology Research Center (RBC) of AAU and are conducting research on major staple crops, namely, Finger Millet, Durum Wheat, Tef, Noug (*Guizotia abyssinica*), Ethiopian Mustard, Sorghum, Enset, with the aim of enhancing the quality and productivity of the crops by integrating plant genomics with conventional breeding.

Survey results indicate that genome editing research in Ethiopia is predominantly concentrated at early and intermediate stages of development. Nearly half of respondents reported engagement in lab-level trials (46.6%), closely followed by early conceptual or literature-based work (44.7%)**,** reflecting a strong emphasis on foundational research and capacity building. A smaller yet substantial proportion indicated involvement in field trials (29.1%) and applied research (26.2%), suggesting gradual progression toward practical implementation. However, only 14.6% of respondents reported engagement in near-deployment applied research, highlighting limited advancement toward large-scale application or commercialization. Very few respondents (5.8%)

reported no genome editing research activity, indicating broad participation across institutions despite the early-stage nature of most work.

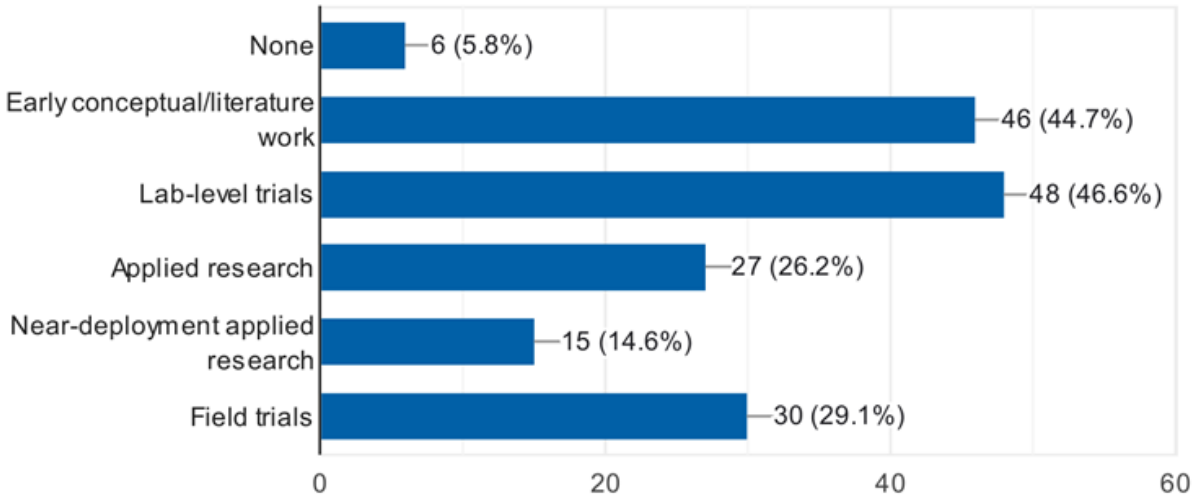


Figure 16. Level of genome editing research currently underway in Ethiopia

Regarding areas of genome editing applications relevant to Ethiopia, respondents identified agriculture-related applications as the most relevant areas for genome editing in Ethiopia (**Figure 16**). Crop improvement**,** including yield enhancement and stress tolerance, was overwhelmingly prioritized (96.2%), followed by industrial biotechnology (69.5%)**,** livestock improvement (62.9%), and environmental biotechnology (61.9%). Applications in diagnostics (45.7%) and human health (41.0%) were also reported, though to a lesser extent. Only a small proportion of respondents selected other applications (3.8%), indicating a strong consensus around a defined set of priority sectors. Overall, the results highlight a clear emphasis on agricultural and bio-based economic applications of genome editing in the Ethiopian context.

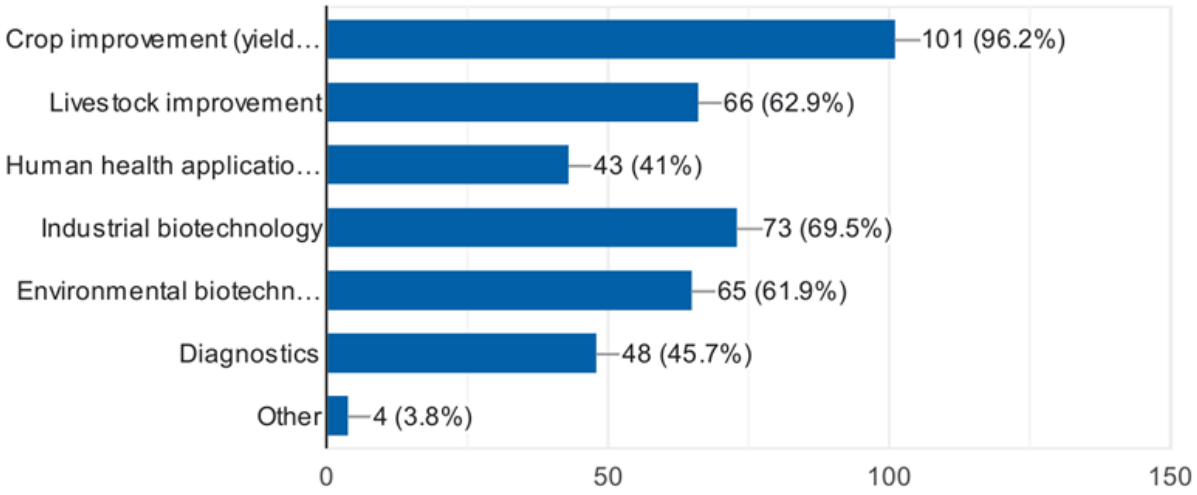


Figure 17. Areas of genome editing applications relevant to Ethiopia

Some of the collaborative genome editing research activities that have been undergoing in Ethiopia in research institutes (EIAR and BETin) and Biotechnology Research Center (RBC) of the Addis Ababa University are highlighted in the following section.

6.1.1. Lodging resistant tef (Ergrostis tef)

Lodging is a major limitation to tef production and for decades the development of lodging resistant varieties has proven difficult with conventional breeding approaches (van Delden et al., **2010**). In collaboration with EIAR, a USA based Donald Danforth Plant Science Center has been working to develop lodging resistant tef varieties through genome editing. The CRISPR/Cas9 system was used to introduce knockout mutations in known dwarfing genes to generate three tef lines. Tef orthologous of three known dwarfing genes, a) the rice (*Oryza sativa* L.) *Semidwarf1* (*Sd1*), b) the sorghum (*Sorghum bicolo*r L.) *Dwarfing1* (*Dw1*) and c) the sorghum (*Sorghum bicolo*r L.) *Dwarfing3* (*Dw3*,) were the three genes edited to confer semi dwarfism and lodging resistance in tef (Beyene et al., **2022**). Three edited tef lines from Magna farmers preferred variety were developed and evaluated in glass houses and fields in the USA. Under the scheme of (Genome Editing in Tef for Uplifting Productivity (GET-UP) project, these edited lines were introduced to Ethiopia following the country's recently published gene editing regulatory guideline for further evaluation in five tef growing locations (Bishoftu, Chefe-Donsa, Melkassa,

Welkitie, and Ambo). The project also supports capacity building on genome editing research at EIAR.

6.1.2. Striga Smart Sorghum for Africa (SSSfA)

Subsistence farmers in Ethiopia traditionally use a combination of several pest management practices (such as cultural control, habitat manipulation, mechanical and physical control, natural biological control, host plant resistance, and use of locally available materials). However, such practices are not enough to fully control pests and the use of synthetic chemical products are often the first choice in their control regardless that they raise environmental concerns such as toxicity to humans and biodiversity.

Striga is a genus of parasitic plants that significantly limits agricultural production in Africa. Current control strategies and cultural practices could not contain the parasite and it is highly limiting sorghum production (Mbuvi *et al*.**,** **2017**). However, earlier results by Corteva Agriscience and Kenyatta University researchers has revealed that CRISPR/Cas technology can be employed to impart striga resistance in a popular, high yielding but Striga susceptible African sorghum variety called Macia (Runo *et al*., **2024**). Based on this, the Feed the Future Striga Smart Sorghum for Africa (SSSfA) consortium sought to expand the findings and build a sustainable model for developing home-grown GEd Striga resistant sorghum. The goal was to initiate commercialization of the first GEd, Striga resistant sorghum in the background of an African sorghum cultivar called Macia, and further develop other Striga resistant sorghum varieties adaptable to local environment and preferred (food and feed) by smallholder farmers, and the industry in Ethiopia and Kenya. This project will develop a self-reliant model for commercialization of GEd Striga resistant sorghum in Kenya and Ethiopia and commercialize GEd Striga resistant sorghum. The consortium includes: ISAAA *Afri*Center, Kenyatta University, and AATF from Kenya, and Addis Ababa University and Bio and Emerging Technology Institute (BETin) from Ethiopia.

6.1.3. Ethiopian Mustard (Brassica carinata)

Ethiopian Mustard has great potential in vegetable oil and oleochemical industries. Such diverse use of the crop has not been sufficiently utilized globally in general and in Ethiopia, in particular, where the crop is dominantly produced. The emergence of novel gene editing tools like

CRIPR/Cas9 is a good opportunity for improving the quality of *B. carinata* through editing targeted genes so that the crop can be applicable for both food/feed and oleochemical industries. The overall aim of this research project is to enhance the role of *B. carianta* for edible oil, feed and oleochemical industries through improving its qualities using CRISPR/Ca9 based gene editing system. The products expected are *B. carianta* genotypes with low erucic and glucosinolate for food and feed application and genotypes with wax ester for industrial application. The project is run by the Institute of Biotechnology in collaboration with Swedish University of Agricultural Sciences (SLU), Sweden.

6.1.4. Better Barley by New Breeding Techniques (BBNBT)

This is a collaborative project between Aarhus University (Denmark) and the Ethiopian Institute of Agricultural Research (EIAR). The project builds technical capacity and a broader knowledge base to enable Ethiopia to produce NBT crops. The project will generate new varieties of barley for different traits including dehulled types. The project will strengthen research capacity by establishing a research network including local research stations and universities in Ethiopia.

