National Biotechnology Research for Development Program (2024-2034)



Bio and Emerging Technology Institute (BETin)

BETin
BIO & EMERGING TECHNOLOGY INSTITUTE

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Abbreviations/Acronyms

AASTU	Addis Ababa Science and Technology University
AAU	Addis Ababa University
ABS	Access and Benefit Sharing
AHRI	Armauer Hansen Research Institute
AIA	Advance Informed Agreement
ARARI	Amhara Regional Agricultural Research Institute
ASTU	Adama Science and Technology University
AU	African Union
BAC	Biotechnology Advisory Committee
BDU	Bahir Dar University
BecA	Biosciences for Eastern and Central Africa
BIOEARN	African Regional Program and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
BRI	Biotechnology Research and Innovation
BRIF	Biotechnology Research and Innovation fund
CBD	Convention on Biological Diversity
CDT-Africa	Center for Innovative Drug Development and Therapeutic Trials for Africa
CFIA	Canadian Food Inspection Agency
CFT	Confined Field Trial
CGIAR	Consultative Group for International Agricultural Research
CIAT	International Center for Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Cente
CoE	Center of Excellence
CPA	Consolidated plan of Action
CPB	Cartagena Protocol on Biosafety
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DDT	Dichlorodiphenyltrichloroethane
EAS	Ethiopian Academy of Sciences
BETin	Bio and Emerging Technology Institute
EEFRI	Ethiopian Environmental and Forest Research Institute
EPA	Environment Protection Authority
EFDA	Ethiopian Food and Drug Authority
EIAR	Ethiopian Institute of Agriculture Research
EIPA	Ethiopian Intellectual Property Authority
ELISA	Enzyme-Linked Immunosorbent Assay
EPA	Environmental Protection Authority
EPHI	Ethiopia Public Health Institute
EU	European Union
FAO	Food and Agricultural Organization

EFDA	Ethiopian Food and Drug Authority
FDRE	Federal Democratic Republic of Ethiopia
GDP	Gross Domestic Product
GHG	Greenhouse Gases
GM	Genetically Modified
GMO	Genetically Modified Organisms
HLI	Higher Learning Institute
HPC	High-Performance Computing
HU	Hawassa Univiersity
IAIP	Integrated Agro-Industrial Parks
IBC	Institutional Biosafety Committee
ICIPE	International Centre for Insect Physiology and Ecology
ICRAF	International Center for Research in Agroforestry
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute
IoB	Institute of Biotechnology
IPR	Intellectual Property Rights
IT	Information Technology
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JKUAT	Jomo Kenyatta University of Agricultural Technology
JU	Jimma University
KARI	Kenya Agricultural Research Institute
LMO	Living modified organisms
MAB	Marker Assisted Breeding
MARI	Michekoni Agricultural Research Institute
MAS	Marker Assisted Selection
METREX	Metabolite-Regulated Expression
MoF	Ministry of Finance
MiNT	Ministry of Innovation and Technology
MoPD	Ministry of Planning and Development
MoI	Ministry of Industry
NABRC	National Agricultural Biotechnology Research Center
AHI	Animal Health Institute
LDI	Livestock Development Institute
NARO	National Agricultural Research Organization
EAS	Ethiopia Academy of Sciences
NBAC	National Biosafety Advisory Committee
NEPAD	New Partnerships for African Development
NGS	Next Generation Sequencing
NM-AIST	Nelson Mandela African Institute of Science and Technology
NSI	National System of Innovation

NTD	Neglected Tropical Diseases
NVI	National Veterinary Institute
OARI	Oromia Agricultural Research Institute
PAH	Polycyclic Aromatic Hydrocarbon
PCB	Polychlorinated Biphenyls
PCP	Pentachlorophenol
PCR	Polymerase Chain Reaction
PHA	Polyhydroxyalkanoates
PLA	Polylactic acid
POP	Persistent Organic Pollutants
PPP	Public-Private Partnerships
QTL	Quantitative Trait Loci
R&D	Research and Development
R4D	Research for Development
RARI	Regional Agricultural Research Institutes
RBRI	Regional Biotechnology Research and Innovation
REM	Restriction Endonuclease Mapping
RI	Research Institute
RSTU	Research, and Science and Technology Universities
RT-PCR	Reverse transcriptase-Polymerase Chain Reaction
SDGs	Sustainable Development Goals
SIGEX	Substrate-Induced Gene Expression
SLU	Swedish University of Agricultural Sciences
SME	Small and Medium Enterprise
SNP	Single Nucleotide Polymorphism
SOP	Standard Operating Procedure
SARI	Southern Agricultural Research Institute
SSR	Simple Sequence Repeat
STI	Science, Technology and Innovation
STIC	Science, Technology and Innovation Council
ToR	Terms of Reference
TRIPS	Trade Related Intellectual Property Rights
TTO	Technology Transfer Office
UoG	University of Gonder
UoN	University of Nairobi
UPOV	International Union for the Protection of New Varieties of Plants
WEMA	Water Efficient Maize for Africa
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

Biotechnology is an innovative, interdisciplinary field that impacts many different sectors, including agriculture, health, industry and the environment. It is emerging as one of the leading technologies for the transition towards carbon-free society and for solving critical societal challenges comprising food and energy supply, health-care systems, fine chemicals production and environmental protection. The growing global demand for food, feed, fiber, biobased and renewable products is changing the nature of bioresources-based production worldwide. A central feature of a knowledge-based bioeconomy is that scientific research and knowledge are applied to bioresources and agricultural systems to not only produce food and feed but also to an increasingly wide range of agro-industrial and value-added products with potential applications in many sectors, including agro-processing, biochemical industries, and energy among others.

The development of the knowledge-based economy is one of the key challenges and opportunities facing Ethiopia. Low level of scientific and technical capacity coupled with international competition is creating pressure for improvements in efficiency, quality and productivity and a growing need to innovate. These pressures are generating the need to take courageous forward-looking steps that will achieve real strategic change, show tangible medium-term results and shape the future of the country. Science, Technology and Innovation (STI) in Ethiopia in general and biotechnology in particular is still under developed. There is a strong desire for the country to take a leap forward and move the country to an acknowledged level in this field through creating an enabling environment for biotechnology development.

In Ethiopia, there is a growing recognition of the need to adopt biotechnology innovations for improving agricultural productivity, health-care systems, industrial development, and environmental protection thereby ensuring sustainable development in the country. The Government has set **Vision 2030**: **Ethiopia, An African Beacon of Prosperity.** In line with this Vision, and key national development plan (2021-2030) and Homegrown Economic Reform Agenda, the National Biotechnology Research for Development (R4D) Program provides a ground for research and innovation for safe application of biotechnology in order to contribute to Ethiopia's knowledge and innovation driven economic growth and transformation.

The Ten-Year National Biotechnology R4D Program takes stock of what has been accomplished so far and provides a framework for the future within which strategic programmatic research and innovation projects and specific actions to promote biotechnology can be envisaged and undertaken. The Program design was done in consultation with a wide range of stakeholders – scientists, educationists, regulators, representatives of society and others and reflects their consensus. It focuses on cross-cutting issues such as research for

development, human resource development, research and industry interface, research capacity building, biotechnology parks and incubation, spin-offs and start-ups, product commercialization, regulatory mechanisms, public education, and awareness building. It is envisaged that clearly thought-out strategies and programs will provide direction and enable action by various stakeholders to achieve the full potential of this technology for the social, economic, and environmental well-being of the nation.

The overall objective of the R4D Program is to promote research and innovation activities at regional and national levels towards building an effective biotechnology R4D base in the country. More specifically, the biotechnology R4D Program aims to achieve the following objectives:

1. Strengthen technical competencies and institutional capacity for biotechnology research and innovation in agriculture, health, industry and environmental sectors.
2. Enhance effectiveness of biotechnology research and innovation in addressing priority areas of the biotechnology sectors for bioeconomy development of the country.
3. Promote competitiveness through fostering innovation, value addition, industrial development and entrepreneurship in synergy with research, academia, the private and industrial actors.
4. Establish and enhance national, regional and international collaboration and partnerships in biotechnology research and innovation.

The national biotechnology R4D Program is designed and organized with due considerations of strategic programmatic areas that are both critical to economic and social development and national security and in dire need of biotechnology research and innovation support. The strategic programmatic areas are designed on the premises of:

- areas desirable for breaking up bottlenecks and for enhancing the sustainability of the national economic growth;
- areas that are desirable for securing enabling technologies and for improving core agricultural, health, industrial and, environmental competitiveness;
- areas that are enviable for addressing major public good R4D issues and boosting the potential in providing public services; and
- areas that are desirable for the development of technologies designed to enhance the capability in ensuring various aspects of national security.

The programmatic areas for addressing the existing agricultural, health, industrial and environmental problems of the country with the support of new discoveries and technological advancement in biotechnology were identified for the ten-year implementation period. The programmatic R4D areas are summarized as follows:

(1) Agricultural biotechnology R4D Program: (a) Plant biotechnology: (i) plant molecular genetic and abiotic stress resistance/tolerance (food security and high value crops) (iii) cell and tissue culture (food security crops, oil, industrial and export crops), (iii) genetic engineering, genome editing and mutagenesis on plants of industrial, agricultural and medical importance; **(b) Animal biotechnology:** (i) animal genetics and breeding (ii) reproductive biotechnology (iii) animal feeds and nutrition (iv) Animal Health (v)Apiculture, and (v) Fish and aquaculture; **(c) Microbial biotechnology:** (i) biofertilizers, (ii) biopesticides; **(d) Community biotechnology in the agricultural system:** (i) agro-ecological community genomics research programs and agro-ecosystems dynamics (ii) climate change variability, phenomics and epigenetics.

(2) Health biotechnology R4D Program: (i) Pathogen biology and host-pathogen interaction; (ii) vaccine development and production; (iii) diagnostics; (iv) therapeutics (drug discovery and development, biopharmaceuticals /biosimilars); (v) traditional medicine; (vi) stem cell and gene therapy; (vii) nano-biotechnology for diagnostics, therapeutics and vaccine delivery.

(3) Industrial Biotechnology R4D Program: (i) industrial enzymes (biocatalysts for industry, food and feed fermentation); (ii) yeast and other industrial microbial biomass (probiotic starter cultures for food fermentation products); (iii) biopharmaceutical products; (iv) biofoods (functional foods, nutraceuticals, single cell proteins, mushroom and algae) and additives; (v) biocosmetics and personal care products; (vi) biomaterials; (vii) biofuels.

(4) Environmental biotechnology R4D Program: (i) bioprocesses for wastewater treatment; (ii) valorization and resource recovery from biowastes and biomass; (iii) bioremediation of contaminated environmental sites; (iv) biodegradation of recalcitrant pollutants; (v) biomining; (vi) bioindicators and biomarkers for environmental pollution monitoring; (vii) biodiversity and bioprospecting.

(5) Biosafety and IPR regimes - enablers for biotechnology R4D: (i) health and environmental safety and standards, policy and regulatory frameworks including IPR as well as incentive schemes for the generation and adoption of biotechnology products.

The shortage of a strong science-base coupled with proper technology and incubation mechanisms as well as enabling policy for moving bioscience innovations to the market place has been a big hindrance in integrating technologies into key sectors like agriculture, health, environment and industry in Ethiopia. Conscious of this fact, the R4D Program in its implementation process, shall apply innovation systems approach to catalyze the translation of research outputs to innovations in a sustainable manner.

The successful implementation of this R4D Program primarily depends on the suitability of the chosen institutional arrangement, the capacities and complementarities of the institutions involved. In the R4D Program implementation, focus on coordination between the various stakeholders, from research institutions, academia and to industry is pivotal. An effective strategy needs to promote development and utilization of biotechnology at three levels:

i. Research and technology development
ii. The development of research findings into products
iii. The commercialization of the products at national and international markets

A strong biotechnology R4D Program therefore requires not only coordination between people and institutions, but also a multidisciplinary approach involving scientists, engineers, economists, lawyers and business managers.

In order to leapfrog in biotechnology research, innovation and product commercialization, there is a strong need for a deliberate and strategic policy-driven intervention in the creation and strengthening of biotechnology R4D base in the country. Policy-driven formation of center (s) of excellence and regional hubs should therefore be the result of systematic policy decisions to foster the development of biotechnology research and innovation.

This document provides a consolidated summary of the study on four areas of biotechnology, as well as biosafety and intellectual property rights (IPR) in the country. The document is organized into six main parts. Part I introduces the contributions of biotechnology to bio-economy in general and its significance to Ethiopia's sustainable development. Part II presents situation analysis of biotechnology development at global and continental levels as well as current status of biotechnology R4D landscape in Ethiopia. Part III presents a national biotechnology R4D program with goals, objectives, guiding principles and programmatic focus areas for agricultural, health, industrial, environmental biotechnology, and biosafety and IPR along with implementation of the R4D programs. Enabling capabilities required for the implementation of biotechnology R4D Program are provided in Part IV. Part V presents the institutional arrangement and synergy for the implementation of the R4D programs, and finally monitoring and evaluation of the implementation of the R4D programs is provided in Part VI of the document.

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PART I. INTRODUCTION

1.1. Biotechnology for the development of knowledge-based bioeconomy

Biotechnology, globally recognized as a rapidly emerging and far-reaching technology, is aptly described as the "technology of hope" for its promise in food, health, industrial and environmental sustainability. The recent and continuing advances in life sciences clearly unfold a scenario energized and driven by biotechnology innovations. Modern biotechnology contributes to a transition[1] that by some has been called the development of a bioeconomy[2] transforming biological resources into new, sustainable, eco-efficient and value-added products[3]. Bioeconomy involves three elements: utilization of renewable biomass and efficient bioprocesses to achieve a sustainable production; utilization of enabling and converging technologies, including biotechnology; and integration across applications such as agriculture, health, industry, and the environment[4]. Biotechnology is one of the key enabling technologies to sustain bioeconomy offering solutions for i) an efficient and sustainable production of plant, animal and microbial-based products; ii) production of bio-energy from biomasses and biowastes; environmental protection and safety in terms of bioremediation; iii) green chemistry processes and applications; iv) sustainable agri-food production and industrial processes, and v) realizing circular economy[5]. Globally, the contribution from bioeconomy to GDP is expected to be on an average of 2.7% by 2030[6].

Bioeconomy encompasses the production of renewable biological resources and the conversion of these resources and waste streams into value added products, such as food, feed, bio-based products and bioenergy. Bioeconomy is the foundation for a circular economy. Circular economy is the economic space where the value of products, materials and resources is maintained in the economy for as long as possible, and minimizes the generation of waste. Common features of bioeconomy and circular economy include:

- Improved resource and eco-efficiency
- low GHG footprint

[1] A transition whereby fuel, energy, plastics are produced by bio-based alternatives instead of using fossil fuel

[2] Bioeconomy can be defined as "the knowledge-based production and utilization of biological resources, biological processes and principles to sustainably provide goods and services across all economic sectors."

[3] Cologne Paper (2007). En route to a knowledge based bio-economy. Expert paper on knowledge based bio-economy, resulting from a meeting held in Cologne, Germany on 30th May 2007 and OECD, 2009, The Bio-economy to 2030, Design a policy agenda (www.oecd./futures/bioeconomy/2030).

[4] Bracco et al. (2018) Assessing the Contribution of Bioeconomy to the Total Economy: A Review of National Frameworks. *Sustainability* 2018, 10, 1698; doi:10.3390/su10061698

[5] A circular economy is an economic system aimed at eliminating waste and the continual use of resources through reuse and recycling to create a closed-loop system, minimizing the use of resource inputs and the creation of waste, pollution and carbon emissions.

[6] OECD (2019) Innovation Systems in The Bioeconomy

- Reducing the demand for fossil carbon
- Valorization of waste and side streams

The revolutionary advances in biosciences are providing an increasingly powerful innovation engine at a global scale for sustainable food, feed, fiber and health care products as well as energy production and development of a diverse range of novel bio-based chemicals and materials. A central feature of a knowledge-based bioeconomy is that scientific research and knowledge are applied to bioresources and agricultural systems to not only produce food and feed but also to an increasingly wide range of agro-industrial and value-added products with potential applications in many sectors, including agro-processing industry, chemical, pharmaceutical industries, and energy, among others.

The transition from a fossil-based economy to a bio-based economy is essential to tackle current and future global climate, social and economic challenges. Bioeconomy is an attractive sector for the development of sustainable, efficient, and integrated use of renewable resources and energies reducing the impacts for a healthy environment. Biotechnology significantly contributes in achieving the transition to a bio-based economy in the following ways:

- A lower carbon economy and environmental sustainability - reduction of greenhouse gas emissions, resource recovery and biowaste use efficiency,
- Building competitive bio-industries - new business opportunities, higher potential for value creation through cascading use of biomass/biowaste and reuse of waste materials, and global market leadership, and
- A resilient and sustainable food chain - contribution to global food security, new agricultural practices to avoid competition between food and non-food use of biomass, and improved animal and human health.

Creating the enabling conditions for the development of biotechnology would require a range of policy interventions addressing specific issues along bio-based value chains. Among the most critical policy interventions as shown in Figure 1 include developing a pre-competitive infrastructure and innovation ecosystem for engineering biology, addressing systemic business risk in bio-based value chains, ensuring the sustainability of feedstocks and supply chains, enhancing policy coordination, promoting public acceptance of these technologies and preventing potential biosecurity risks.

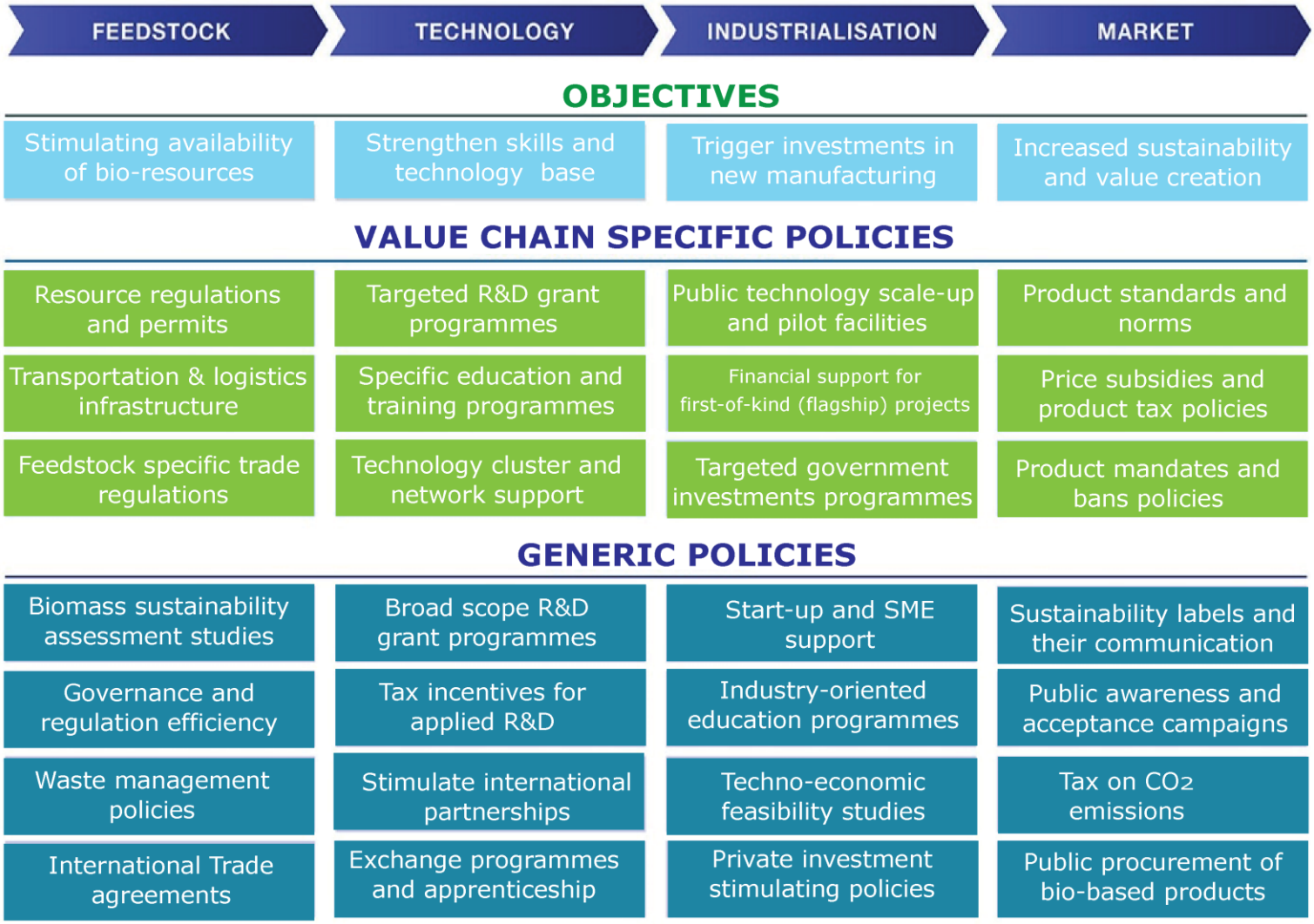


Figure 1. A bioeconomy policy framework[7]

1.2. Biotechnology for Ethiopia's bioeconomy development

Ethiopia is recognized as a mega biodiversity country and biotechnology offers opportunities to convert its biological resources into economic wealth and employment opportunities. Innovative products and services that draw on renewable resources bring greater efficiency into industrial processes, protect environmental degradation and drive a bio-based economy. For this to materialize, Ethiopia needs to tap into modern biosciences.

[7] Source: Ole Jørgen Marvik and Jim Philp (2020), The systemic challenge of the bioeconomy: A policy framework for transitioning towards a sustainable carbon cycle economy, https://doi.org/10.15252/embr.202051478

The recent and continuing advances in life sciences clearly unfold a scenario energized and driven by modern biotechnology providing an increasingly powerful innovation engine at a global scale for sustainable agricultural production, agro-processing, waste treatment, energy production and development of a diverse range of novel bio-based chemicals and materials. The growing global demand for food, feed, fiber, biobased and renewable products is changing the nature of bioresources-based production worldwide. A central feature of a knowledge-based bioeconomy is that scientific research and knowledge are applied to bioresources and agricultural systems to not only produce food and feed but also to a wide range of agro-industrial and value-added products with potential applications in many sectors, including agro-processing, biochemical industries, and energy among others. For a country like Ethiopia, biotechnology is a powerful enabling technology that can positively revolutionize agriculture, healthcare, industrial processing, and environmental sustainability.

1.2.1. Improving agricultural productivity and ensuring food security

About 50% of the gross domestic product (GDP) of Ethiopia is from agriculture and around 80% of the labour force depends on agriculture. In addition, the agricultural sector constitutes over 90% of the export commodity[8]. However, the country is still challenged with food and nutrition security due to lower productivity of crops and animals (livestock, fisheries and apiculture), heavy production losses due to biotic and abiotic stresses; heavy post-harvest crop damage and declining availability of water as an agricultural input. Agricultural biotechnology has the potential to overcome these challenges to ensure the food and nutrition security in the country.

The spectrum of biotechnology application in agriculture is very wide and includes generation of improved crops, animals, plants of agroforestry importance and microbes; use of molecular markers to tag genes of interest; acceleration of breeding through marker-assisted selection; fingerprinting of cultivars, landraces and germplasm stocks; DNA based diagnostics for pests/ pathogens of crops, animals and fish; assessment and monitoring of agro-biodiversity; in vitro mass multiplication of elite planting material; genetic engineering, genome editing, -omics[9], digital image data management, embryo transfer technology for animal breeding; food and feed biotechnology.

In order to effectively and efficiently utilize the opportunities that the various agricultural biotechnologies can offer to Ethiopia's agricultural development, it is of paramount importance to build capacity based on the current needs of the country; without compromising potential opportunities that may be available in the immediate future and beyond.

[8] Demissie Chaniyalew (2017). The quest for change: Ethiopia's agriculture and pastoral policies, strategies and institutions. Printed by www.masterprintaddis.com ISBN:978-99944-70-69-63.

[9] Refers to genomics, transcriptomics, proteomics and metabolomics

1.2.2. Biotechnology for improving health care systems

Advances in novel approaches to health biotechnology in stem cells, regenerative medicine (tissue engineering), biosimilar humanized antibody and nucleic acid-based therapeutics are offering new opportunities in medical biotechnology that provide insight in improving health care systems. Frequently emerging infectious diseases such as COVID-19 and non-communicable diseases have leveraged collaborative actions in solving global health problems by academic institutions, research centers and pharmaceutical industries in striving to find curative and preventive measures and new biologics for diseases. Moreover, enhanced clinical efficacy, precision medicine, and personalized drugs are revolutionizing the pharmaceutical industries globally.

There is also a growing tendency of understanding the importance of biotechnology for Ethiopia's social and economic development. Accordingly, the Ethiopian Government is planning to improve its health care service coverage as well as increase national capacity for the production of health care products. At present, there is a growing demand for imported therapeutics, vaccines and diagnostics as local production is almost nonexistent. The country has taken steps to initiate and integrate biotechnology into its national innovation systems as well as training and research in biosciences expecting that biotechnology will make a significant contribution to the country's health care systems.

1.2.3. Enhancing bio-based industries for sustainable national bioeconomy

Industrial biotechnology plays a significant role in contributing to the biobased economic development through industrial bioprocesses[10] such as bioenergy, biochemicals, biomaterials (biosurfactants, biopolymers, and bioplastics), biocatalysts and nutraceuticals. The rapid progress in fermentation technology, enzyme engineering, metabolic engineering, synthetic biology and integrated -omics approaches coupled with computational systems biology have significantly revolutionized the research and innovation of industrial biotechnology in fast-growing economies.

The Ethiopian agro-processing industrial sector is still far from being an engine of growth and economic transformation. The use of biotechnological innovations for process efficiency and enhanced production of bio-based products is in its early stage in the country. The sector's contribution to job creation and export promotion are limited. The agro-processing industrial sector is operating at low level due to limited research and innovation support resulting in low-value and low-technology products and insufficient domestic sectoral linkages.

[10] Referring to utilization of microorganisms and their products for the development of high value products.-+

In addition to the National Biotechnology Roadmap, attempts have been made to formulate directions for biorefinery and microbial biotechnology in selected industries to stimulate research and innovation in industrial biotechnology. Research and innovation based on biocatalytic and fermentation technologies in combination with modern biosciences are essential for value-added product development and motivate business thereby contributing to the bio-economy growth in the country.

1.2.4. Biotechnology for resource recovery, value addition and sustainable environmental management

The increasing economic growth over the last decade in Ethiopia has been characterized by expanding industries and rapid population growth, which in many cases resulted in negative impact on ecosystem services and on water resources. Biotechnology has a significant role in addressing the environmental pollution threats by developing efficient waste and wastewater management technologies and up-scaling of emerging pilot technologies, with a focus on the agro-processing sector using an innovation systems framework that includes R4D actors, industry, policy and regulatory institutions and other stakeholders. Moreover, the threat posed by climate change on the country's bio-resources requires that immediate measures be put in place to secure production and sustainability of the natural resource base. It also addresses issues of climate change adaptation and coping strategies within the framework of sustainable environmental management.

Environmental biotechnology is essential for the development of a circular economy in waste valorization by integrating energy production and resource recovery into the production of clean water and climate change mitigation. Employing biotechnological tools for the resource recovery from biowaste is gaining attention in the context of sustainability and circular bioeconomy. The country has great potential to utilize huge quantities of available waste as bioresources for boosting the waste-derived bioeconomy. Development of a waste-derived economy could also address the majority of sustainable development goals (SDGs). Features of circular bioeconomy include:

- Improved resource and eco-efficiency
- low GHG footprint
- Reducing the demand for fossil carbon
- Valorization of waste and side streams

There are large untapped bioresources (bio-wastes) from the agro-processing sector (sugar, coffee, tanneries and abattoirs, food processing) in the country that could be building blocks for expanded utilization of bioprocesses and the growth of agro-industries. This also includes the transformation of traditional agro-industries such as sugar refineries, breweries, tanneries, dairy industry etc., where innovations in

biotechnology can convert agro-bio waste into valuable products such as, biofuel, biofertilizer, feed, nutritional supplements, high value chemicals and at the same time minimize environmental impact. A wider application of environmental biotechnology has even larger implications, as it would fullfill three basic needs: (a) improvement in health and sanitation through pollution control; (b) generation of renewable energy for household activities, such as cooking, lighting, and heating, and running small-scale businesses, for example, poultry farming and aquaculture, and (c) supply of digested materials (biosolids) as organic fertilizer for crop production. Thus, biotechnology plays a significantly greater role not only in controlling pollution but also in supplementing valuable resources: energy and value-added products while attaining the *zero-pollution* vision of agro-process industries of the country.