6.2. Funding and Partnerships

Traditionally, the public sector's knowledge-generating capacity has been measured by the number and quality of publications and trained students that emerge. In such a model, researchers collaborated closely but often without too much regard to securing wider economic value and social benefits. Today, more attention is being given to ways of valorizing these benefits and to organizing advanced degrees such as doctorates in ways that address industrial interest, involve joint supervision and provide a wider range of skills. In many countries, their contribution to innovation is now regarded as part of universities' mission, and they are expected to ensure that intellectual property arising from publicly funded research is identified and commercialized for the benefit of the tax-payer and the economy. Metrics relating to knowledge transfer and innovation are increasingly seen as important in the allocation of research and other funding for universities, as well as for research and technology organizations.

At the same time, new patterns of industrial innovation have emerged (often referred to as "Open Innovation") that emphasize the joint use of internal and external resources achieved through a

combination of collaboration and competition. Companies are seeking to obtain knowledge more quickly from external sources and use more of their results as sources of innovation and research and technology organizations are becoming more market-oriented. In seeking to achieve beneficial outcomes, it is important that all parties fully understand the trends and drivers and take these into account in the approaches they take. Industry needs to recognize governments' intent that universities play a greater part in the commercialization of research and the creation of new ventures. Universities need to understand how industry operates in order to remain competitive. Governments need to ensure that they do not place contradictory pressures on the research and innovation system.

Genome editing projects in Ethiopian research institutions are financed by different donors. In addition to genome edited product development, most of the projects are devised to support institutional capacities, both infrastructure and technical, for genome editing research. Some existing projects are listed below:

Table 4. Ongoing Genome Editing Research Project and Responsible Institutes

Project	**Crop**	**Trait**	**Collaborators**	**Funding**
Genome Editing in Tef for Uplifting Productivity (GET-UP)	Tef	Lodging resistance	EIAR and Donald Danforth Plant Science Center	Gates Foundation
Striga Smart Sorghum for Africa (SSSfA)	Sorghum	Striga parasitic weed resistance	ISAAA *Afri*Center, Kenyatta University, AATF, AAU and BETin	USAID
Improving Oil Quality of Ethiopian Mustard	Brassica carinata	Oil improvement	Addis Ababa University and Swedish University of Agricultural Sciences (SLU), Sweden	Sida
Better Barley by New Breeding Techniques	Barley	Disease and quality	EIAR and Aarhus University	DANIDA (Danish Government)

6.3. Research and Development Challenges and Roadblocks

As discussed above, EPA has been closely working with EIAR and approving GMOs for contained research, CFTs and Environmental release. Since Genome Editing research is a recent phenomenon for Ethiopia, the development and approval of GEd guideline took a long time. As a consequence, implementation of the guideline has also been slow. Biotechnology research is generally challenging in Ethiopia due to limited access to laboratory supplies and services including molecular biology reagents (plasmids, oligo DNA, restriction enzymes, engineered bacteria strains for plant transformation, etc), consumables, and DNA sequencing services. The absence of reliable local suppliers and lengthy procurement system are the major hurdles to the supply chain of biotechnology research inputs. Most indigenous crops do not have an established transformation protocol which is a prerequisite to genetic modification by genome editing. This gap can be addressed through research as the GEd research advances in the country.

It is well known that most genome editing technological components are patented by institutions in the USA and China (Martin-Laffon *et al*., **2019**). The CRISPR/Cas system is patented by the Broad Institute (MIT) and University of California (UC Barkeley) with complex legal dispute between the two institutions (Martin-Laffon *et al*., **2019**; Ricroch, **2023**). The CRISPR/Cas technology can also be accessed for research from other companies such as Corteva AgriScience together with their additional patented technologies like plant transformation enhancing morphogenic genes. However, commercialization of products developed using the technology needs further negotiations with the licensing company due to Intellectual Property Rights (IPRs). In general, settling an agreement to use the genome editing technologies with companies on IPR is challenging for developing countries not limited to Ethiopia.

From survey results, major research and development barriers are shown in **Figure 7**. Respondents identified multiple, interrelated barriers constraining genome editing research and development in Ethiopia. Funding limitations were the most frequently reported challenge (90.5%), followed by inadequate laboratory infrastructure (84.8%) and reagent shortages (79.0%). Human capacity constraints were also prominent, with 63.8% of respondents citing a lack of trained staff. Institutional and governance-related barriers included regulatory uncertainty (51.4%), limited partnerships (50.5%), and biosafety constraints (46.7%). Overall, the findings

indicate that both material resource limitations and systemic institutional challenges significantly hinder progress in genome editing research.

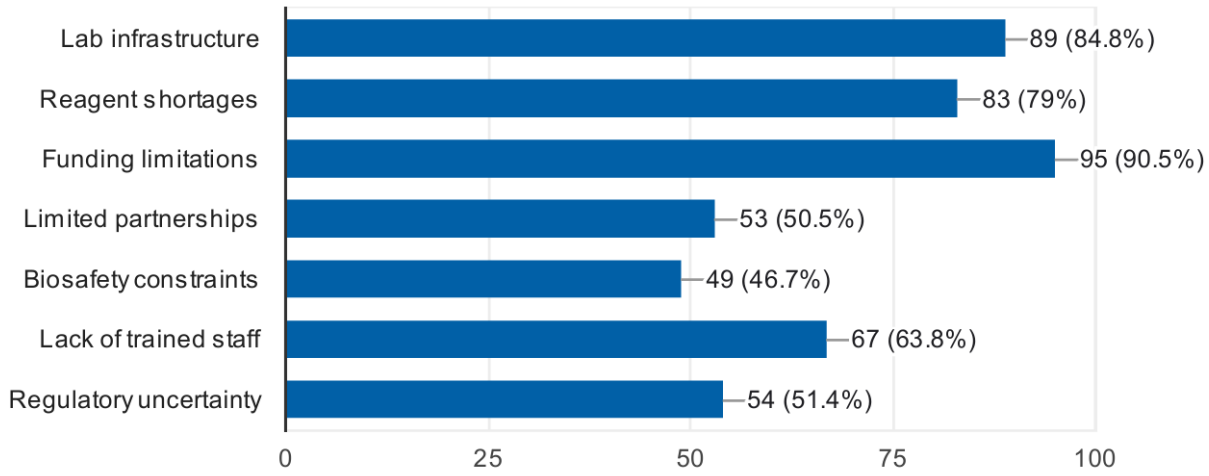


Figure 18. Major research and development barriers

Chapter 7. IPR and Commercialization Pathways for Genome Editing

7.1 Intellectual Property Rights Framework for Genome Editing in Ethiopia

Ethiopia's agricultural sector faces mounting pressures from climate change, pest infestations, and population growth, necessitating urgent adoption of innovative breeding technologies such as genome editing (GEd). However, the nation's current intellectual property rights (IPR) framework requires targeted adaptations to effectively govern these emerging technologies while balancing innovation incentives with public interest, farmer rights, and biodiversity conservation. The following analysis outlines (**Table 4**) critical reforms needed across five key IPR instruments.

7.1.1 Patent System Modernization

Ethiopia's patent regime is anchored in the Inventions, Minor Inventions and Industrial Designs Proclamation No. 123/1995, which provides 15-year patent terms extendable by five years contingent on local working requirements. For GEd innovations, this framework demands urgent clarification regarding patentable subject matter. Article 4(1)(b) currently excludes "essentially biological processes," yet fails to distinguish between transgenic approaches (SDN3) and newer site-directed nuclease technologies that introduce no foreign DNA (SDN1/SDN2). This ambiguity mirrors historical debates in European patent law, where the European Patent Office (EPO) has grappled with defining the boundaries of biological processes.

In order to align with TRIPS Article 27(3)(b) while addressing Ethiopia's development priorities, legislative amendments must explicitly: (1) differentiate SDN1/SDN2 mutagenesis from SDN3 transgenic modifications; (2) codify that targeted genome editing via CRISPR-Cas systems constitutes a "non-biological process" when precision tools are employed; and (3) incorporate TRIPS-compliant flexibilities that permit exclusions based on public order or morality where necessary to protect human, animal, or plant life. Such reforms would build upon Ethiopia's existing compulsory licensing provisions—which already allow government exploitation for national security, nutrition, and health needs—by providing legal certainty for both local researchers and international technology partners.

7.1.2 Expedited Plant Breeders' Rights Pathway

The Plant Breeder's Right Proclamation No. 1068/2017 established Ethiopia's *sui generis* system for protecting new crop varieties. However, conventional examination timelines—often exceeding 3-4 years are incompatible with GEd's rapid development cycles, particularly for climate-adaptive traits in strategic crops like teff, sorghum, and Ethiopian mustard. Drawing from international best practices, Ethiopia should institute an expedited examination track of 12-18 months for GEd varieties demonstrating clear societal benefits, such as drought tolerance or pest resistance.

Critical procedural reforms include accepting molecular data (e.g., SNP profiles) as supplementary evidence of distinctness, uniformity, and stability (DUS), reducing reliance on multi-season field trials. The proclamation's explicit recognition of farmers' rights to save, use, and exchange seeds must be preserved, with GEd-specific carve-outs ensuring that smallholder privileges remain intact. This balanced approach would accelerate commercialization of resilient varieties while honoring Ethiopia's agrobiodiversity heritage.

7.1.3 Strengthening Trade Secret Protections for CRISPR Protocols

While Ethiopia's Commercial Code provides general unfair competition safeguards, GEd technologies—particularly optimized CRISPR protocols, gRNA design algorithms, and proprietary transformation know-how—require enhanced protection mechanisms. The current framework lacks explicit recognition of trade secrets in research collaborations, creating vulnerabilities in university-industry partnerships.