Biotechnology has a great potential for converting bioresources (animal, plant, microbial and aquatic) into commercially useful products and processes complementing conservation and sustainable use of biodiversity. While our traditional knowledge would be the basis for bioprospecting, ethics and equity should be our guiding principles in benefit sharing.

1.3. Need for developing a 10-year National Biotechnology R4D Program

Biotechnology can deliver the next wave of technological changes that can be as radical and even more pervasive than that brought about by information technology. Employment generation, intellectual wealth creation, expanding entrepreneurial opportunities, augmenting industrial growth and sustainable development are a few of the compelling factors that warrant a focused approach for this sector.

In Ethiopia, there is a growing recognition of the need to adopt biotechnology innovations for improving agricultural productivity, health care systems, industrial development, and environmental protection thereby ensuring sustainable development in the country. The country has also developed Science, Technology and Innovation (STI) policy, biosafety and IPR frameworks that will enable the development, use and commercialization of the technology. Despite these initiatives, the country still has inadequate required R4D capacity and competence for applying biotechnology innovations for enhancing sustainable socio-economic development.

The Government of Ethiopia has set Vision 2030: ***Ethiopia: An African Beacon of Prosperity*** where building a climate-resilient middle-income economy is one of the key strategic pillars of Ethiopia's Ten-Year Perspective Plan for the period 2021-2030. Ethiopia's Ten-Year Development Plan: *A Pathway to Prosperity*, puts the four economic sectors (agriculture, health, industry and the environment) as top priority areas of development. In line with this Vision, and the National Development Plan (2021-2030) and Homegrown Economic Reform Agenda, biotechnology provides solutions to Ethiopia's knowledge and innovation driven green economic growth and transformation.

The National Biotechnology R4D Program initiative aligns with Ethiopia's newly formulated Development Plan and a Homegrown Economic Reform Agenda. The Program provides critical R4D focus areas for implementation and will also propose a framework for stronger coherence between the various policies and funding instruments, and a better alignment of the research agenda for innovation in biotechnology. It highlights the R4D Program initiatives needed to deliver the full potential of biotechnology in the four bio-economy sectors, taking into account the needs of farmers, entrepreneurs, consumers and the society at large. This Program is timely and relevant for creating a coordinated programmatic research agenda for biotechnology in the country.

The biotechnology development in Ethiopia has, over the last two decades, taken shape through a number of scattered and sporadic academic and fractured institutional research initiatives mainly in agriculture and health sectors. There is a dire need for building capacity to enable the country to take advantage of the powerful tools and rapidly increasing number of biotechnology applications to improve livelihoods, ensure food security and safeguard human health, increase industrial competitiveness and protect the environment. Therefore, to create favorable conditions for sustainable development and deployment of biotechnology and serve as an engine for the knowledge-based and innovation driven bioeconomy, it is imperative to formulate strategic biotechnology R4D programs rooted in the Ethiopian perspective to drive biotechnological innovations for enhancing sustainable development of the country and achieve Sustainable Development Goals (SDGs). Formulating such a Program will largely help facilitate that the country not only pools the existing scattered efforts and resources to build biotechnology capacity but also expand the base to create global leadership in biotechnology R4D by unleashing the full potential of all that the country has to offer.

Recognizing the pivotal role of biotechnology for the sustainable development of the country, the Ethiopian Bio- and Emerging Technology Institute (BETin), MiNT of Federal Democratic Republic of Ethiopia (FDRE) has initiated the development of a "*Ten Year National Biotechnology R4D Program (2024-2034)*" that is aligned with and support the national and sectoral development plans. Accordingly, BETin has reached out to the EAS to work out the National Biotechnology R4D Program. The EAS has selected and established a team of high-level professionals covering all areas of biotechnology including biosafety and IPR to steer the process guided by clearly defined terms of references (ToR).

1.4. Objectives

1.4.1. General objective

To prepare a Ten-Year National Biotechnology R4D Program that will contribute significantly to improved food security, healthcare systems, sustainable environmental management, improved industrial processes and production, and enhanced livelihoods in Ethiopia.

1.4.2. Specific objectives

The specific objectives of the study were to:

1. Assess biotechnology development at national, continental, and global levels,
2. Assess the status of biotechnology R4D landscape in Ethiopia,
3. Identify and map existing biotechnology R4D resources (facilities, human and financial including computational and bioinformatics) in the country,
4. Identify gaps in key frontier biotechnology sectors in the country,
5. Formulate biotechnology R4D programs for implementation over the coming 10 years taking the national and sectoral development plans into consideration,
6. Prepare financial and capacity building requirements for the implementation of the Ten-Year National Biotechnology R4D Program,
7. Identify and recommend mechanisms and directions for creating viable biotechnology research and industry interface as well as dissemination and use of technologies and innovations emanating from biotechnology R4D programs,
8. Assess and recommend mechanisms for translating biotechnology innovations into viable commercial enterprises/startup biotech companies,
9. Recommend improvement of existing and development of appropriate biosafety and IPR regimes as enablers of the National Biotechnology R4D Program,
10. Identify and recommend appropriate institutional arrangement and synergies for the implementation of the Ten-Year Biotechnology R4D Program, and
11. Recommend biotechnology R4D Program implementation monitoring and evaluation schemes.

1.5. Scope of the Study

The scope of the study covers situation analysis of national, continental, and global biotechnology development; existing biotechnology R4D landscape in the country; and preparation of a Ten-Year National Biotechnology R4D Program aligned with Ethiopia's ten-year national perspective development and sectoral plans. For the implementation of the R4D Programs, the study also recommends enabling mechanisms and directions for creating research and industry interface as well as dissemination and use of technologies and innovations emanating from biotechnology R4D programs including institutional arrangement and synergy for developing scalable innovations.

1.6. Limitations of the Study

There are scattered and limited activities related to biotechnology research in the country coupled with inadequate data management at institutional levels, classified and organized information with regard to

biotechnology R4D landscape was inadequate. Since modern biotechnology is slowly taking place in some Ethiopian universities and research institutions in its fragmented and uncoordinated manner, information on existing biotechnology research is also limited, thus restricting the data size. The program design for biotechnology R4D was therefore made based on existing capacity gaps and the increased need for technological solutions for the pressing socio-economic challenges of the country.

1.7. Methodology

1.7.1. Desk review

A thorough and comprehensive desk review of relevant sources and documents on biotechnology was undertaken to determine the status of biotechnology research and innovation from global, continental and national perspectives. Secondary data was also collected from institutional and national reports, roadmaps, policies, strategies and plans including review of projects, research, human and financial management databases of important stakeholders of biotechnology. The current biotechnology research landscape, technology dissemination and use, existing gaps in technology and institutional capacity was analyzed to better understand the issues that need to be addressed in the Ten-Year National Biotechnology R4D Program.

1.7.2. Survey

Purposive sampling techniques were employed to obtain an adequate level of understanding of the current situation of the four sectors of biotechnology R4D landscape in Ethiopia. A detailed survey on universities (n=12), federal research institutes (n=14), regional research institutes (n=5), regional and international organizations (n=5), industries and agro-industrial parks (n=32) was conducted using structured questionnaires and interviews with overall response rate of 62%. Data on the current biotechnology research status, existing facilities, human and financial resources as well as institutional collaboration and synergy in research activities in the country was collected. Interview guides were also developed and focused group discussion/interviews were conducted with selected professionals and leaders of Government organizations, higher learning and research institutions as well as private organizations to get information and insight regarding biotechnology development in the country. The selected organizations were also visited to get a clear picture on the status of biotechnology R4D in Ethiopia.

1.7.3. Data analysis

The collected data was analyzed using descriptive methods and qualitative comparisons for the preparation of the Ten-Year National Biotechnology R4D Program.

PART II. SITUATION ANALYSIS

2.1. Global trends in biotechnology development

The global biotechnology research and innovation in agriculture, health, industry, and environment has been increasing over the years and is expected to increase in the coming decades [11]. The global growth rate of biotechnology between 2015 and 2020 is 1.3%[12]. It is expected that the biotechnology sectors will achieve a steady increase in the next ten years and that more investments will be made in research and innovation worldwide[13]. The data related to the world biotechnology market size, number of businesses and employment for 2019 were 295 billion USD, 11,343 and 886,386, respectively (Fig. 2).



Figure 2. Market size, number of businesses and employment in 2019 biotechnology worldwide

In 2005, biotechnology was the leading world industry with respect to agriculture and pharmaceutical industries. From 2010 to 2020, more emphasis was on biotechnology in the pharmaceutical field. Even if agricultural biotechnology was increasing steadily between 2005 and 2020, a clear trend towards larger growth in the pharmaceutical sector was observed (Fig. 3)[14]. Research and innovation in the latest advances in life sciences, as well as implementing other emerging technologies are critical for harnessing biotechnology innovations for a sustainable future.

[11] OECD (2019) Innovation Systems in The Bioeconomy, OECD

[12] A brief overview of global biotechnology. Donald K. Martin et al. (2021). https://doi.org/10.1080/13102818.2021.1878933

[13] IBISWorld [Internet]. World biotechnology industry. Available from: https://www.ibisworld.com/global/ market-research-reports/global-biotechnology-industry/.

[14] 25th World Biotechnology Congress [Internet]. Available from: https://world.biotechnologycongress.com/

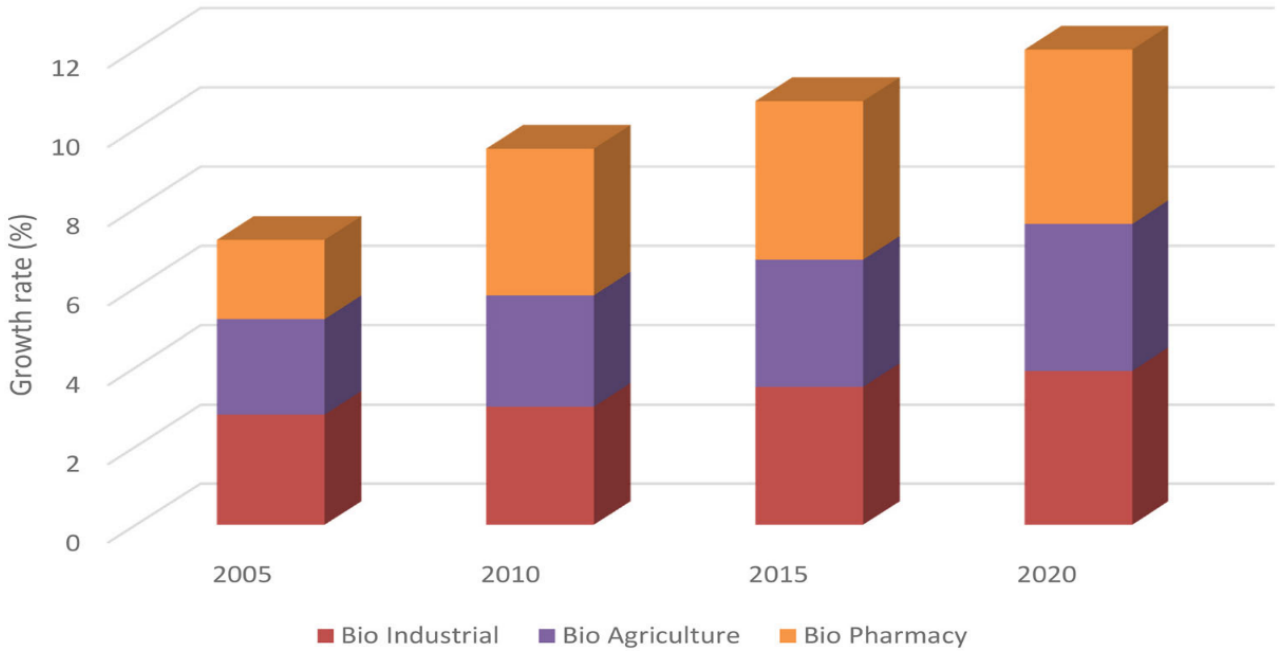


Figure 3. Global trend in biotechnology sectors between 2005 and 2020

2.1.1. Agricultural biotechnology

Agricultural biotechnology has developed incrementally over the past century, but progress has accelerated greatly over the last two decades, leading to important scientific achievements and impressive technological advances. Genetic engineering, sequencing, bioinformatics, reproductive biotechnology and other bio-services; and more currently, genome editing in plants and animals have become the most popular aspect of agricultural biotechnology with production of crops and animals with traits of interest that are important for the farmer, the consumer, and the environment.

Globally, several countries including some developing countries have made continuous advancements in agricultural biotechnology that enabled them to significantly benefit from the technology in several aspects. Tissue culture, genetic engineering, and gene/genome editing are the main technologies employed by the different countries. Since recent times, there has been extensive commercialization of genetically modified (GM) crops globally with more than 190 million hectares of land devoted for their production[15]. These crops have been in use since 1996, the USA being the leading global GM producer, followed by Brazil and Argentina[16]. A total of 72 countries have adopted these crops of which 29 countries are in official production of crops with soybean, maize, cotton, and canola being the most adopted GM crops (Fig. 4). The

[15] ISAAA, International Service for the Acquisition of Agri-biotech Application (2020). Accomplishment Report.
[16] Note that Argentina has a stringent and enabling biosafety regulations in place.

production of GM crops by developing countries exceeded the industrialized countries in 2012 indicating the increasing trend in adoption of the technology[17] (Fig. 5)[18].

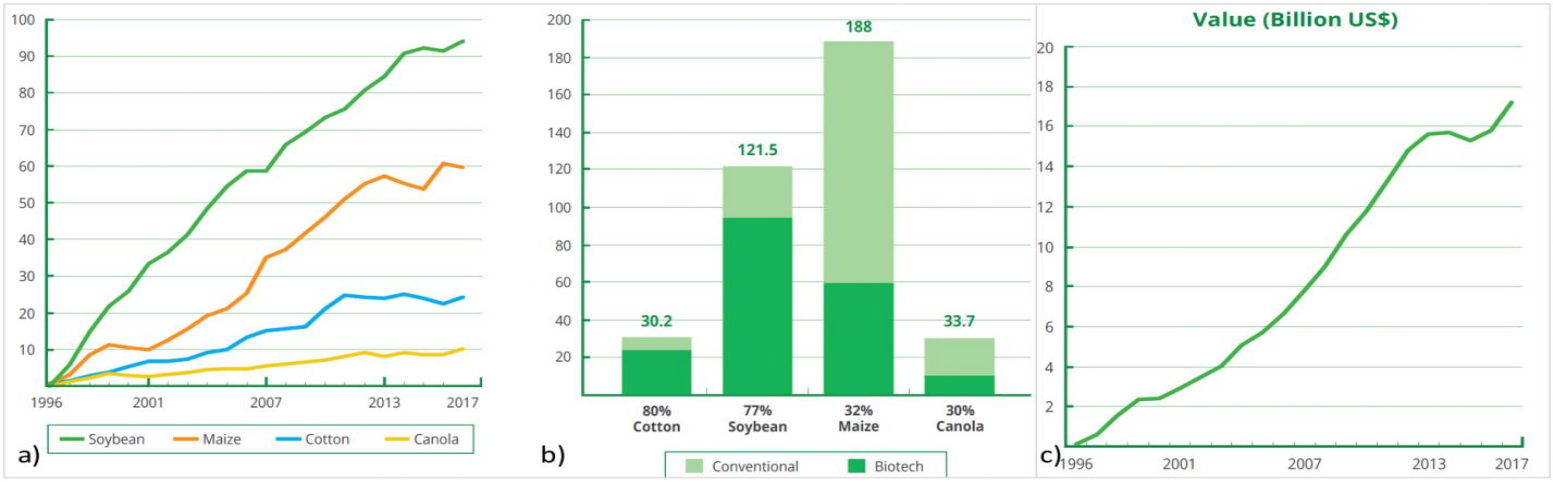


Figure 4. a) Global area of biotech crops from 1996 to 2017: by crop (Million hectare); b) Global adoption rate for principal biotech crops, 2017 (Million hectares); c) Global value (USD) of the biotech crop market

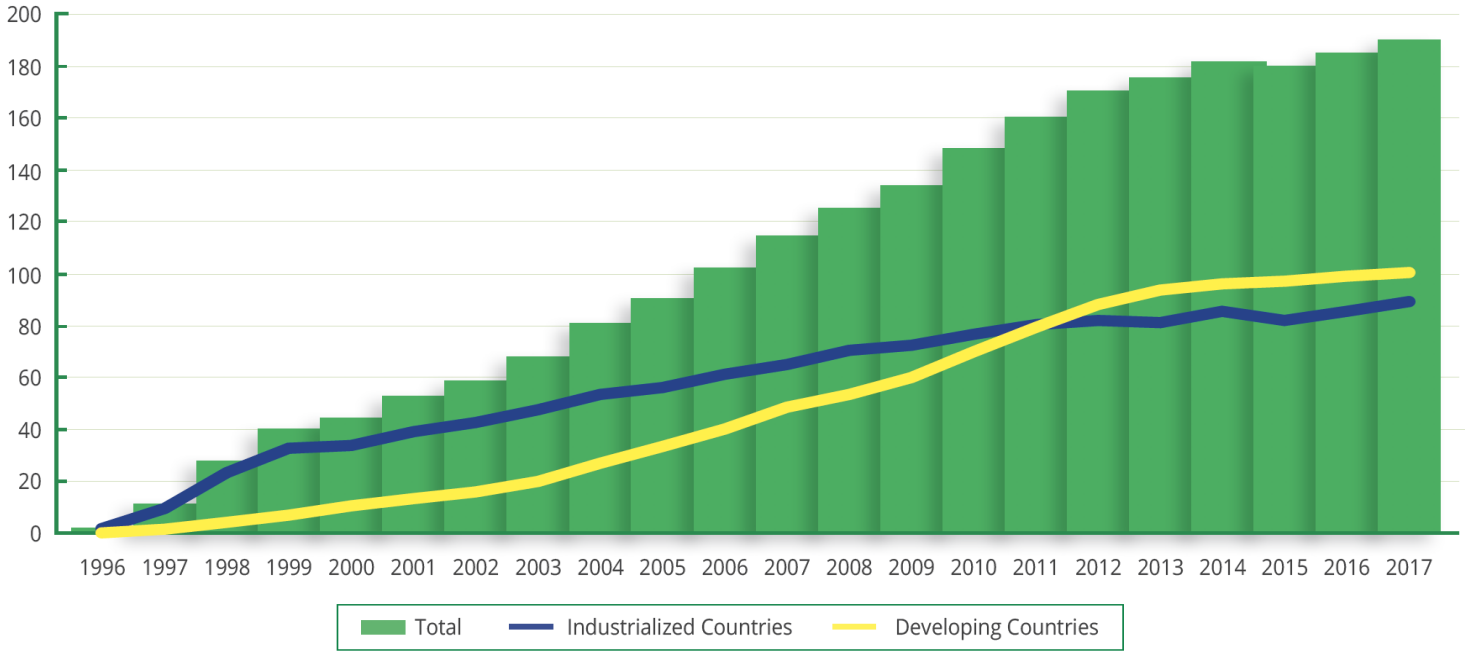


Figure 5. Global area of biotech crops, 1996 to 2017: Industrialized and developing countries (production =in million hectares)

[17] ISAAA, International Service for the Acquisition of Agri-biotech Application (2020). Accomplishment Report.

[18] ISAAA, 2017. Global status of commercialized biotech/GM crops in 2017: Biotech crop adoption surges as economic benefits accumulate in 22 years. ISAA brief No. 53. ISAAA: Ithaca, NY

Despite its enormous potential, planting and commercialization of GM crops have often been controversial particularly in Europe where a stringent regulatory system exists to introduce new transgenic traits into crops. However, with the emergence of genome editing technologies (CRISPR-Cas9), the controversy and concerns of GM crops is beginning to decline, leading to enhanced pace of technology adoption[19]. The number of market-oriented genome editing applications by countries and distribution of genome editing traits by applications is shown in Figure 6[20].

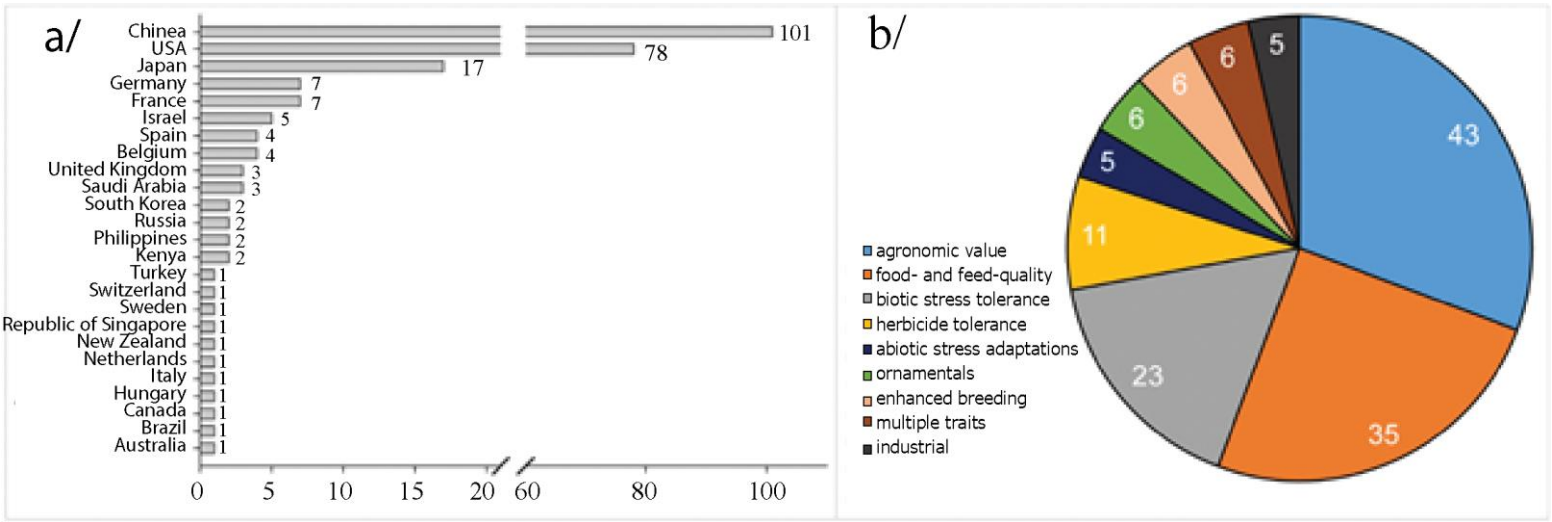


Figure 6. a) Number of market-oriented genome editing applications by countries in which the corresponding author is located[21]; b) Distribution of genome editing traits by applications

Similarly, animal biotechnology has also gained momentum at a global scale. The world demand for animal-based food products is anticipated to increase by 70% by 2050[22], signaling the pivotal role of advanced technologies and methods to improve the genetic quality of livestock. Manipulation and benefiting from the reproductive physiology/hormones of livestock species for more than a century and their genomic information in the last few decades have contributed to improving production and productivity of livestock species globally. In the high-income countries, the wider application of biotechnological innovations have accelerated the success of genetic gain for the livestock production and demonstrated incredible contribution to their national GDPs[23] (Fig. 7).

[19] Dent, M. (2021). Genetic Engineering in Agriculture 2021-2031: Genome editing (CRISPR, TALENs, ZFNs), Transgenics (GMOs), Synthetic Biology, and Breeding in Crop Agriculture: Technology and Market Analysis.

[20] Menz J, Modrzejewski D, Hartung F, Wilhelm R and Sprink T (2020) Genome Edited Crops Touch the Market: A View on the Global Development and Regulatory Environment. Front. Plant Sci. 11:586027. doi: 10.3389/fpls.2020.586027

[21] Multiple counts possible if the author has more than one affiliation or multiple corr. authors were named

[22] Georges M, Charlier C, Hayes B, 2019. Harnessing genomic information for livestock improvement. *Nat Rev Genet* **20,** 135–156. https://doi.org/10.1038/s41576-018-0082-2.

[23] FAO, 2021. Animal production. Available at: http://www.fao.org/animal-production/en/ accessed June 30, 2021.

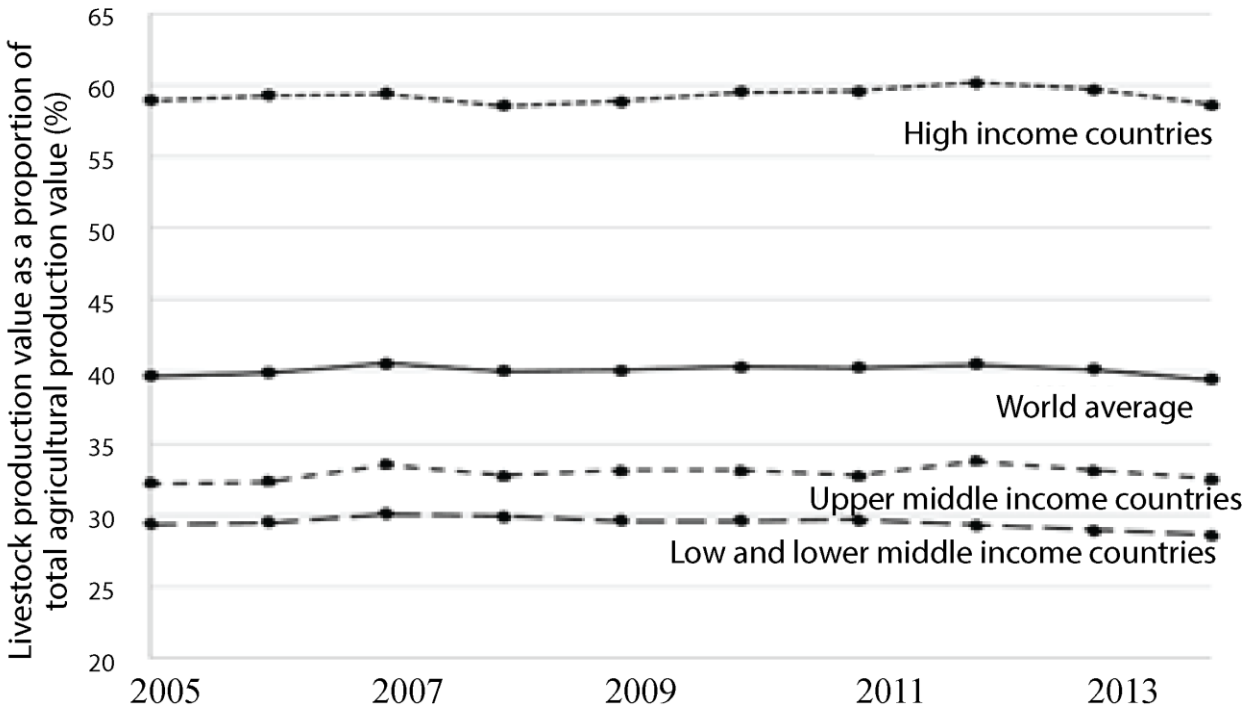


Figure 7. The contribution of livestock gross production value to total agricultural gross production value[24]

In Australia, the livestock sector takes the lion's share of the national GDP. The domestic and export sales of red meat and livestock in 2018-19 accounted for $28.5 billion, of which red meat exports contributed $17.2 billion and domestic sales accounted for the remaining $11.3 billion (Fig. 8a)[25]. The beef cattle export in Australia worths $1.35 billion[26]. More recently (July 2021), the country exported 134,842.13 ton of beef to 100 countries around the globe[27]. The main sources of the red-meat are the ranches where the Boran breed, which was taken from Ethiopia via Kenya and Zambia in *embryo* form in the early 1990s[28], has heavily supported the beef industry in Australia. Brazil has been the world's largest exporter of beef, providing close to 20% of total global beef exports in 2018 (Fig. 8b)[29]. One of the ingredients for the success of these countries was that they have maintained and used the ranches and multiplication centers as nuclei to generate high grade parental stock and produce successive generations, maintaining the parental lines that serve for the wider production.