Reforms should institutionalize mandatory Material Transfer Agreements (MTAs) and Confidentiality Disclosure Agreements (CDAs) for all GEd-related exchanges, standardizing clauses on undisclosed know-how, experimental data, and breeding materials. This would prevent misappropriation of publicly funded research while enabling technology transfer, addressing the practical reality that many Ethiopian research institutions lack robust IP management capacity. Such measures align with WIPO's Trade Secret Protection Guidelines and would protect the tacit knowledge essential for adapting GEd tools to local germplasm.

7.1.4 Geographical Indications and Collective Trademarks for GEd Products

Ethiopia's trademark system, governed by the Trademark Registration and Protection Proclamation No. 501/2006, offers a foundation for origin-based branding. For GEd products, developing a collective mark such as "Ethiopia-GEd" would serve multiple functions: signaling adherence to stringent biosafety standards, differentiating Ethiopian-developed varieties from imported alternatives, and capturing premium markets that value ethical innovation.

This mechanism would leverage the existing Nice Classification system administered by the Ethiopian Intellectual Property Authority (EIPA) while creating a certification scheme requiring: (1) verification that products address priority agricultural challenges; (2) compliance with benefit-sharing agreements under the Nagoya Protocol; and (3) traceability through molecular fingerprinting. Such branding would transform IPR from a purely protective tool into a market-development instrument.

7.1.5 Integrating Traditional Knowledge through Nagoya Protocol Mechanisms

Ethiopia's ratification of the Nagoya Protocol positions the nation to pioneer access and benefit-sharing (ABS) frameworks for GEd innovations derived from farmer-maintained landraces. The Protocol's objective—ensuring fair benefit-sharing from genetic resources—is particularly salient given Ethiopia's contributions to global agriculture, including coffee and teff genetic diversity.

GEd-specific adaptations must mandate: (1) mandatory disclosure of traditional knowledge origins in patent applications; (2) binding benefit-sharing agreements with farming communities whose landraces serve as parental material; and (3) establishment of a national registry documenting farmers' contributions and corresponding benefits (e.g., technology access, monetary compensation, or capacity building). This approach addresses historical inequities where genetic resources were extracted without adequate recognition, while complying with the Protocol's requirement for "fair and equitable sharing of benefits arising from the utilization of genetic resources".

In conclusion, Ethiopia's IPR modernization for GEd requires more than piecemeal amendments; it demands a harmonized strategy that accelerates innovation, protects smallholder rights, and valorizes traditional knowledge. By distinguishing GEd types in patent law, expediting breeders'

rights, fortifying trade secret protocols, launching origin-based branding, and operationalizing Nagoya-compliant benefit-sharing, Ethiopia can create a model framework for responsible agricultural innovation in the Global South. These reforms would ensure that CRISPR and related technologies serve national development goals while remaining anchored in principles of equity and biodiversity conservation.

Table 5**.** Intellectual Property Rights (IPR) Regime for GEd Products

IPR Instrument	**Current Legal Basis**	**GEd-Specific Adaptations Needed**
Patents	Patent Proclamation No. 123/1995 (15 years + 5 year extension)	Clarify patentability of GEd inventions: Distinguish SDN1/SDN2 (no foreign DNA) from SDN3 (transgenic). Revisit Article 4(1)(b) on "essentially biological processes" to explicitly include targeted mutagenesis via CRISPR. Align with TRIPS Article 27(3).
Plant Breeders' Rights (PBR)	Plant Breeder's Right Proclamation No. 1068/2017	Fast-track PBR for GEd varieties: Create expedited examination pathway (12-18 months) for GEd crops that address climate/pest priorities (teff, sorghum, mustard). Allow molecular data (SNP profiles) as supplementary evidence.
Trade Secrets	Commercial Code (unfair competition)	Protect CRISPR protocols & know-how: Institutionalize Material Transfer Agreements (MTAs) and Confidentiality Disclosure Agreements (CDAs) for university-industry collaborations.
Trademarks	Trademark Registration & Protection Proclamation	Brand "Ethiopia-GEd": Develop collective trademark for Ethiopian-developed GEd products to signal quality, safety, and origin.
Traditional Knowledge	Nagoya Protocol (access and benefit-sharing)	Integrate farmers' rights: Mandate benefit-sharing agreements with farming communities that provide landraces used as GEd parental material. Document in national registry.

7.2. Commercialization Pathways for Genome-Edited Products in Ethiopia

Ethiopia stands at a critical juncture in agricultural biotechnology, having recently published its Guideline on the Regulation of Genome-Edited Products in 2025 (AfriSCI Dialogue, 2024). This

regulatory milestone transitions genome editing (GEd) from policy design to early implementation, yet significant structural and operational barriers remain. This analysis examines the multi-dimensional pathways required to transform GEd research into commercially viable products that reach Ethiopian farmers.

7.2.1 Regulatory Commercialization Pathway: From Lab to Market

Ethiopia's commercialization pathway is defined by a risk-proportionate, case-by-case regulatory approach that distinguishes GEd from transgenic GMOs (The Reporter Ethiopia, 2025). The guideline establishes two critical gates: (1) Institutional Biosafety Committee review for research and confined field trials, and (2) Ethiopian Environmental Protection Authority approval for commercial release.

The regulatory framework excludes SDN1 and SDN2 GEd products lacking foreign DNA from GMO classification, aligning with progressive models in Nigeria and Kenya (Mbaya, 2022,). This positions Ethiopia as an emerging regulatory reference point in Africa. However, unlike India's 1-2 year approval timeline (Mbaya, 2022), Ethiopia's process remains untested, with no GEd product yet approved for commercial cultivation. However, procedural ambiguity persists-the pathway requires explicit standard operating procedures for: molecular characterization thresholds, environmental release criteria, and post-market monitoring protocols—elements currently absent but essential for investor certainty.

7.2.2 Private Sector Engagement and PPP Models

Commercialization hinges on public-private partnerships (PPPs), yet Ethiopia's seed sector remains dominated by public research institutions with limited private capacity (CGIAR, 2024). The African Union Development Agency (AUDA-NEPAD) reports strong private sector interest from MIDROC Investment Group, Luna Group (Fresh Corner grocery chain), Corteva Agriscience, and BASF (https://www.thereporterethiopia.com/48385/). These entities seek partnerships with the Ethiopian Institute of Agricultural Research (EIAR) to co-develop and distribute GEd seed varieties, but the absence of commercialized products deters investment.

The TELA maize project exemplifies a viable PPP model, linking international organizations with national agricultural research systems for transgenic technology transfer (CGIAR, 2024).

For GEd, this model must be adapted to: (1) clarify IP ownership of CRISPR protocols developed through joint funding; (2) establish technology stewardship agreements ensuring smallholder farmer access; and (3) create tiered licensing structures that differentiate large-scale commercial farmers from subsistence producers. Without such frameworks, multinational corporations may prioritize export-oriented crops over Ethiopia's orphan crops (teff, enset), undermining food security objectives.

7.2.3 Market Entry Strategies and Brand Differentiation

Ethiopia's fragmented seed system and weak extension services create significant last-mile delivery challenges (CGIAR, **2024**). Effective commercialization requires hybrid strategies combining:

Early-Entry Niche Markets: Target commercial farmers and agribusinesses with high-value GEd crops (e.g., disease-resistant coffee, improved oilseeds) before scaling to smallholders. This generates revenue streams while building regulatory track records.

Geographic Phased Rollout: Initiate in stable, high-potential regions (e.g., Oromia, Amhara highlands) with strong extension networks, expanding to conflict-affected areas only after demonstrating socio-economic benefits, mitigating risks from political instability (CGIAR, **2024**).

Origin Branding: Leverage Ethiopia's coffee reputation by creating a "GEd-Resilient Ethiopian" certification mark, signaling quality and ethical benefit-sharing under Nagoya Protocol requirements. This addresses consumer skepticism while capturing premium prices in domestic and diaspora markets.

7.2.4 Funding and Investment Landscape

Funding constraints critically impede commercialization. While CGIAR and bilateral donors support upstream research, downstream activities—variety registration, seed multiplication, farmer demonstrations—lack dedicated financing. Ethiopia must establish a GEd Commercialization Fund with blended finance: public seed money attracting private venture capital, impact investors, and development finance institutions. This fund should prioritize:

Derisking Investments: Provide first-loss guarantees for private sector trials of orphan crops with limited market size but high food security value.

Capacity Building: Finance EPA and National Biosafety Advisory Committee training on GEd risk assessment, accelerating decision-making competence (CGIAR, **2024**).

Infrastructure: Upgrade national agricultural research stations with confined field trial facilities, molecular labs, and seed processing equipment—currently bottlenecks cited by EIAR directors (The Reporter Ethiopia, **2025**).

7.2.5 Stakeholder Engagement and Social License

Public perception remains a latent risk. Anti-GMO activism, though focused on transgenics, could spill over to GEd, particularly given low public awareness of technical distinctions (CGIAR, **2024**). Ethiopia must implement a proactive communication strategy targeting:

High-Level Officials: Secure political buy-in by framing GEd as a climate adaptation necessity, not merely a technological option (CGIAR, **2024**).

Farmers: Use farmer field schools and radio campaigns in local languages to demonstrate GEd's alignment with traditional seed saving rights under Proclamation No. 1068/2017 (Federal Democratic Republic of Ethiopia, **2017**).

Religious and Community Leaders: Ethiopia's deep religious traditions require engagement with Orthodox, Muslim, and Protestant leaders to address ethical concerns, building trust through transparency about benefits and risks.

Ethiopia's commercialization pathway is best conceptualized as a "staged, stakeholder-integrated pipeline" requiring simultaneous action across regulatory, financial, and social dimensions:

The pathway's success depends on converting policy ambition into operational clarity. As Ethiopia navigates political instability and capacity gaps (CGIAR, **2024**), maintaining momentum through external technical partnerships and sustained domestic funding will determine whether GEd becomes a transformative force for food security or remains a research curiosity. The window for leadership is narrow—regulatory alignment with global best practices must occur before public skepticism fossilizes, or investors redirect capital to more predictable markets.