[24] Salmon GR, MacLeod M, Claxton JR, Ciamarra UP, Robinson T, Duncan A, Peters AR, 2020, Exploring the landscape of livestock 'Facts'. Global Food Security 25 (2020) 100329.

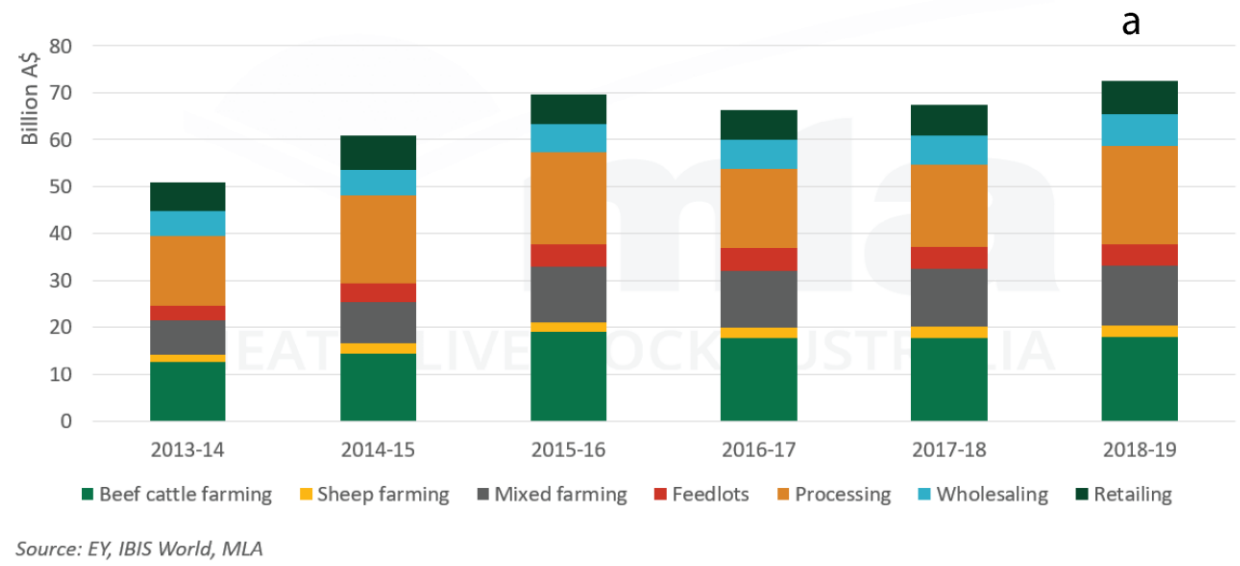
[25] The economic significance of Australia's red meat and livestock industry: https://www.mla.com.au/prices-markets/market-news/2020/the-economic-significance-of-australias-red-meat-and-livestock-industry/#

[26] Australian livestock exporters council: https://auslivestockexport.com/about-alec/economic-impact

[27] International market: https://www.mla.com.au/marketing-beef-and-lamb/international-markets/#; Australian Red-meat export statistics: https://www.agriculture.gov.au/export/controlled-goods/meat/statistics

[28] Rare breeds trust of Australia: https://rarebreedstrustofaustralia.tidyhq.com/public/pages/sc-boran

[29] United States Department of Agriculture (USDA), 2019. Economic Research Service. https://www.ers.usda.gov/amber-waves/2019/july/brazil-once-again-becomes-the-world-s-largest-beef-exporter/



Source: EY, IBIS World, MLA

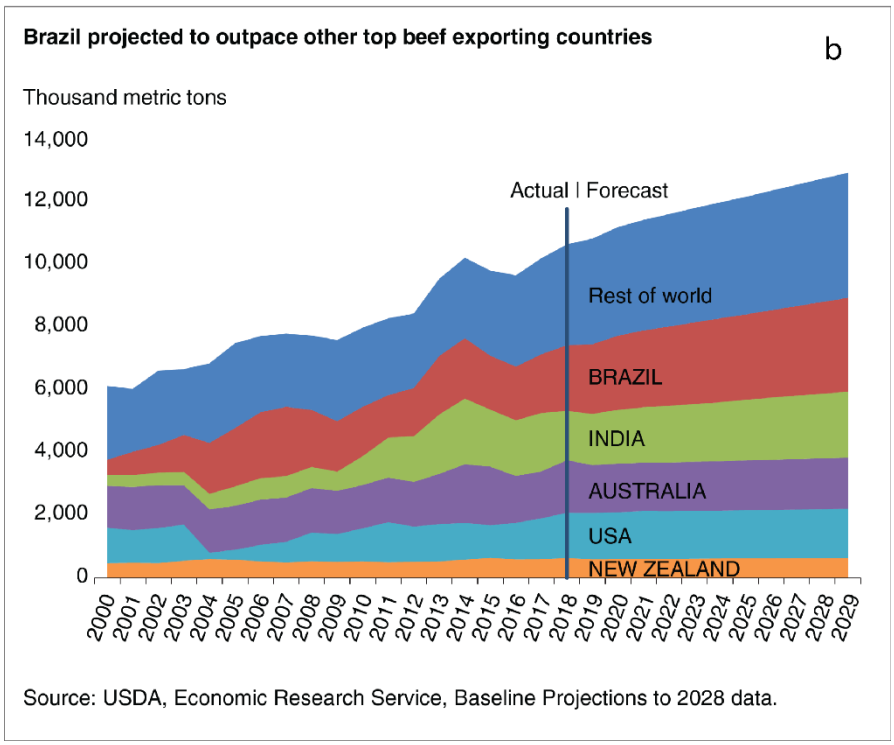


Figure 8. (a) Livestock industry turnover by sub-sector in Australia and (b) trend of actual and forecast beef exports by countries from 2000 to 2029

Synchronizing endocrine progesterone profiling with genomic selection have been used to improve fertility of dairy animals in Sweden[30], Finland[31], Ireland[32], The Netherlands and Canada[33]. In addition, important traits such as feed intake and efficiency in dairy and beef animals have been complemented with genomic selection in commercial farms in USA, UK, Ireland, the Netherlands, Finland, Sweden, Germany, Australia and New Zealand[34,35].

Genomic selection has led to spectacular advances in animal production in many domestic species including honeybees[36]. Globally, honey bees (*Apis mellifera* L.) include several recognized subspecies that differ in their biological properties and agricultural characteristics. One of the important areas of bee breeding is the preservation of bee subspecies genotypes diversity, which can be used as a starting material for breeding and crossbreeding[37]. The genetic selection program on honeybees in Canada[38,39], established in 1881, can be a very good example on how genomic selection is practical in honey bees.

Biotechnology in fisheries and aquaculture also offers ample opportunities to reduce hunger and improve nutrition, alleviate poverty, generate economic growth and ensure better use of natural resources[40]. For instance, fisheries sustain millions of jobs and is among the most widely traded food commodities at a value of $145 billion annually of which 6% originates from developing countries, thus hoped to help meet the demand for nutritious food of the nearly 10 billion people projected to live on earth by 2050 (Fig. 9)[41].

[30] Tarekegn GM, Gullstrand P, Strandberg E, Båge R, Rius-Vilarrasa E, Christensen JM, Berglund B, 2019.Genetic parameters of endocrine fertility traits based on in-line milkprogesterone profiles in Swedish Red and Holstein dairy cows. J. Dairy Sci. 102:11207–11216. https://doi.org/10.3168/jds.2019-16691.

[31] Häggman, J., J. M. Christensen, E. A. M.ntysaari, and J. Juga. 2019. Genetic parameters for endocrine and traditional fertility traits,hyperketonemia and milk yield in dairy cattle. Animal 13:248–255.

[32] Nyman, S., S. I. Duchemin, D. J. de Koning, and B. Berglund. 2019. Genome-wide association study of normal and atypical progesterone profiles in Holstein-Friesian dairy cows. J. Dairy Sci. 102:3204–3215.

[33] Bruinjé TC, Colazo MG, Ribeiro ES, Gobikrushanth M, Ambros DJ, 2018. Using in-line milk progesterone data to characterize parameters of luteal activity and their association with fertility in Holstein cows. J. Dairy Sci. 102:780–798

[34] Berry DP et al., 2014. International genetic evaluations for feed intake in dairy cattle through the collation of data from multiple sources. Journal of Dairy Science, 97(6), pp.3894–3905.

[35] Manzanilla-Pech CIV et al., 2016. Genetic parameters between feed-intake-related traits and conformation in 2 separate dairy populations the Netherlands and United States. Journal of dairy science, 99(1), pp.443–457.

[36] Otte M, Netschitailo O, Kaftanoglu O, Wang Y, R.E. Page Jr RE, Beye M, .Improving genetic transformation rates in honeybees. Scientific Reports 8:16534. DOI:10.1038/s41598-018-34724-w

[37] Syromyatnikov MY, Borodachev AV, Kokina AV, Popov VN, 2018.A Molecular Method for the Identification of Honey Bee Subspecies Used by Beekeepers in Russia. Insects, 9, 10; doi:10.3390/insects9010010

[38] Ontario Resistant Honey Bee Selection Program. https://www.ontariobee.com/ORHBS

[39] OBA (Ontario Beekeeper's Association), 2012. Strategic directions summary 2013-2018: https://www.ontariobee.com/sites/ontariobee.com/files/OBA_StratPlan_Feb6.pdf

[40] FAO (Food and Agricultural Organizations for the United Nations), 2021. Sustainable Development Goals. http://www.fao.org/sustainable-development-goals/goals/goal-14/en/

[41] FAO 2017. Working for Sustainable Development Goals (SDG 14): Effective and sustainable management of marine resources is essential for achieving SDG 14, and in contributing to food security and nutrition for all. http://www.fao.org/3/i7298e/i7298e.pdf

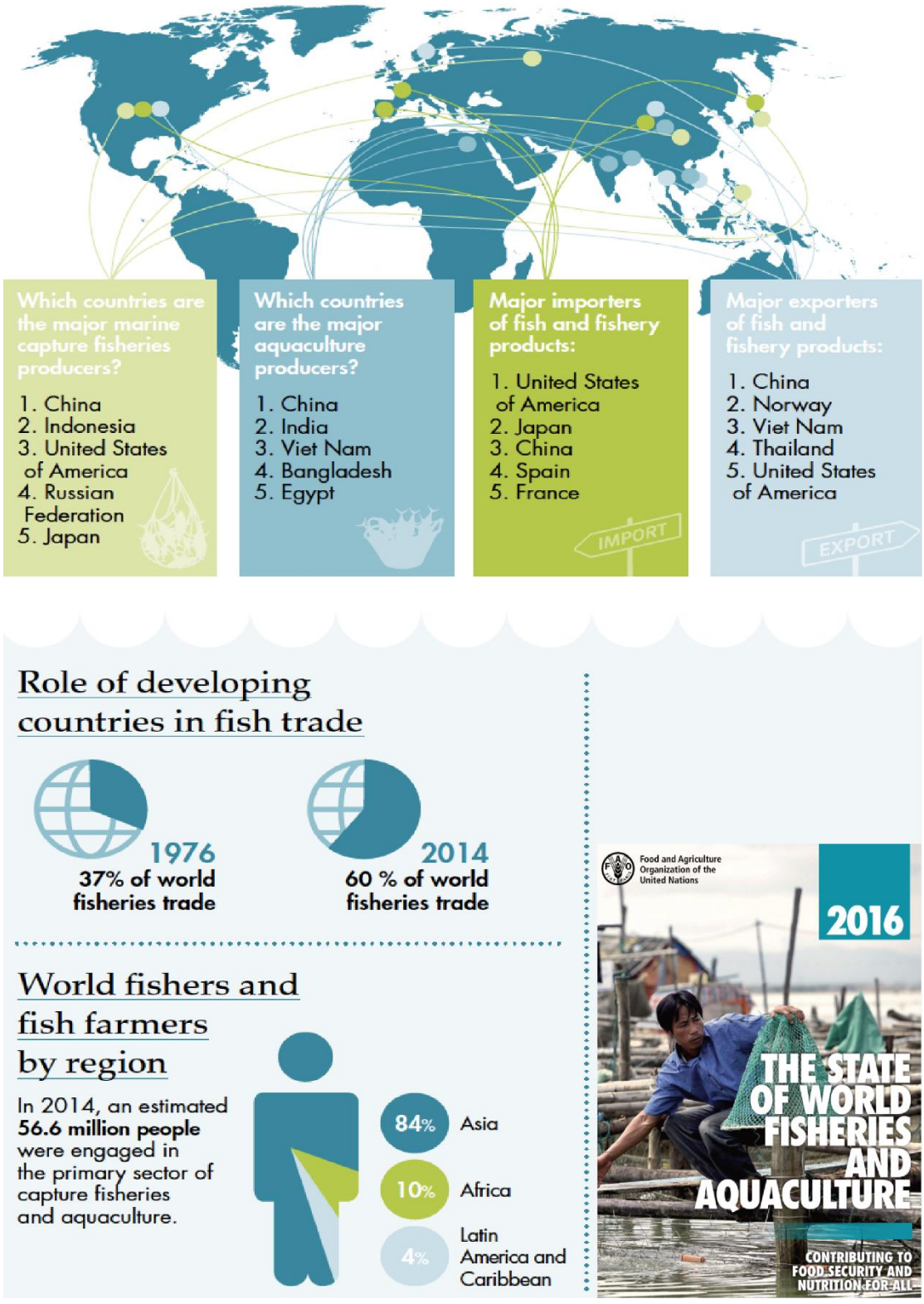


Figure 9. World fishery: shared by regions[42]

[42] *Ibid.*

2.1.2. Health biotechnology

The health biotechnology sector has received governmental and private support in some middle- and high-income countries. For example, in European countries, cell and gene therapies and immunotherapies are the fastest-growing areas, with 40% of investment funding and are designed for chronic health problems such as cancer and neurological disorders[43]. Similarly in Latin America, the increased burden of chronic conditions in the population has demanded health biotech products,[44] resulting in increasing engagement in regenerative medicine and anti-cancer research in addition to the existing research on infectious diseases[45].

Vaccine research has tremendously increased since the 80's with innovations of more than 40,000 patents and publications globally (Fig. 10). The global vaccination coverage between 2019-2020, according to the WHO, is approximately 85%[46]. Given the huge and growing clinical impact of vaccines, the clinical vaccine manufacturing market is expected to experience a growth of over 113 percent with a predicted incremental growth of over $492 million[47]. The preclinical segment of vaccine development accounted for a share of 13 percent of the global vaccine contract manufacturing market in 2020 and there are now several serum-based vaccines in the pipeline for wide-range of contagious diseases (Fig. 11).

The emergence of pandemics and epidemics forcing national and international bodies to invest in health biotechnology research and innovation, which is likely to increase the production of vaccines and thus drive growth in the vaccine contract manufacturing market. The recent genome-based vaccines developed for COVID-19 is a good example of the contribution of biotechnological innovations for the urgent need of vaccines.

In addition, the uses of gene therapy and stem cell-based technologies have further revolutionized therapeutic approaches especially to non-communicable diseases such as cancer. Therapeutic research is currently focusing on nanoparticle-based development for small compound drugs to suite the delivery and nano-encapsulation processes[48].

[43] Le Deu F and da Silva JS (2019). Biotech in Europe: A strong foundation for growth and innovation: European companies have an opportunity to play a stronger role in the industry by focusing on three factors. August 23, 2019. https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/biotech-in-europe-a-strong-foundation-for-growth-and-innovation#. Accessed on July 2021.

[44] Romeu B and Cristiá RP (2021). The CECMED Office of Innovation: A Core Initiative to Bolster Novel Pharmaceutical Products-The Cuban Approach. Ther Innov Regul Sci. 2021 Jan;55(1):163-169.

[45] Palma V, Pitossi FJ, Rehen SK, Touriño C, & Velasco I. (2015). Stem cell research in Latin America: update, challenges and opportunities in a priority research area. Regen. Med. (2015) 10(6), 785–798

[46] https://www.who.int/news-room/fact-sheets/detail/immunization-coverage

[47] *Ibid*.

[48] www.grandviewreseaarch.com (Accessed September 4, 2021)

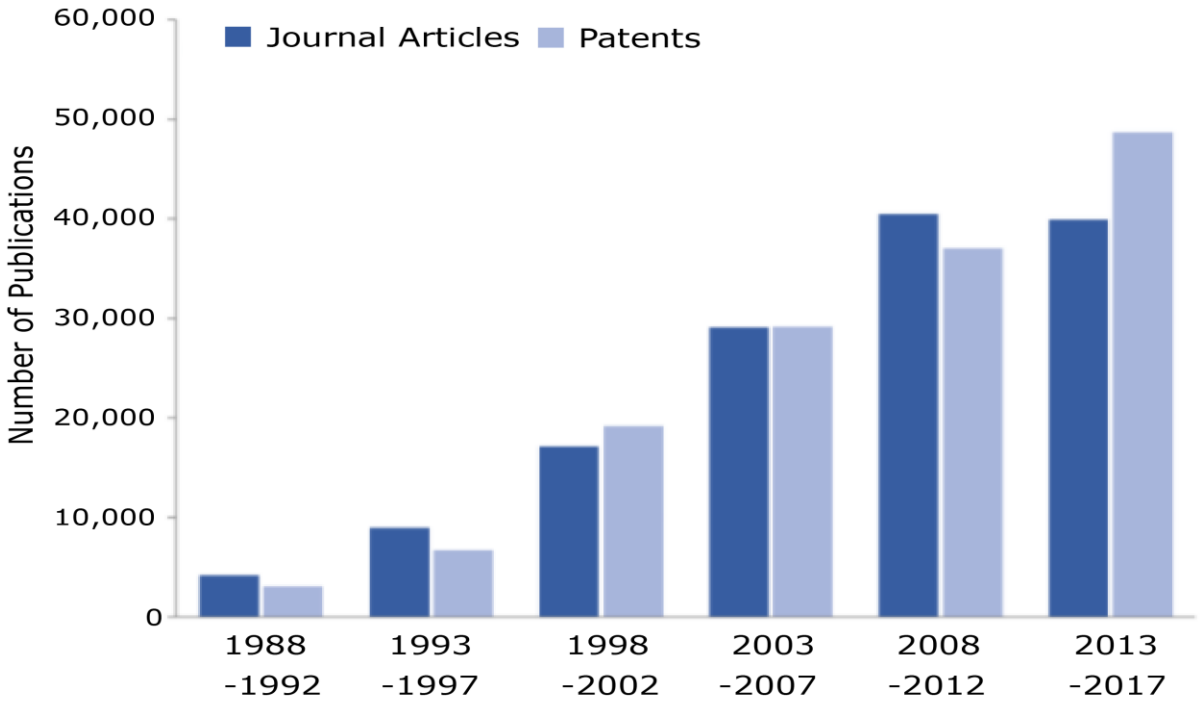


Figure 10. Number of vaccine journal articles and patents published 1988-2017[49]

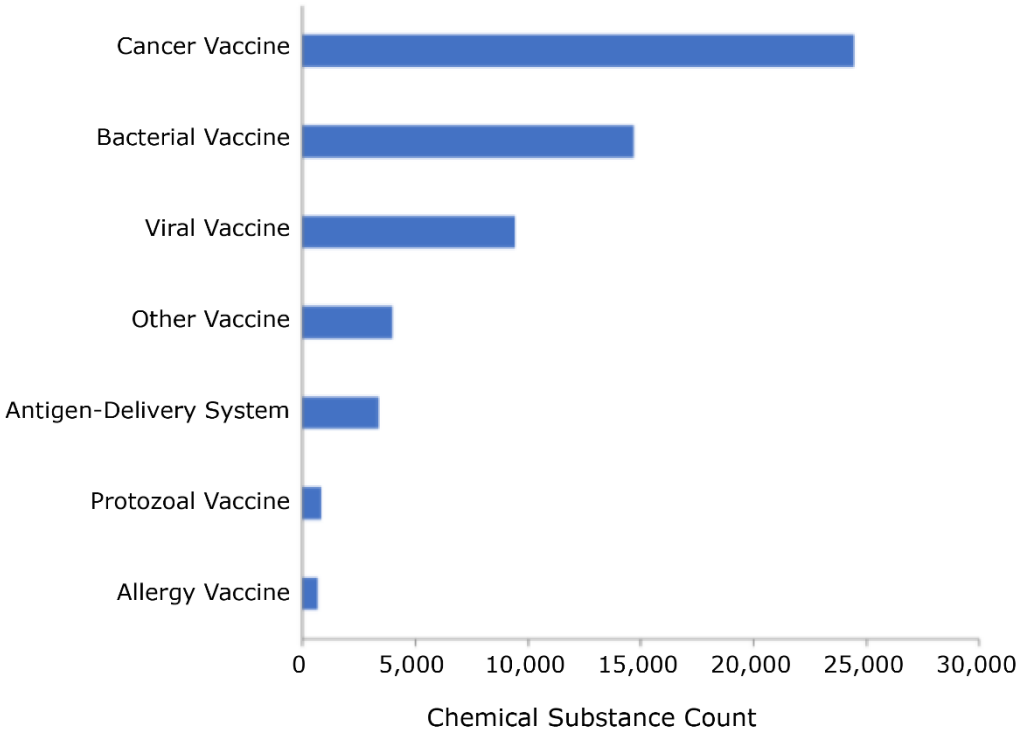


Figure 11. Distribution of vaccine-related substance classes[50]

[49] https://www.who.int/news-room/fact-sheets/detail/immunization-coverage (accessed on November 11, 2021)

Molecular diagnostic techniques are currently getting attention in the diagnostics market and economy of the health sector. In 2020, PCR dominated the market for molecular diagnostics and accounted for the largest revenue share (83.3%)[51]. Increasing use of high-throughput PCR technology to detect SARS-CoV2 is expected to drive the market (Fig.12). In addition, Next Generation Sequencing (NGS) technologies for the molecular diagnostic market are integrally linked to drug discovery, novel drug development, and personalized medicine. The NGS technologies also increase the number of genome profiling initiatives and research for novel drugs.

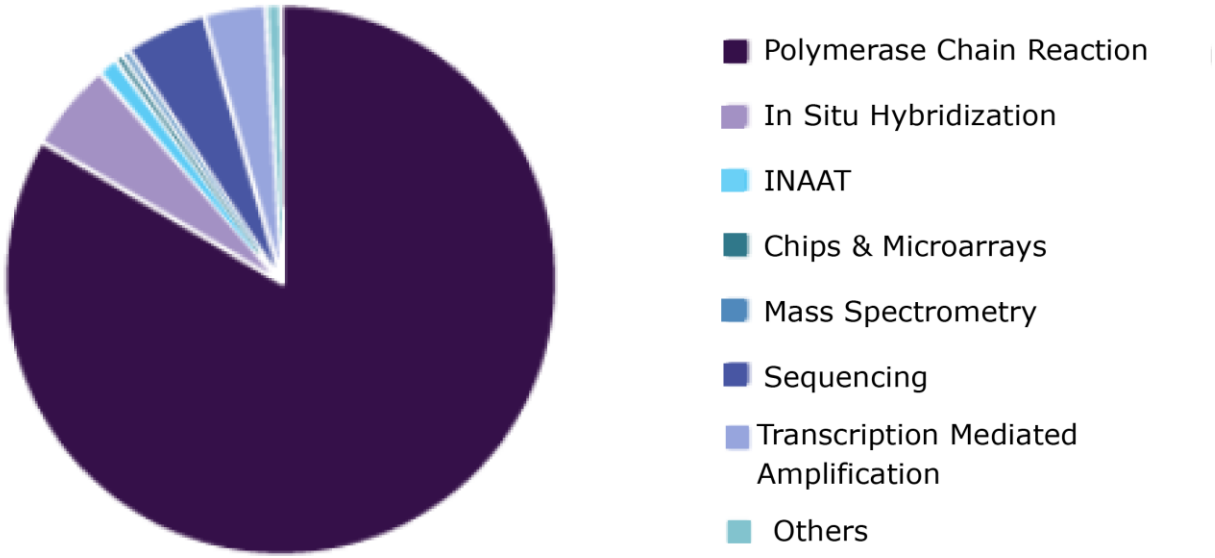


Figure 12. Global molecular diagnostics market share by technology in 2020[52]

2.1.3. Industrial biotechnology

Globally, the focus of applications of industrial biotechnology is on increasing market share of biobased products using advanced biotechnological innovations at scales of economic viability thereby increasing resource use efficiency, food and nutrition security, improving health care systems, creating new jobs, improving livelihood and mitigating climate change [53].

Technologies and investments associated with beverages, dairy products, baker's yeast, organic acids and antibiotics are huge, both in terms of tonnage and value. Among the fine chemicals, antibiotics such as

[50] *Ibid.*
[51] *Ibid.*
[52] www.grandviewreseaarch.com (Accessed September 4, 2021)
[53] Bugge, M.; Hansen, T.; Klitkou, A. What Is the Bioeconomy? A Review of Literature. Sustainability 2016, 8, 691.

penicillin, cephalosporins and tetracyclines are the major industrial products[55]. In the USA, for example, the fine chemicals market value is about 12,000 million USD, of which antibiotics comprise greater than 50%[55]. Commercial enzymes for processing food, feed, detergents and other industrial biobased products take the lion's share in the global biotechnology market (Fig 13). Furthermore, baker's yeast, food additives (antioxidants, colors, flavors, stabilizers, enhancers), novel foods, glucose and high fructose syrups, functional modifications of proteins, and toxin removal have currently gained a great commercial importance. Denmark, Germany, Japan, Sweden, United Kingdom, United States and Switzerland are among the top manufactures of bio-based commercial products including medicinal and pharmaceutical products[54]

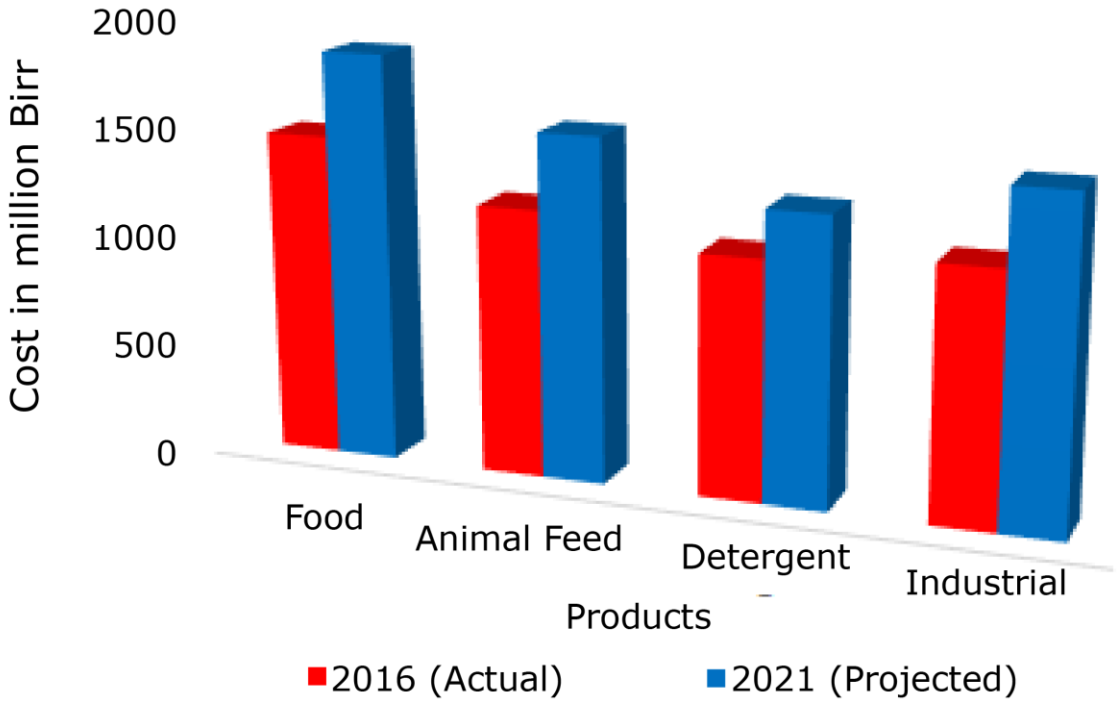


Figure 13. The Global Enzyme Market [55]

In Europe, the industrial biotechnology market is estimated to develop from 28 billion EURO in 2013 to 40 billion EURO in 2020, and predicted up to 50 billion EURO in 2030 (Fig. 14). This development represents an annual compound average growth rate of 7% between 2013 and 2030 (excluding antibiotics and biogas).