Chapter 8. Ethical, Social, and Communication Aspects

The advent of genome editing (GEd) technologies, particularly CRISPR-Cas systems, presents transformative opportunities for Ethiopia's agricultural sector, offering solutions to climate change, pest pressures, and food insecurity. However, realizing these benefits requires navigating complex ethical imperatives, social dynamics, and communication challenges. As Ethiopia develops its regulatory framework and implementation strategies, a tripartite approach addressing these dimensions is essential for building public trust, ensuring equitable access, and fostering sustainable adoption. This report synthesizes current considerations across ethics, social engagement, and strategic communication, providing a foundation for responsible GEd governance.

8.1 Key Ethical Considerations

Ethical governance of GEd in Ethiopia centers on four pillars: safety, equity, benefit-sharing, and international alignment. Safety remains paramount, with major concerns including off-target effects, unintended mutations, and unknown long-term consequences—particularly given limited vetting of editing tools on diverse African genotypes (CGIAR, **2024**). Ethiopia's guideline mitigates these risks through a risk-proportionate, case-by-case approach, ensuring that each product undergoes rigorous assessment before approval (AfriSCI Dialogue, **2024**).

Equity and access constitute the second ethical pillar. With smallholder farmers comprising 95% of Ethiopia's agricultural producers, the framework must dismantle cost barriers to prevent widening gaps between large commercial and subsistence farmers. This requires deliberate policies ensuring GEd seeds remain affordable and accessible, avoiding scenarios where proprietary technologies exacerbate existing socioeconomic disparities.

Benefit-sharing addresses the moral imperative to equitably distribute gains derived from Ethiopia's rich genetic resources and indigenous knowledge systems. Frameworks must mandate compensation and recognition for farming communities whose landraces serve as parental material, respecting traditional practices while fostering innovation (Lachenmeier and Montagnon, **2024**).

Finally, Ethiopia aligns its ethical framework with international standards, particularly WHO governance principles of justice, personal autonomy, and collective beneficence, while adapting these to Africa-specific contexts and developmental priorities (CGIAR, **2024**). This dual alignment ensures global credibility while maintaining cultural and contextual relevance.

8.2 Social Aspects

8.2.1 Public Engagement Framework

Ethiopia is pioneering an authentic African value-laden public engagement model comprising three interconnected components (CGIAR, **2024**). Public communication focuses on informing stakeholders and correcting misconceptions, particularly avoiding the "GMO" controversy that has plagued transgenic technologies. Public consultation emphasizes democratic deliberation, ensuring inclusive representation of minorities and marginalized groups. Public participation facilitates genuine dialogue in policy decision-making, embedding ethical governance in community values.

8.2.2 Stakeholder Categories

Stakeholder mapping reveals distinct groups requiring tailored engagement strategies (CGIAR, 2024). Technology developers possess high comprehension of GEd mechanisms, while policy/decision-makers maintain basic understanding as crop improvement technology. Technology users, multipliers, and promoters—including extension agents and seed companies—exhibit limited familiarity and often confuse GEd with traditional GMOs. Critically, marginalized voices such as women farmers, youth groups, pastoralist communities, and disabled populations require dedicated inclusion mechanisms to prevent their exclusion from benefits.

8.2.3 Social Impact Considerations

Socioeconomic inequalities represent a significant concern, as GEd technologies potentially exacerbate disparities between resource-endowed commercial farmers and smallholders who may struggle to afford annual seed purchases, undermining traditional seed-saving practices vital for economic survival (The Reporter Ethiopia, **2025**). Gender dimensions reveal that women, bearing primary responsibility for labor-intensive tasks like weeding and pesticide application, stand to benefit directly from GEd innovations reducing these burdens.

Cultural heritage preservation demands respect for indigenous knowledge systems and local agricultural contexts to secure social acceptance. Autonomy and consent raise intergenerational ethical questions, particularly regarding heritable interventions, though disease prevention may paradoxically enhance future autonomy. Public perception surveys indicate stakeholders harbor concerns about potential risks, safety issues, GMO confusion, intellectual property challenges, health fears, and market preferences that could impede adoption (CGIAR, **2024**).

8.3 Communication Aspects

8.3.1 Strategic Communication Plan

The Bio and Emerging Technology Institute (BETin) leads development of Ethiopia's Genome Editing Communication and Advocacy Strategy, emphasizing evidence-based, culturally resonant messaging. Other institutions such as EIAR, which hosts Open Forum for Agricultural Biotechnology (OFAB) Ethiopia also provide support in communication on GEd technology. Ethiopia is also an active participant and collaborator of the AUDA-NEPAD initiative Genome Editing communication strategies. Aligning all these strategies positions communication not merely as information dissemination but as trust-building infrastructure essential for implementation across Ethiopia and Africa.

8.3.2 Communication Channels and Approaches

Stakeholder-specific strategies ensure targeted outreach. For farmers, engagement leverages 13 universities graduating biotechnology experts who serve as rural communication nodes, exemplified by BETin's December 2025 training program demonstrating Ethiopian-led capacity (CGIAR, **2024**). For policymakers, capacity building secures high-level official buy-in. Public outreach employs diverse channels including journal papers, conferences, social media, website subscriptions, newspapers, and radio stations. For the media, dedicated journalist training ensures accurate reporting that distinguishes GEd from GMOs.

8.3.3 Messaging Strategy

Cultural resonance guides messaging, utilizing local languages, respecting traditional communication channels, and engaging religious and traditional leaders. Evidence-based communication grounds claims in scientific research while avoiding overly optimistic promises.

Value-laden communication integrates societal values as a vital component for building public trust and maintaining stakeholder support (CGIAR, **2024**).

8.4 Transparency and Trust-Building Measures

Transparency mechanisms include case-by-case public consultation for each GEd product before Environmental Protection Authority approval, long-term monitoring commitments for effects on individuals and society, and ensuring informed consent where farmers comprehend technology implications—including demonstrated benefits such as 25% yield loss reduction in teff (CGIAR, **2024**). A product-based approach focuses communication on final product characteristics rather than process, using presence/absence of transgenes as the key determinant to simplify public understanding.

In conclusion, Ethiopia's GEd commercialization pathway depends on ethical integrity, social inclusion, and strategic communication. The risk-proportionate regulatory approach addresses safety concerns, while benefit-sharing mechanisms honor genetic resource contributions. Public engagement models must ensure marginalized voices—particularly women and smallholder farmers—shape technology deployment. Communication strategies led by BETin must maintain cultural resonance and transparency to build trust. Success requires synchronizing these dimensions: ethical frameworks must be socially embedded through inclusive participation, and communication must translate ethical commitments into accessible narratives. As Ethiopia advances from policy to practice, maintaining this integrated approach will determine whether GEd becomes an equitable tool for agricultural transformation or exacerbates existing inequalities.

Chapter 9. Regional and International Collaboration

Ethiopia's ambition to harness genome editing (GEd) for agricultural transformation is inextricably linked to its capacity for strategic regional and international collaboration. As a nation with limited domestic biotechnology infrastructure but immense agrobiodiversity wealth, Ethiopia's GEd ecosystem depends on multi-level partnerships that span policy harmonization, research co-development, capacity building, and commercialization. This report analyzes Ethiopia's collaborative architecture, examining how partnerships with international research centers, regional bodies, philanthropic organizations, and private sector actors are shaping the country's GEd trajectory. The analysis reveals a multi-stage framework that leverages global expertise while embedding African value systems into technology governance.

9.1 Multi-Level Collaboration Architecture

Ethiopia's collaboration strategy operates across five functional levels, each addressing distinct capacity gaps (**Table 8.1**). At the policy and regulatory level, partnerships with the International Food Policy Research Institute's Policy and Biosafety Support (IFPRI-PBS) and the African Union Development Agency (AUDA-NEPAD) provide technical advisory support for guideline development and regional harmonization (CGIAR, 2024). AUDA-NEPAD and the African Biosafety Network of Expertise (ABNE) play pivotal roles in aligning Ethiopia's framework with continental standards, while ISAAA AfriCenter contributes advocacy and policy advisory services (CGIAR, **2024**). The African Union's Science & Technology division coordinates continental policy positions, ensuring Ethiopia's voice informs AU-wide GEd governance (CGIAR, **2024**).

Research and development partnerships anchor Ethiopia's technical capacity. The Donald Danforth Plant Science Center and Michigan State University (USA) provide foundational research collaboration and training, transferring expertise in CRISPR applications for orphan crops (CGIAR, **2024**). Industry engagement with Corteva Agriscience facilitates market-oriented R&D, while regional collaboration with Kenyatta University and ISAAA AfriCenter enables sharing of best practices and joint problem-solving (CGIAR, **2024**). These bilateral and

multilateral arrangements allow Ethiopian scientists to participate in cutting-edge research without requiring full domestic infrastructure.

Capacity building constitutes a critical collaboration level, with Haromaya University partnering with European universities to develop postgraduate biotechnology programs. AUDA-NEPAD's training workshops complement academic programs by targeting mid-career regulators and extension officers. Funding support from the Bill & Melinda Gates Foundation, USAID Feed the Future, and Swedish International Development Cooperation Agency (SIDA) provides the financial backbone for infrastructure development, pilot projects, and scaling activities.

Commercialization partnerships integrate the Ethiopian Institute of Agricultural Research (EIAR) with private sector actors for product development and field trials, while local seed associations and farmer groups serve as adoption and outreach channels (CGIAR, **2024**). This multi-level architecture ensures collaboration addresses the entire innovation pipeline, from policy design to farmer adoption.

9.2 Cross-Stage Collaboration Matrix

Ethiopia's collaborative model varies systematically across three developmental stages (**Table 5**). During policy development, collaborations focus on learning from Nigeria, Kenya, Ghana, and Malawi's regulatory experiences, with AUDA-NEPAD providing technical advisory support and the AU High-Level Panel offering guidance from its 2019 Addis Ababa meeting (CGIAR, 2024). International regulatory frameworks, including WHO governance principles (**2021**) and Cartagena Protocol best practices, inform biosafety ethics and risk assessment capacity building. The product-based regulatory approach—focusing on transgene presence/absence—emerges from these international dialogues, distinguishing GEd from GMOs and simplifying approval pathways.