[54] Global Opportunity Analysis and Industry Forecast, 2020–2027; https://www.alliedmarketresearch.com/enzymes-market
[55] Global Opportunity Analysis and Industry Forecast, 2020–2027; https://www.alliedmarketresearch.com/enzymes-market

Benefits from biotechnology both help the EU economy to grow and provide new jobs and support sustainable development, public health and environmental protection[56]. The contribution of industrial biotechnology for the EU bioeconomy development accounts for food and beverage (~55%), manufacture of wood and paper (~17%), bio-based chemicals, pharmaceuticals and biofuels (all together ~4%), bio-based textiles (~4%), leather, feed, biomaterials and cosmetic industries (all together less than 3%)[57].

Industrial biobased products have increased as a result of new technologies such as targeted gene-based technologies, enzyme engineering, genome editing and synthetic biology followed by robotics, microfluidics and artificial intelligence, which enabled a wide range of products. In addition, new technologies in biorefineries allow the separation of high-purity feedstock streams.[58]

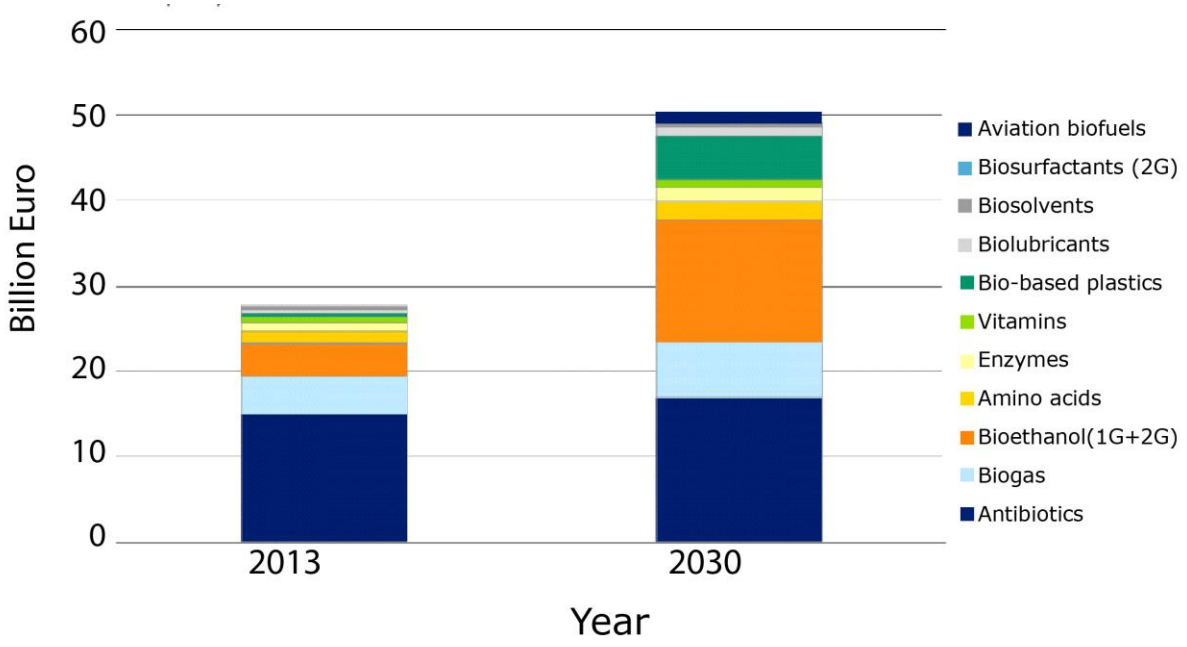


Figure 14. Industrial biotechnology market demand in the EU between 2013-2030[55]

[56] Allied Academies. (2019). 3rd World congress on Biotechnology; Edinburgh, Scotland; 2019 June 12-13. Available from: https://biotechnology.alliedacademies.com/2019. Retrieved date May 12, 2021.

[57] Y. Lokko, et al.(2017). Biotechnology and the bioeconomy-Towards inclusive and sustainable industrial development, New Biotechnol. (2017), http://dx.doi.org/10.1016/j.nbt.2017.06.005.

[58] Nathan Danielson, Sarah McKay, Paul Bloom, Jennifer Dunn, Neal Jakel, Timothy Bauer, John Hannon, Michael C. Jewett, and Brent Shanks.Industrial Biotechnology-an industry at an inflection point. Dec 2020.321-332.http://doi.org/10.1089/ind.2020.29230.nda, Published in Volume: 16 Issue 6: December 16, 2020

2.1.4. Environmental biotechnology

Globally, environmental contamination with inorganic and organic[59] pollutants has increased over the years due to rapid industrialization, urbanization, intensive agricultural and anthropogenic activities[60]. Environmental biotechnology is providing an increasingly powerful innovation engine at a global scale for sustainable environmental management (waste management, waste treatment, pollution control; energy production) and cleaner industrial products and processes through the development of a diverse range of novel bio-products. Due to advances in molecular biology and biochemical methods, knowledge of the ecological, genetic, and metabolic diversity of organisms and their use for wastewater treatment and bioremediation processes have shown considerable advances. For example, in biological wastewater treatment processes, enhanced nutrient removal and efficient transformation of pollutants[61]; bioaugmentation and monitoring of anammox bacteria for the removal of inorganic nitrogen have become an emerging green technology in wastewater treatment plants[62]. In Denmark, there are also more than 50 biological wastewater treatment plants that are bio-monitored for their microbial community structure and function in association with the treatment efficiencies[63].

Regarding biodegradation and bioremediation, a number of countries have used a consortium[64] of microorganisms for the degradation of priority and recalcitrant pollutants in engineered systems for the treatment of municipal and industrial wastewaters. In phytoremediation processes, the use and acquisition of organisms or their products in the efficient transformation of pollutants such as pesticides and heavy metals have been demonstrated[65] (Fig. 15).

[59] petroleum hydrocarbons, pesticides, agrochemicals, pharmaceutical product

[60] Dhananjay Kumar, Sangeeta Anand, Poonam, Jaya Tiwari, G. C. Kisku, and Narendra Kumar (2019). Removal of Inorganic and Organic Contaminants from Terrestrial and Aquatic Ecosystems Through Phytoremediation and Biosorption. IN Env. Biotech for sustainable future, Springer. ISBN 978-981-10-7284-0

[61] Seyoum Leta **(**2004) Developing and optimizing processes for biological nitrogen removal from tannery wastewaters in Ethiopia. PhD Thesis. Royal Institute of Technology, Stockholm, Sweden. ISBN 91-7283-830-2

[62] Yunpeng Zhao, Shufeng Liu, Bo Jiang, Ying Feng, Tingting Zhu, Huchun Tao, Xi Tang, and Sitong Liu (2018). Genome-Centered Metagenomics Analysis Reveals the Symbiotic Organisms Possessing Ability to Cross-Feed with Anammox Bacteria in Anammox Consortia. Environmental Science & Technology 52 (19), 11285-11296. DOI: 10.1021/acs.est.8b02599

[63] Jiang C, Peces M, Andersen MH, Kucheryavskiy S, *et al.* (2021). Characterizing the growing microorganisms at species level in 46 anaerobic digesters at Danish wastewater treatment plants: A six-year survey on microbial community structure and key drivers. Water Res. 193:116871. doi: 10.1016/j.watres.2021.116871. Epub 2021 Jan 25. PMID: 33578056.

[64] Consortium is defined as two or more bacterial or microbial groups living symbiotically.

[65] Marousˇek, J., Itoh, S., Higa, O., et al. (2013). Enzymatic hydrolysis enhanced by pressure shockwaves opening new possibilities in Jatropha Curcas L. processing. Journal of Chemical Technology and Biotechnology, 88, 1650–1653.

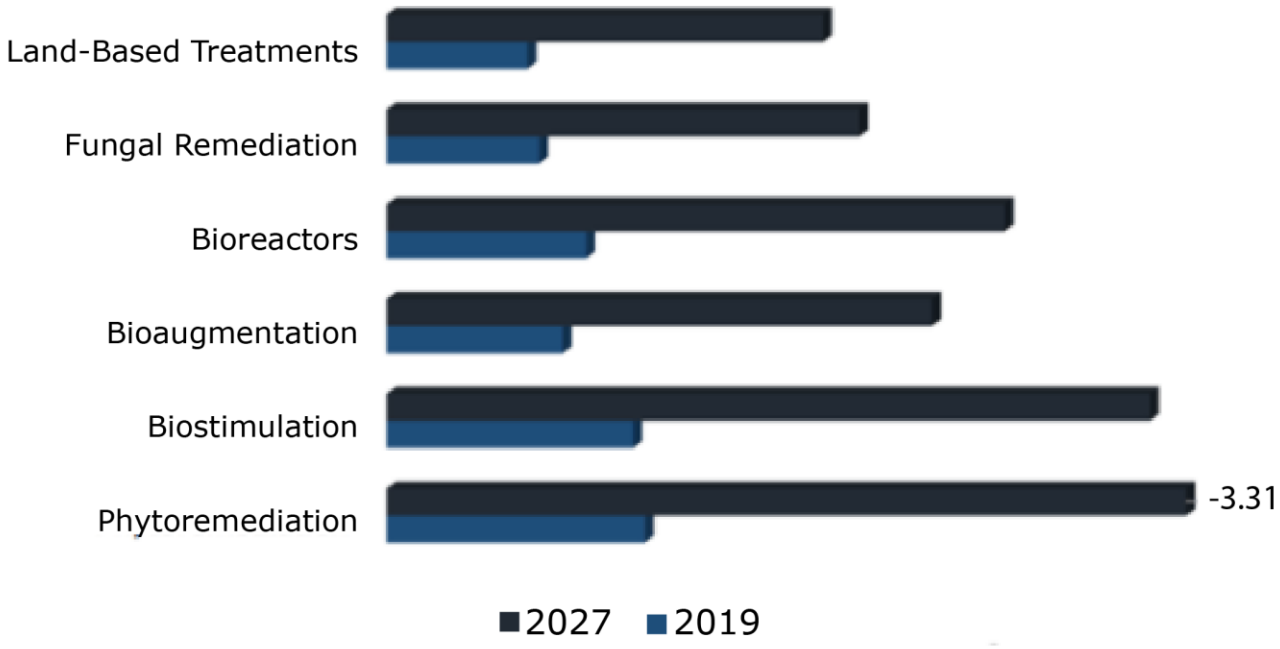


Figure 15. Bioremediation market-technology dynamics in billions of USD[66]

Environmental biotechnology has also opened up opportunities for the generation of eco- friendly products, and the production of biofuels from biowastes[67]. The coupling of technologies has been credited with achieving an enhanced performance of the biological systems[68]. In the high-income countries such as Europe and North America, easier access to cutting-edge green technologies has opened new opportunities for biowaste valorization into added value products (Fig. 16)[69]. In low-income countries, although the volume of biowaste is large and diverse, the support from the public sector and industry does not allow opportunities for transformation of biowaste into valuable products, thus resulting in the generation of a high amount of anthropogenic greenhouse gas emissions and effluents. Studies done in south Africa indicated that the value of this unutilized biowaste is equivalent to USD 20 billion per year if a valorization approach was applied instead of waste dumping and open-air burning[70].

[66] https://www.emergenresearch.com/industry-report/bioremediation-market (Accessed Sept 04, 2021)

[67] Samir Kumar Khanal (2008) Anaerobic Biotechnology for Bioenergy Production: Principles and Applications John Wiley & Sons, Inc. ISBN: 978-0-813-82346-1

[68] Sanabria, J., Acevedo, D., Morales, M., et al. (2010). Improvement of methane production using photoFenton as pretreatment of vinasses. Manizales, Colombia: Congreso Iberoameicano de Biotecnologı´a.