At the research and development stage, collaborations shift to bilateral partnerships for specific crops. The GETUP Project on teff lodging resistance exemplifies this model, with the Donald Danforth Plant Science Center and Michigan State University providing CRISPR-Cas9 expertise while EIAR leads field testing in Bishoftu (CGIAR, **2024**). Ethiopia's mustard improvement program collaborates with Addis Ababa University Institute of Biotechnology on low erucic acid

traits, with potential for commercial edible oil production. Regional R&D partnerships, such as the Striga Smart Sorghum for Africa project led by Kenyatta University with Ethiopian participation, enable shared development costs and cross-border variety adoption (Runo *et al*., **2024**).

The commercialization stage demands intense private sector engagement. The TELA maize program serves as a blueprint for public-private partnerships (PPPs), linking EIAR, the African Agricultural Technology Foundation (AATF), Corteva, and national seed companies (CGIAR, **2024**). These partnerships address seed multiplication, distribution to small and large-scale farmers, and market development. International donors provide scaling support through direct funding for farmer adoption and technology dissemination, while local seed associations ensure last-mile delivery.

9.3 Flagship Bilateral and Regional Partnerships

Three crop-specific partnerships illustrate Ethiopia's collaborative depth. The teff improvement program demonstrates how international research centers can align with national priorities. CRISPR-mediated lodging resistance addresses a critical constraint causing up to 25% yield loss, with the Donald Danforth Center and Michigan State University providing technical expertise while EIAR ensures adaptation to Ethiopian agroecologies. The Bill & Melinda Gates Foundation's scaling support bridges the gap between research and commercial distribution (CGIAR, **2024**).

The Ethiopian mustard (Brassica carinata) oil quality project showcases university-industry collaboration. Addis Ababa University Biotechnology Research Center leads R&D on low erucic acid traits using CRISPR-Cas9, with stakeholder validation of training materials and policy support for trait approval (Li *et al*., **2025**). This partnership targets both edible oil production for domestic consumption and industrial applications, addressing Ethiopia's foreign exchange constraints while improving nutrition.

The sorghum Striga resistance partnership exemplifies regional South-South collaboration. The "Striga Smart Sorghum for Africa" project, led by Kenyatta University with Ethiopian

participation, develops CRISPR-based resistance to the parasitic weed. Joint policy workshops on Striga management and shared socioeconomic impact assessments align regulatory approaches, while commercial seed production serves both Kenyan and Ethiopian markets, demonstrating economies of scale (Runo *et al*., **2024**).

9.4. Private Sector Engagement and PPP Models

Ethiopia actively courts private sector participation across all collaboration stages. During policy development, private sector consultations informed the GEd guideline's IPR and benefit-sharing frameworks (CGIAR, **2024**). Companies including MIDROC Investment Group, Luna Group, Corteva Agriscience, and BASF have expressed interest in GEd partnerships, viewing Ethiopia as a strategic African market (The Reporter Ethiopia, **2025**). It is expected that on-farm trials and seed production research engage these firms in R&D, while commercialization partnerships will focus on distribution networks.

The TELA maize program provides a replicable PPP model, combining public research capacity with private sector efficiency in seed multiplication and marketing (CGIAR, **2024**). However, challenges persist: the absence of commercialized GEd products deters investment, and unclear IP ownership in joint projects creates uncertainty (The Reporter Ethiopia, **2025**). Addressing these requires explicit technology stewardship agreements ensuring smallholder access and tiered licensing structures differentiating large commercial farmers from subsistence producers.

9.5. Challenges and Coordination Mechanisms

Despite robust collaboration frameworks, several challenges threaten effectiveness. Fragmented coordination across multiple partners risks duplication and inconsistent messaging. Ethiopia mitigates this through BETin's central coordination role, but stronger integration mechanisms are needed. Capacity asymmetries between international and domestic partners may lead to technology dependence; the training-of-trainers model with Ghent University and Ethiopian universities aims to build sustainable local expertise (CGIAR, **2024**). Regulatory misalignment with neighboring countries could impede regional trade; AUDA-NEPAD's harmonization efforts must accelerate to create a seamless East African GEd market. Intellectual property complexity

in multi-partner projects requires clear MTAs and benefit-sharing agreements, particularly for farmer-maintained landraces used as genetic resources (The Reporter Ethiopia, **2025**).

In conclusion, Ethiopia's regional and international collaboration strategy represents a nuanced approach to leapfrogging into GEd maturity. By leveraging partnerships for policy, R&D, capacity, funding, and commercialization, Ethiopia accesses global innovation while retaining sovereignty over technology governance. The multi-stage collaboration matrix ensures appropriate partner engagement at each development phase, from AUDA-NEPAD's policy guidance to Corteva's commercial expertise. Flagship projects in teff, mustard, and sorghum demonstrate practical application, while PPP models provide pathways to scale.

Success hinges on maintaining this collaborative architecture while strengthening domestic absorptive capacity. Ethiopia must ensure partnerships transfer not just technology but also institutional capabilities—regulatory competence, IP management, and extension systems. As the country moves from policy to first commercial approvals, coordination mechanisms must mature to prevent fragmentation. Ultimately, Ethiopia's collaborative model could serve as a template for other African nations, demonstrating how strategic international engagement can accelerate agricultural innovation while embedding African values in technology governance.

Table 6. Regional and international collaboration on GEd

Collaboration Level	**Partner / Organization**	**Role / Area of Support**
Policy & Regulatory	IFPRI-PBS	Policy/Regulatory
	AUDA-NEPAD and ABNE	Regional policy harmonization, communication strategy
	ISAAA AfriCenter	Advocacy & policy advisory
	African Union (AU) Science & Technology	Policy coordination
Research & Development	Donald Danforth Plant Science Center (USA)	Research collaboration
	Michigan State University	Research & training

	(USA)	
	Corteva Agriscience	Industry R&D collaboration
	Kenyatta University & ISAAA AfriCenter (Kenya)	Regional research collaboration
Capacity Building & Training	Haramaya University + European universities	Skills development
	AUDA-NEPAD	Training & workshops
Funding & Investment Support	Bill & Melinda Gates Foundation	Financial support
	USAID Feed the Future	Funding & technical assistance
	SIDA / European agencies	Grants & collaboration
Commercialization / Field Deployment	EIAR (Ethiopian Institute of Agricultural Research)	Product development & field trials
	Corteva Agriscience	Market-oriented support
	Local seed associations & farmer groups	Adoption & outreach

Chapter 10. Genome Editing Readiness index

Ethiopia's Genome Editing Readiness Index (Table 6) provides a diagnostic framework. Scores range from 1.5 (Commercialization Readiness) to 3.0 (Regulatory Framework), with a mean of 2.1 indicating moderate overall preparedness.

10.1 Strengths

The highest scores appear in Regulatory Framework (3.0) and Collaboration (3.0), reflecting Ethiopia's progressive risk-proportionate guidelines and robust international partnerships. The exclusion of SDN1/SDN2 from GMO classification and case-by-case evaluation protocols demonstrate regulatory sophistication. Collaboration architecture spanning IFPRI-PBS, AUDA-NEPAD, AATF, and bilateral research partnerships provides strong external support.

10.2. Critical Gaps

The lowest scores reveal systemic vulnerabilities. Commercialization Readiness (1.5) indicates severe deficits in downstream capacities—from seed multiplication infrastructure to market linkages and extension services (CGIAR, 2024). This gap threatens to convert research successes into "valley of death" failures where promising varieties never reach farmers.

Ethical & Social Governance (1.7) and Public Awareness & Engagement (1.8) scores signal profound social integration challenges. Limited systematic public engagement, nascent benefit-sharing implementation, and insufficient gender-responsive strategies risk social rejection and inequitable outcomes. The disconnect between policy ambition and grassroots understanding could enable anti-technology advocacy to gain traction, particularly given Ethiopia's history of civil society mobilization.

Research Activity (2.5) and R&D Infrastructure (2.0) indicate moderate but insufficient scientific capacity. While Ethiopia hosts active GEd research programs, limited molecular biology infrastructure and trained personnel constrain throughput and sophistication.

10.3 Integrated Recommendations

Addressing readiness gaps requires synchronized action across ethical, social, and communication dimensions:

Ethical Governance Strengthening: Establish a National GEd Ethics Committee integrating biosafety, social science, and community representation to oversee benefit-sharing agreements, monitor long-term impacts, and ensure equity in technology distribution. This would raise the Ethical & Social Governance score from 1.7 to institutionalized best practice.

Social Inclusion Acceleration: Implement mandatory stakeholder mapping and engagement protocols for all GEd projects, requiring documented inclusion of women, youth, pastoralists, and disabled communities. Develop gender-responsive communication toolkits and fund community-based organizations as GEd information hubs. This targeted investment could improve Public Awareness & Engagement from 1.8 to 2.5 within three years.

Communication Infrastructure: BETin should expand from advocacy to become a permanent GEd Communication Authority, with dedicated regional offices and language-specific teams. Establish a national GEd information portal providing real-time project updates, risk assessment summaries, and farmer testimonies in Amharic, Oromiffa, and Tigrinya. This would professionalize communication and build sustained trust.

Capacity-Building Integration: The Ghent University partnership model should be institutionalized as a national training-of-trainers program, with Ethiopian universities mandated to integrate GEd extension modules into all agricultural curricula. This addresses both R&D Infrastructure (2.0) and Public Awareness (1.8) simultaneously.

Commercialization Derisking: Create a GEd Commercialization Fund with blended finance, targeting the 1.5 readiness gap. The fund should provide first-loss guarantees for orphan crops, finance infrastructure upgrades at EIAR research stations, and support farmer demonstration plots. Bilateral partnerships should include explicit technology transfer milestones ensuring local capacity building, not just research execution.

Regional Leadership: Leverage Ethiopia's high Collaboration score (3.0) to establish an East African GEd Center of Excellence, hosted at EIAR but governed by a consortium including Kenya, Uganda, and Tanzania. This would transform Ethiopia from technology recipient to regional hub, addressing sustainability concerns in current partnerships.

In conclusion, Ethiopia's GEd readiness profile presents a paradox: sophisticated regulatory frameworks and strong international partnerships coexist with fragile social license and limited commercialization capacity. The readiness index diagnostic reveals that technological potential cannot compensate for ethical governance deficits and social integration gaps. Success requires treating communication and social engagement not as add-ons but as core infrastructure equivalent to laboratories and regulatory bodies.

The country's commitment to a risk-proportionate, Africa-centric approach offers a model for the Global South, yet translating policy into practice demands urgent attention to the weakest readiness dimensions. By synchronizing ethical oversight, inclusive social engagement, and strategic communication with scientific and regulatory advancement, Ethiopia can position GEd as a truly equitable tool for agricultural transformation. Failure to address these foundational elements risks replicating historical patterns where agricultural innovations bypass the poorest farmers, exacerbating inequality and undermining food sovereignty.

Table 7**.** Ethiopia Genome Editing Readiness Level

Dimension	Readiness Level	Indicators / Evidence
Regulatory Framework	Moderate – Emerging Strength	Guideline on Regulation of Genome-Edited Products published in 2025 under the EPA. Built on amended Biosafety Proclamation and commitments under CBD/Cartagena Protocol
Institutional Capacity (Gov't & Policy)	Moderate – Growing	Environmental Protection Authority (EPA) as competent authority.) National Biosafety Advisory Committee (NBAC) in place. Bio and Emerging Technology Institute (BETin) coordinating policy and communication strategy development.
R&D Infrastructure & Human Capital	Moderate – Needs Investment	Several universities/trainers offer biotechnology/modern breeding training. Ongoing genome editing projects on crops (teff, mustard, sorghum).
Research Activity (Projects & Implementation)	Moderate – Active but Early Stage	At least three active crop genome editing projects (teff, Ethiopian mustard, sorghum).
Regional & International Collaboration	Strong – Connected	AUDA-NEPAD support for communication strategy and capacity building. International R&D partnerships (e.g., with Danforth, MSU) integrated into projects (not explicitly cited here but documented in a broader landscape).
Public Awareness & Stakeholder Engagement	Low–Moderate	National communication strategy development underway. Stakeholder focus group dialogues held on genome editing (sorghum case).
Ethical, Social & Environmental Readiness	Low–Moderate	Regulatory focus on product safety exists. Less documented structured ethics frameworks specific to genome editing.
Commercialization & Deployment Pathways	Early Stage	Guidelines pave way for confined field trials and future deployment.

10.4. Comparative performance of readiness with Kenya and Argentina

The comparative analysis (**Table 7**) reveals three distinct developmental stages. Argentina operates as a global innovation hub, leveraging decades of biotechnology investment, robust private sector leadership, and regulatory maturity to compete internationally. Its primary challenges involve maintaining public trust and preventing market concentration.

Kenya functions as an emerging regional leader, with sufficient capacity to develop and test GEd products but requiring strengthened commercialization pathways and enhanced public engagement to achieve scale. Kenya's strategic position allows it to serve as a knowledge broker between global innovators and African adopters.

Ethiopia remains in an early implementation phase, possessing promising policy frameworks but requiring massive investment in infrastructure, capacity, and social integration to avoid technology failure. Ethiopia's greatest vulnerability lies in its low commercialization readiness (1.5) and ethical governance (1.7)—gaps that could result in GEd technologies benefiting only elite farmers, thereby exacerbating inequality and undermining national food security goals.

For Ethiopia to advance, it must prioritize three areas:

1. Infrastructure investment: Upgrade R&D facilities and seed systems to move from 2.0 to 3.0+ scores
2. Social integration: Implement systematic public engagement and benefit-sharing to raise ethical governance from 1.7 to 2.5+
3. Commercialization derisking: Create blended finance mechanisms and PPP models to elevate commercialization readiness from 1.5 to 2.5+

The ranking suggests that while Ethiopia can learn from Kenya's regional collaboration models and Argentina's regulatory best practices, direct technology transfer is insufficient. Ethiopia must build domestic absorptive capacity and social legitimacy to ensure GEd serves its 95% smallholder farmer population rather than bypassing them.

Table 8**.** Comparative ranking of Ethiopia with Kenya and Argentina

Readiness Dimension	**Ethiopia**	**Kenya**	**Argentina**
Regulatory Framework	3.0	3.5	4.5
Institutional Capacity	2.5	3.0	4.5
R&D Infrastructure	2.0	3.0	4.5
Research Activity	2.5	3.5	4.5
Collaboration	3.0	3.5	4.0
Public Awareness & Engagement	1.8	2.5	3.5
Ethical & Social Governance	1.7	2.5	3.5
Commercialization Readiness	1.5	2.5	4.5
Overall Readiness Score	2.1	3.0	4.3

Chapter 11. Strength, Weakness, Opportunity and Threat (SWOT) Analysis

This SWOT analysis provides a structured assessment of the current state of biotechnology research, development, and commercialization within the country. It identifies internal strengths and weaknesses as well as external opportunities and threats that influence the growth and sustainability of the biotechnology sector.

The analysis highlights key strengths, such as strategic prioritization at the policy level, strong mission-driven public research institutions, an emerging skilled workforce, and the existence of a national biotechnology roadmap. These strengths provide a foundation for advancing biotechnology innovation and translating research into practical applications.

At the same time, the sector faces significant weaknesses, including underfunded research and development, fragmented coordination among institutions, limited commercialization pathways, and inadequate infrastructure and maintenance capacity. Addressing these weaknesses is critical to unlock the sector's full potential.

Externally, there are significant opportunities, including rich biological resources, government commitment to science, technology, and innovation (STI), expanding industrial and educational capacities, and international collaborations. Harnessing these opportunities can accelerate biotechnology-driven economic growth, enhance employment, and support bio-based industries.

However, the sector is also exposed to threats such as limited access to consumables, high staff turnover, underutilization of genetic resources, lack of integrative platforms, and insufficient funding mechanisms. These challenges require coordinated policy interventions, public-private partnerships, and strategic investment to ensure long-term sector resilience.

Overall, this SWOT analysis serves as a strategic tool to guide policymakers, stakeholders, and investors in identifying actionable priorities, leveraging existing advantages, mitigating risks, and fostering a sustainable and globally competitive biotechnology ecosystem, specifically, Genome Editing which is expected to address current challenges in agriculture, health, industry and environment.

Table 9. SWOT Analysis Matrix

Strengths	**Weaknesses**
• Clear strategic prioritization at policy level • Strong, mission-driven public research institutes. • Established (if cautious) biosafety regulatory system. • Major investment Integrated Agro- - Industrial parks that could enhance employability of Biotechnology graduates. • Growing pool of qualified and skilled life science graduates and expansion of postgraduate biotechnology programs in higher learning institutions • Presence of National biotechnology roadmap for transforming the biotech sector • Availability of moderately equipped public and private Tissue Culture laboratories • Private enterprises reputation and aspiration for excellence, quality, encouraging new comers • Established human capacity and infrastructure for vaccine production and at NVI and diagnostic facilities in other public institutes • Established regulatory and compliance mechanisms congruent to international standards of R&D	• Severe underfunding of R&D across the board • Fragmented coordination and weak collaboration between institutes and universities. • Weak commercialization pathway: Underdeveloped TTOs, IP management, and startup finance. • Dilapidated and inadequate infrastructure for frontier research. • Minimal private sector engagement in co-creation and R&D funding. • Limited infrastructure capacity, finance, and human resource in all institutions • Lack of capacity for lab equipment/ facility maintenance and repair • Lack of semi-commercialized public Tissue Culture laboratory • Absence of institutionalized quality control system • Lack of market-linkage for biotech products and commercialization pathways • Absence of a Strong Integrative Platform • Inefficient procurement system and absence of some equipment and inputs at local markets • Lack of foreign currency for purchase of suppliers
Opportunities	**Threats**
4. Rich biological resources in the country that could be harnessed for economic development. **5.** The country recognizes science, technology and innovation (STI) and biotechnology as the engine of economic growth **6.** Commitment of the government to foster biotech R&D **7.** High demand for quality products **8.** There is a growing industrial sector with a growing consumer market; **9.** The country has adopted a ten-year comprehensive economic	• Unavailability of consumables and materials in the local market • High staff turn-over and brain drain of skilled professionals • Expensive molecular biotech facilities • Underutilization of genetic resources • High attrition rates of human resources due to brain-drain attributed to various socio-economic reasons. • Absence of a Strong Integrative Platform the industry, as well as between public and private sector actors • Inappropriate utilization of research capacity due to low investment into

development plan and sectoral development plans. **10.** The country formulated a Biotechnology Roadmap **11.** Presence of a national Biotechnology Institute (BETin) that catalyzes and streamlines the development of biotechnology and emerging technologies in the country. **12.** Access to international collaboration through bilateral and multilateral engagements and supportive development partners **13.** Expansion of higher learning institutions with programs in biotechnology training and research that can be easily absorbed into the biotechnology industry with hands-on skill training and targeted specializations **14.** Bioeconomy strategy for diversification of export value-added commodities in a range of sectors.	research and development. - Very limited resources to effectively implement the R&D programs in biotechnology - Public-private partnerships involving academia, research and the private sector are very limited and or non-existent - Lack of comprehensive biotechnology policies, including policies on technology dissemination, product development partnerships and intellectual property right (IPR) systems - Inadequate funding and venture capital; - Inadequate incentives for effective product development through public-private partnerships. - Opposition to the technology on unsubstantiated risks to human health and the environment

Chapter 12: Conclusions and Recommendations

12.1 Conclusions

Ethiopia has achieved a significant level of regulatory readiness, characterized by a fundamental shift from legal prohibition (2009) to institutional enablement (2015-2025). The political will, demonstrated by the 2024 policy mandate for science-led agriculture and the practices undergoing on the different GMO transactions, validates the operational functionality of the biosafety system.

The country's readiness for agricultural biotechnology is robust, underpinned by strong alignment between High-Level Policy Alignment and its operational capacity. This is evidenced by a clear national directive that explicitly links the deployment of biotechnology to achieving food security and facilitating commercialization. Furthermore, a fully functional Legal Pathway is in place, demonstrating to manage both the initial stages of research through a Special Permit and the eventual commercial release of genetically modified products and gene edited plants and their products.

This system is supported by a network of regulatory and research agencies, specifically EPA with the science-based advice from the National Biosafety Advisory committee (NBAC), the Ethiopian Institute of Agricultural Research (EIAR), The Bio and Emerging Technology Institute (BETin), each assigned specific responsibilities across all stages of the biotechnology regulation lifecycle. The regulatory system's primary vulnerabilities lie not in legislative intent but in infrastructure capacity and enforcement efficacy. Specifically, the failure to control borders, test imports for GMO content, and finalize the legal framework for liability poses an ongoing risk to both public health and biodiversity integrity.

12.2 Strategic Recommendations

Based on Ethiopia's national strategy framework, the following 14 strategic recommendations are organized under five core pillars, each with specific implementation actions:

12.2.1 Establish a National Genome Editing Platform (NGEP)

12.2.1.1 Designate Centers of Excellence at BETin, EIAR, NVI & Leading Universities

Consolidate Ethiopia's fragmented GEd research capacity by establishing dedicated Centers of Excellence at BETin, EIAR, NVI & Leading Universities. This creates centralized hubs for protocol standardization, quality control, and advanced training, reducing duplication and ensuring consistent research standards across institutions.

12.2.1.2 Standardize SOPs under 2025 GEd Guidelines

Develop and mandate uniform Standard Operating Procedures (SOPs) for all GEd research activities, aligning with Ethiopia's 2025 regulatory guidelines. This ensures reproducibility, safety, and regulatory compliance while streamlining institutional biosafety committee reviews and accelerating project approvals.

12.2.1.3 Develop a National Priority Crop-Trait List

Create a consultatively-derived list prioritizing GEd applications for climate-resilient orphan crops (teff, sorghum, enset, sesame) and nutritionally-enhanced staples. This focuses limited resources on solving Ethiopia's most pressing agricultural challenges rather than pursuing research disconnected from farmer needs.

12.2.2. Prioritize Climate-Resilient & Orphan Crops

12.2.2.1 Align GEd Research Calls to Climate & Nutrition Goals

Direct all competitive GEd research funding toward traits addressing climate adaptation (drought tolerance, heat resistance) and nutritional security (biofortification). This ensures GEd innovations directly contribute to Ethiopia's Climate Resilient Green Economy strategy and malnutrition reduction targets.

12.2.2.2 Reduce IP Barriers through Public-Good Licensing

Implement a national policy requiring publicly-funded GEd technologies to be licensed under public-good terms, using models like the African Agricultural Technology Foundation (AATF) approach. This guarantees smallholder farmers can access improved varieties without restrictive royalty payments or technology use agreements.

12.2.3. Close Human Capital & Brain Drain Gaps

12.2.3.1 Launch GEd MSc-PhD-Postdoc Pipeline

Establish a comprehensive fellowship program training 50 GEd specialists annually through international partnerships (e.g., Ghent University model) with mandatory return-to-Ethiopia service requirements. This addresses the critical shortage of molecular biologists and builds sustainable domestic expertise.

12.2.3.2 Introduce Return-Service & Diaspora Schemes

Create attractive packages incentivizing Ethiopian GEd experts in the diaspora to return, including research grants, faculty positions, and startup funding. Simultaneously implement return-of-service obligations for scholarship recipients to prevent brain drain.

12.2.3.3 Competitive Incentive & Grant Packages

Establish salary premiums, research budgets, and publication incentives for GEd scientists to retain talent within Ethiopia's public research institutions, making them competitive with international offers and private sector alternatives.

12.2.4. Create a Commercialization Bridge

12.2.4.1 Establish National Bio-Innovation Hub

Develop a physical and virtual hub connecting researchers, seed companies, investors, and farmers. The hub provides shared laboratory facilities, business incubation services, regulatory navigation support, and matchmaking for public-private partnerships—directly addressing the Commercialization Readiness gap (current score: 1.5).

12.2.4.2 Adopt AATF-Style PPP Product Pipelines

Replicate the African Agricultural Technology Foundation's proven product development partnership model, where international technology providers, public research institutions (EIAR), and private seed companies share costs, risks, and rewards across the commercialization pipeline.

12.2.4.3 Enable Spin-Offs & Startup Incubation

Create a dedicated fund and mentorship program supporting GEd-based agri-startups, providing seed capital, IP management assistance, and regulatory fast-tracking. This fosters private sector innovation beyond the public research system.

12.2.5. Improve Regulatory Efficiency & Predictability

12.2.5.1 Implement Risk-Proportionate GEd Review Pathways

Operationalize Ethiopia's 2025 guideline by creating clear, tiered review pathways: expedited 6-month approval for SDN1 edits (no foreign DNA), 12-month review for SDN2, and full evaluation for SDN3. This provides regulatory certainty essential for private sector investment.

12.2.5.2 Introduce Regulatory Timelines & Parallel Reviews

Mandate legally-binding decision timelines for EPA and institutional biosafety committees while allowing parallel (rather than sequential) reviews of molecular characterization, field trials, and environmental assessments—cutting approval times by 40-50%.

12.2.5.3 Capacity Building for EPA

Implement intensive, ongoing training programs for Environmental Protection Authority reviewers and National Biosafety Advisory Committees, including international secondments to Argentina's CONABIA and Kenya's NBA. This addresses the current bottleneck where regulatory agencies lack GEd-specific expertise, causing indefinite project delays.

These 14 recommendations represent a sequenced implementation roadmap. Recommendations 1 and 5 (Platform and Regulatory Efficiency) should be implemented immediately to enable all other actions. Recommendations 3 (Human Capital) and 4 (Commercialization) require 2-3 year investment horizons, while Recommendation 2 (Prioritization) provides the strategic lens ensuring all activities serve Ethiopia's food security and climate adaptation goals.

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Annexes

Annex 1. GEd research capacity assessment across major research and academic institutions

Resources	Functional facility (in quantity) accessible for GEd R&D						
	EIAR	**BETin**	**AAU**	**Haramaya Univ**	**Jimma Univ**	**Hawassa Univ**	**Mekelle Univ**
1. Molecular Biology Equipment							
● PCR machine	3	2	3	2	3	4	1
● qPCR machine	1	1	1	1	0	1	4
● Electroporator	1	0	0	0	0	0	0
● Fluorescence microscope	1	0	0	0	0	1	0
● Biolistic system	1	0	0	0	0	0	0
● Gel electrophoresis system	4	3	4	3	10	8	4
● Gel documentation system	1	2	2	0	1	3	1
● Nanodrop	1	0	1	1	1	3	2
● Benchtop Centrifuges	4	1	5	1	4	2	1
● Micropipettes	5	3	10	4	3	5	6
● Vortex mixer	4	1	5	2	3	2	3
● Analytical balance	1	2	2	2	3	3	4
● pH meter	1	1	6	2	2	5	1
● Water bath	3	4	5	2	1	3	3
● Heat blocks	2	2	2	1	0	3	0
● Lab refrigerators (–20 °C)	4	7	10	2	6	5	1
● Freezers (–80 °C)	1	1	2	1	2	2	1
2. Availability of Tissue Culture Facility							
● Laminar flow hoods	2	2	3	1	1	3	0
● Heat sterilizer	4	0	1	0	2	0	2
● Growth chambers	1	1	0	1	1	2	0
● Autoclaves	3	3	4	2	2	3	1
● Water purification system	2	0	2	2	2	2	1
● Green house	1	0	1	2	0	0	0
3. Bacteria Culture Handling Facility							
● Shaking incubator (28oC/37oC)	2	1	2	2	0	2	2
● Biological safety cabinet (BSL2)	1	1	1	0	0	1	0

• Inoculating loops (reusable)	2	2	1	5	0	2	5
• Cold Rooms	2	0	0	0	1	1	2
4. Human Resource in Genome Editing and Related Fields							
• GEd trained researchers (MSc)	3	3	4	3	0	1	0
• GEd trained researchers (PhD)	1	1	0	3	0	0	0
• Technitians	0	0	0	0	0	0	0
• Molecular biology skills	5	10	10	7	4	5	4
• Plant tissue culture skills	12	6	4	2	2	5	5
• Bioinformatics skills	4	10	3	7	2	3	2
5. Access to DNA sequencing							
• Available service in the lab	0	0	0	0	1	1 (Iseq100)	0
• Established outsourcing service	0	0	1	0	0	0	0

Annex-II. Assessment of the State of Genome Editing (GEd) in Ethiopia

Respondent Profile

1. Full Name (optional)

2. Category of your institution/organization

- ☐ Policy Maker
- ☐ Biosafety Regulator
- ☐ Academic/University
- ☐ Research Institution
- ☐ Extension/Development Agent
- ☐ Private Sector
- ☐ NGO/Advocacy
- ☐ Media/Communications
- ☐ Other_____

3. Your Role / Position Level

- ☐ Senior Leadership
- ☐ Middle Management
- ☐ Technical Expert
- ☐ Researcher/Scientist
- ☐ Lecturer/Faculty
- ☐ Graduate Student
- ☐ NBAC member
- ☐ Other:

Section 3: Policy, Legal, and Institutional Landscape

4. Does Ethiopia currently have a legal framework that adequately governs genome editing?

- ☐ Yes
- ☐ Partially
- ☐ No
- ☐ Not sure

5. How well is genome editing addressed in Ethiopia's national science & technology policies?

- ☐ Not addressed

- Slightly addressed
- Moderately addressed
- Fully addresses

6. Which institutions do you consider responsible for genome editing governance? (Select at least two)

- MinT
- MoA
- Parliament / Standing Committee
- EPA
- EFDA
- EIAR
- BETin

7. Level of clarity in institutional mandates

- Unclear
- Somewhat clear
- Clear
- Unsure

8. Ethiopia's readiness to develop a national genome editing policy, strategy or roadmap

- Not ready
- Slightly ready
- Moderately ready
- Ready
- Fully ready

9. Alignment with African Union frameworks (e.g., AGRA, AUDA-NEPAD, AURGEP)

- Not aligned
- Weakly aligned
- Moderately aligned
- Well aligned

10. Effectiveness of governance for genome editing

Scale: 1 (Very ineffective) → 5 (Very effective)

- 1
- 2
- 3
- 4

- 5

11. Are existing biosafety laws sufficient to regulate genome editing?

- Yes
- Partially
- NO
- Unsure

12. Regulation of genome-edited products

- Treated as GMOs
- Treated as conventional
- No regulatory guidance exists
- Unsure

13.Capacity of regulatory authorities in risk assessment

- Very weak
- Weak
- Moderate
- Strong
- Very strong

14. Key regulatory gaps (select all that apply)

- No guidance for SDN1/SDN2/SDN3
- Limited lab inspection capacity
- Lack of detection equipment/facility
- Weak institutional coordination
- Lack of trained biosafety personnel
- Public trust issues
- Other: _____

15. Public confidence in regulatory bodies

- Very low
- Low
- Moderate
- High

16. Adequacy of the biosafety system to oversee genome editing

- 1 (Not adequate)
- 2

- 3
- 4
- 5 (Fully adequate)

17. Which regulatory areas require strengthening from regulatory perspectives? (select all that apply)

- Risk assessment procedures
- Approval pathway for research
- Approval pathway for commercialization
- Monitoring & compliance
- Institutional coordination
- Public engagement requirements

Key policy gaps Ethiopia must address (open response)

SECTION 4: Awareness & Knowledge on Genome Editing

18. How familiar are you with genome editing technologies (e.g., CRISPR/Cas9)?

- Very familiar
- Moderately familiar
- Somewhat familiar
- Heard of it, but do not know details
- Not familiar at all

19. Have you ever received training related to genome editing?

- Yes
- No

20. If yes, specify the type of training received

---

21. Major barriers for fully harnessing GEd (select all that apply)

- Limited coordination
- Lack of policy direction
- Lack of technical expertise

- ☐ Limited budget
- ☐ Low political awareness
- ☐ Public concerns
- ☐ Other: _____

SECTION 5: GEd Education

22. Level of genome editing content in university curricula

- ☐ None
- ☐ Minimal
- ☐ Moderate
- ☐ Advanced
- ☐ Comprehensive

23. Institutions actively teaching or researching genome editing (select all that apply)

- ☐ Addis Ababa University
- ☐ University of Gondar
- ☐ AASTU
- ☐ Haramaya University
- ☐ Jimma University
- ☐ A(Adama)STU

24. Human capacity sufficiency in GEd education

- ☐ Very insufficient
- ☐ Insufficient
- ☐ Adequate
- ☐ Strong
- ☐ Very strong

25. Does your institution currently work on genome editing?

- ☐ Yes
- ☐ No
- ☐ Planning to start
- ☐ Not applicable

26. List ongoing or planned genome editing projects, if any

27.Main capacity gaps GEd education (select all that apply)

- ☐ Skilled lab technicians
- ☐ Bioinformatics specialists
- ☐ Molecular biology lecturers
- ☐ Lab equipment
- ☐ Reagents & consumables
- ☐ Other: _____

28. University–industry/research collaboration strength

- ☐ Very weak
- ☐ Weak
- ☐ Moderate
- ☐ Strong
- ☐ Very strong

29. Academic preparedness to contribute to genome editing R&D

- ☐ 1 (very low)
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5 (very high)

Section 5: RESEARCH & DEVELOPMENT

30. Level of genome editing research currently underway in Ethiopia (select all that apply)

- ☐ None
- ☐ Early conceptual/literature work
- ☐ Lab-level trials
- ☐ Applied research
- ☐ Near-deployment applied research
- ☐ Field trials

31. Which genome editing applications are relevant to Ethiopia? (Select all that apply)

- ☐ Crop improvement (yield, stress tolerance)
- ☐ Livestock improvement
- ☐ Human health applications
- ☐ Industrial biotechnology

- ☐ Environmental biotechnology
- ☐ Diagnostics
- ☐ Other ----------

32. Priority sectors for genome editing (select top 3)

- ☐ Crop improvement
- ☐ Livestock genetics
- ☐ Human health
- ☐ Industrial biotech
- ☐ Environmental biotech
- ☐ Microbial
- ☐ Other: _____

33. Major R&D barriers (select top 3)

- ☐ Lab infrastructure
- ☐ Reagent shortages
- ☐ Funding limitations
- ☐ Limited partnerships
- ☐ Biosafety constraints
- ☐ Lack of trained staff
- ☐ Regulatory uncertainty

34. Strength of international R&D partnerships

- ☐ None
- ☐ Weak
- ☐ Moderate
- ☐ Strong
- ☐ Very strong

35. Enabling environment for GEd R&D?)

- ☐ 1 (very low)
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5 (very high)

Section 7: ETHICS, PUBLIC ENGAGEMENT & COMMUNICATION

36. Current level of public awareness of genome editing

- None
- Low
- Moderate
- High
- Very high

37. Ethical, social or cultural concerns most commonly raised (select all that apply)

- Environmental risks
- Health risks
- Religious concerns
- 'Tampering with nature”
- Food safety concerns
- Equity and access
- Other: _____

38. Media portrayal of genetic technologies (including GEd)

- Negative
- Mostly negative
- Neutral
- Mostly positive
- Always positive

39. Strength of public participation in Modern Biotechnology debates

- Very weak
- Weak
- Moderate
- Strong
- Very strong

40. Public understanding of genome editing

- 1(Very Low)
- 2
- 3
- 4
- 5 (very high)

41. How prepared is Ethiopia to communicate genome editing to the public?

- Well prepared
- Moderately prepared

- ☐ Minimally prepared
- ☐ Not prepared
- ☐ Not sure

42. Who should lead communication efforts? (Select all that apply)

- ☐ Government ministries
- ☐ Universities
- ☐ Research institutions
- ☐ Media organizations
- ☐ Civil society/NGOs
- ☐ Professional societies
- ☐ International partners

SECTION 7: Capacity, Gaps and Needs Assessment

43. What major capacity gaps exist in your institution? (Select all that apply)

- ☐ Laboratory equipment
- ☐ Computational capacity
- ☐ Trained manpower
- ☐ Funding constraints
- ☐ Regulatory understanding
- ☐ Collaboration and partnerships
- ☐ Public communication capacity

44. Priority area requiring immediate capacity building (select top 3)

- ☐ Technical training
- ☐ Regulatory training
- ☐ Infrastructure development
- ☐ Equipment procurement
- ☐ Funding mechanisms
- ☐ Public engagement tools

45. Explain why the priorities you selected are important

Section 9: Intellectual Property, Licensing, Access and Commercialization

46. What mechanisms are needed to protect IP while ensuring access to genome-edited technologies?

- ☐ Stronger national IP policies
- ☐ Material Transfer Agreements (MTAs)
- ☐ Public–private partnership frameworks
- ☐ Open-access licensing
- ☐ Other: _____

47. How important is international licensing for Ethiopia's future GE commercialization efforts?

- ☐ Very important
- ☐ Moderately important
- ☐ Slightly important
- ☐ Not important

48. Which genome-edited products are likely to have the highest market demand in Ethiopia? ***(Choose all that apply)***

- ☐ Drought-tolerant crops
- ☐ Pest-resistant crops
- ☐ Improved livestock breeds
- ☐ Nutrient-enhanced foods
- ☐ Industrial biotechnology inputs
- ☐ Pharmaceuticals/health products
- ☐ Other: _____

49. What are the main economic barriers to commercializing GEd products?

- ☐ High development costs
- ☐ Unclear market approval pathways
- ☐ Limited private-sector participation
- ☐ Low public awareness
- ☐ Donor dependency
- ☐ Other: _____

50. How would you rate Ethiopia's current biosafety regulatory readiness for commercialization of genome-edited products?

- ☐ Fully ready
- ☐ Partially ready
- ☐ Somewhat ready
- ☐ Not ready
- ☐ Unsure

51. Which capacity gaps limit commercialization in Ethiopia? ***(Choose all that apply)***

- ☐ Limited biosafety evaluation facilities
- ☐ Inadequate field trial infrastructure
- ☐ Lack of regulatory expertise
- ☐ Limited private-sector engagement
- ☐ Weak product registration systems
- ☐ Lack of funding for scale-up
- ☐ Other: _____

52. In your opinion, what is the earliest realistic timeline for Ethiopia to commercialize genome-edited agricultural products?

- ☐ 1–2 years
- ☐ 3–5 years
- ☐ 6–10 years
- ☐ More than 10 years
- ☐ Not sure

Section 8: Future Directions

53. Priority national actions (select top 3)

- ☐ National policy/roadmap development
- ☐ Regulatory update for genome editing
- ☐ Establish a national genome editing discussion platform
- ☐ Establish a national GEd research center of excellence.
- ☐ Invest in lab infrastructure
- ☐ Strengthen postgraduate programs
- ☐ International partnerships
- ☐ Public Communication strategy
- ☐ Other: ----------

54. Preferred governance model

- ☐ Centralized national authority
- ☐ Multi-agency coordination
- ☐ University-led innovation hubs
- ☐ Public–private partnership model
- ☐ Other: _____

55. Most important national enabling factor

- ☐ Policy
- ☐ Funding

- Capacity building
- Infrastructure
- Regional/global collaboration

Please provide any final comments or recommendations



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