[69] Mirabella, N.; Castellani, V.; Sala, S. Current options for the valorization of food manufacturing waste: A review. J. Clean. Prod. 2014, 65, 28-33

[70] Mirabella, N.; Castellani, V.; Sala, S. Current options for the valorization of food manufacturing waste: A review. J. Clean. Prod. 2014, 65, 28-33

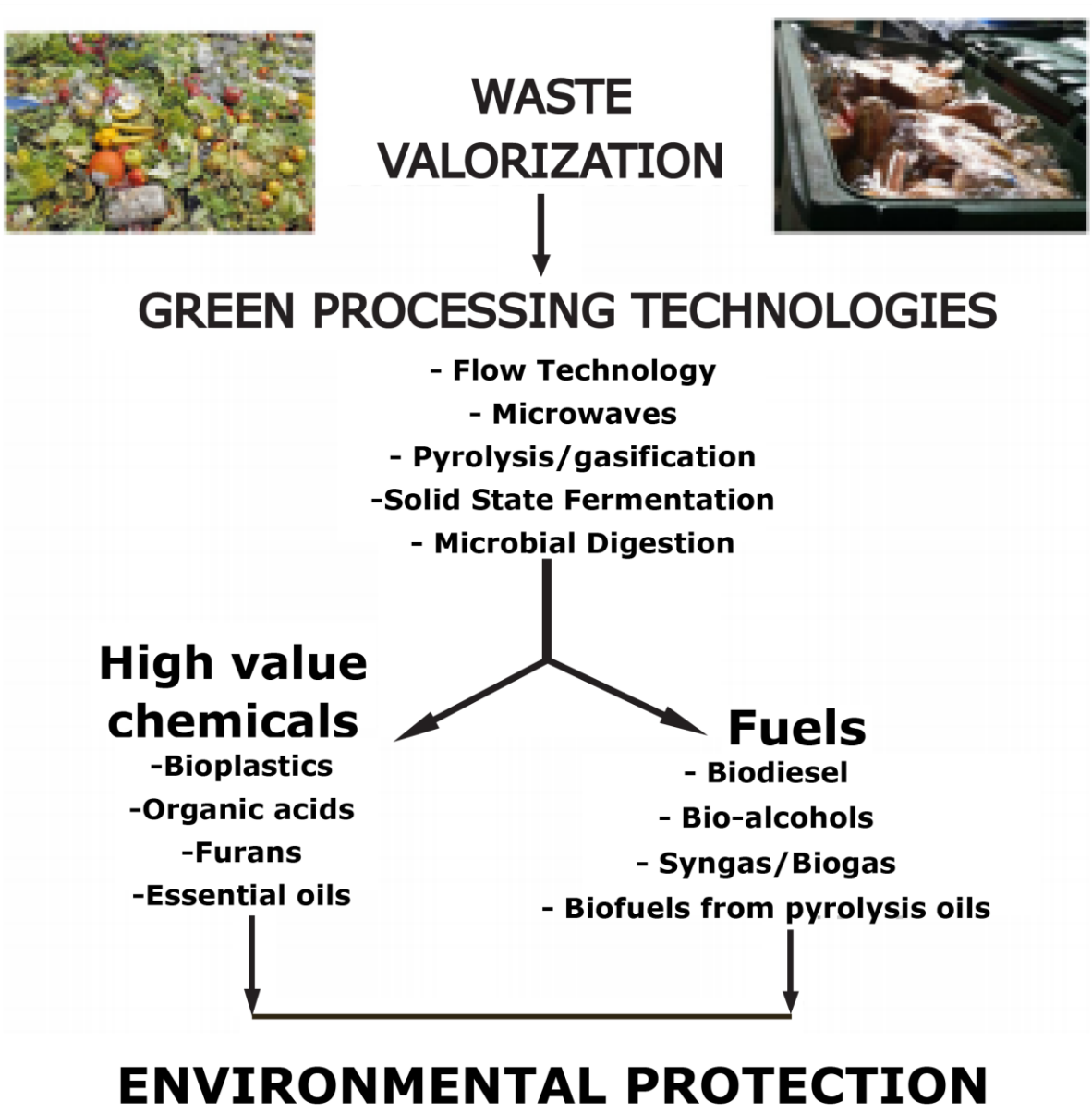


Figure 16. A schematic presentation of green processing technologies for waste valorization

Progress in the understanding of microbial diversity along with the use of molecular techniques and the development of new diagnostic methods have opened a new range of alternatives for research and innovation in treatment processes[71]. Detection and biomonitoring using biosensors and biomarkers have been developed and are now in the market[72]. Using the potential of microbial biodiversity, the study of ecological adaptation of bacterial consortia and the use of –omics and computational techniques as well as

[71] Divakara, B. N., Upadhyaya, H. D., Wani, S. P., et al. (2010). Biology and genetic improvement of Jatropha curcas L.: A review. Applied Energy, 87, 732–742.

[72] Mataveli LRV, Antunes NJ, Pereira MP, Brigagao L, Magalhaes de CS, Luccas PO (2010) Evaluation of a simple and low cost potentiometric biosensor for pharmaceutical and in vivo adrenaline determination. Biosens Bioelectron 262:798–802

the generation of micropollutant sensors, will give rise to reliable and innovative options for cost effective and sustainable management of wastes.

2.1.5. Biosafety and IPR

The biosafety regulatory systems including policies, legislations and procedures ensure the application of biotechnology innovations for health and environmental safety[73]. Most regulatory instruments have focused on genetically modified organisms (GMOs) and have been extensively debated at various national and international forums. The Convention on Biological Diversity (CBD)[74], the Nagoya Protocol on Access and Benefit Sharing (ABS) and International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) regulate access and use of technology and genetic resources for food and agriculture. The Cartagena Protocol (CPB) is the first legally binding international agreement governing the movement of living modified organisms (LMOs) across national borders. The Codex Alimentarius Commission was also established by FAO and WHO to develop internationally acceptable standards for use in the areas of food quality and food safety. The use of proprietary biotechnology products and processes are also governed by Intellectual Property Rights (IPRs), which include International Union for the Protection of New Varieties of Plants (UPOV) and TRIPs Agreement under World Trade Organization (WTO).

The safety of GMO is of great public concern and is under stringent regulation in European nations. The EU Regulation No 1829/2003 automatically binds all the Member States regarding GM food and feed. Additionally, Regulation 1830/2003 deals with tracing and labeling of GM products thus ensuring protection to human, animal and environmental health. In the United States, the commercialization of GMO has rapidly advanced through permissive regulatory reviews[75]. In Canada, the regulation of biotechnology products is coordinated between the Canadian Food Inspection Agency (CFIA), Health Canada, and Environment Canada, with the mandate to incorporate new or amend existing regulations[76]. Biosafety regulations can target a "process" or "product" resulting from biotechnology research and innovation. The former involves specific requirements on the processes used to produce the novel product while the latter emphasizes on the novel characteristics of the product. The question of whether biotechnology regulation should be based on the process or the product has long been debated, with different jurisdictions adopting

[73] Komen, J. (2012). The emerging international regulatory framework for biotechnology. GM Crops and Food 3(1): 78-84.

[74] CBD: Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes. Montreal: Secretariat of the Convention on Biological Diversity; 2000

[75] Baram (2011). Governance of GM Crop and Food Safety in the United States. In: Michael Baram and Mathilde Bourrier. Governing Risk in GM Agriculture, Cambridge University Press, New York, pp289.

[76] Directive Dir 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada.

different approaches. The European Union has adopted a process-based approach, Canada has adopted a product-based approach, and the United States and Argentina have implemented a hybrid system[77].

Intellectual Property Rights (IPRs) are the rights given to persons over the creations of their intellect. They usually give the creator an exclusive right over the use of his/her creation for a certain period. IPRs, as they pertain to the biotechnology sector, concern the legal ownership and exclusive rights to patents, trademarks, and trade secrets. It is important for public research organizations and enterprises to protect the innovation that they generate with IPR, which provide a basis for return on investment in research and development, by granting monopoly rights for a certain period to their owners. Just like with other industries, IPRs allow biotech firms to establish ownership and protect their products from the threat of competitors.

The IP created by biotechnology product and process developers can take several forms, consisting of vaccines, seeds, plants, microorganisms, devices, softwares, protocols, processes, brands and domain names, among others. Most of these assets may attract more than one form of IP protection. In the biotechnology sector, the most common forms of IP are "patent" and "plant variety protection (PVP)", although other forms may also be applicable and be used in practice.

Patentable inventions should be new, involve an inventive step and industrially applicable. "Patent" is a system of laws giving protection to inventors and investors involved in an invention to protect the creation of the inventor for a limited period of years against use for profit without their consent. Each country has its own specific type of patent law as per an international agreement or treaty or individually. But there is a tradition of strong international cooperation by means of international conventions.

2.2. Biotechnology development in Africa

2.2.1. Agricultural biotechnology

In Africa, biotechnology innovations in agriculture include tissue culture, molecular characterization, marker assisted selection and molecular diagnostics for plant and animal improvement for livelihoods and food security. African farmers are heavily reliant on unimproved traditional or landrace varieties and indigenous animal genetic resources[78]. However, biotechnology research and innovation activities in agriculture are conducted in a number of universities and research organization in Africa such as, Kenya (Kenyatta University, JKUAT, UoN, KARI), Uganda (Makerere University, NARO) and Tanzania (MARI,

[77] Turnbull C, Lillemo M and Hvoslef-Eide TAK (2021). Global Regulation of Genetically Modified Crops Amid the Gene Edited Crop Boom – A Review. Front. Plant Sci. 12:630396.

[78] Data on adoption of modern varieties in sub-Saharan Africa are scarce. Preliminary estimates for 10 key staples indicate that modern varieties account for 10 to 40 per cent of planted area, the notable exceptions being maize and potatoes with adoption rates of 67 and 59 per cent respectively. See Alene, A. et al. (2011), 'Measuring the effectiveness of Agricultural R&D in Sub-Saharan Africa from the Perspectives of Varietal Output and Adoption: Initial Results from the Diffusion of Improved Varieties in Africa Project', paper prepared for the ASTI/IFPRI-FARA Conference, Accra, 5–7 December, 2011.

NM-AIST), universities and research institutes in Nigeria, Ghana, Morocco, Cameroon, Egypt and South Africa.

There are also a number of other players in the agricultural bioscience arena in Africa, operating at regional and international levels. Biosciences research and innovation support by SIDA in the countries in Eastern Africa through BIOEARN and Bio-Innovate Programs focus on regional research and innovation collaborative projects. Among the CGIAR centers, ILRI (livestock), ICRAF (agroforestry), CIAT (cassava, bean and forages), CIMMYT (maize and wheat), IITA (root crops and banana), ICRISAT (sorghum, chickpea, etc.), and CIP (potato, sweet potato) are important players in agricultural research in Eastern Africa. ICIPE is also an African-based international organization working on advancing research involving insects for food and health in Africa, focusing on insect multidisciplinary research, product discovery and development. The biosciences for eastern and central Africa (BecA-ILRI Hub), on the other hand, provides shared agricultural and biosciences platform services for high-end bioscience projects (e.g. genomics and genotyping) and capacity building activities.

2.2.2. Health biotechnology

In Africa, health biosciences research and innovation activities are conducted in universities and research institutes. The number of universities conducting research in health bioscience has shown to increase from 30% in 2003 to 93% in 2014. Similarly, research capacity in institutes under the Ministries of Health have also increased from 20% (2003) to 51% (2014)[79]. These progresses are also seen in some biotechnology products that have reached the commercial stage in Africa. For example, companies in South Africa (Biovac) and Egypt (Vascera) producing vaccines for TB, tetanus, typhoid, measles, cholera, hepatitis B and pneumonia have shown progress in the last few years[80]. Africa's vaccine market value is USD 1.3 billion and is expected to reach USD 2.35 billion in 2030[81]. The current capacity of vaccine development in Africa is still limited[82].

About 80% of the African population use traditional medicine for primary healthcare[83]. In the last decades, there have been a plethora of herbal plants that are known for their use in biotechnology research and innovation including the identification of active compounds for drug discovery.

[79] Kirigia et al. Health Research Policy and Systems (2015) 13:61 DOI 10.1186/s12961-015-0054-3

[80] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-needs-vaccines-what-would-it-take-to-make-them-here. Accessed on Aug 20, 2021

[81] *Ibid.*

[82] *Ibid.*

[83] Ozioma J.E. Herbal Medicines in African Traditional Medicine. http://dx.doi.org/10.5772/intechopen.80348. Accessed Aug 2021.

2.2.3. Industrial biotechnology

African countries have limited capacity in industrial biotechnology research and innovation. Some of the research and innovation activities include sugarcane-based bioethanol production and other bio-based products from feedstocks of cassava, beetroot, jatropha, ground nut and others[84]. As mentioned in section 2.2.2, biopharmaceutical research and innovations have employed industrial biotechnology innovations for vaccine productions. However, Africa has not yet built capacity in industrial-biotechnology for its industrial competitiveness. Given the rich biomass, feedstock and fermentation practices for industrial biotechnology, Africa needs to invest in developing relevant technologies and capabilities in industrial biotechnology research and innovation.

2.2.4. Environmental biotechnology

Though there are many national, regional, and international initiatives in the areas of biotechnology research and innovation in Africa, only a few are addressing environmental biotechnology-related research activities[85]. Some of the environmental biotechnology activities include identification of microorganisms for use in bioremediation[86], biological removal of potential chemical stressors from the environment to bioenergy generation from organic waste, microbial-based products derived from water hyacinth (known as OBD+) which is able to break-down oil and grease from wastewater[87], biotechnology for biofuels and biocatalysts[88]. Similarly, research on industrial and environmental biotechnology (biogas, bioremediation, biofertilizers and biopesticides) are conducted at the University of Dar es Salam, Tanzania[89]. The status of biotechnology infrastructure and human resource in Africa is also shown to be scanty, with few project-based activities in the different regions. The Eastern African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN) embarked on capacity building phase (1999-2004) and R4D phase (2006-2009)[90] . Subsequently, the Bio-resources Innovations Network for Eastern Africa Development (Bio-innovate) focused on product development and pilot testing phase (2010-2014) followed by product piloting and commercialization phase (2018-2021)[91], were Sida-

[84] IRENA (2016), Bioethanol in Africa: The case for technology transfer and South-South cooperation, International Renewable Energy Agency, Abu Dhabi.

[85] Mtui, Godliving Y. S (2011) Status of biotechnology in Eastern and Central Africa. *Biotechnology and Molecular Biology Review* Vol. 6(9), pp. 183-198

[86] Bello-Akinosho, M., Adeleke, R., Thantsha, M.S. & Maila, M. 2017. Pseudomonas sp.(Strain 10–1B): A potential inoculum candidate for green and sustainable remediation. Remediation 27: 75-79

[87] Adeoti, John O. (2002) Technology and the Environment in Sub-Saharan Africa: Emerging trends in the Nigerian manufacturing industry. https://doi.org/10.4324/9781315187105

[88] Olembo NK, M'mboyi F, Nyende B, Oyugi, K, Ambani L (2010). Status of biotechnology in Sub-Sahara Africa: A cross-country analysis. ABSF. Nairobi Kenya, p. 98

[89] Parawira W (2009). Biogas technology in Sub-Saharan Africa: Status, prospects and constraints. Rev. Environ. Sci. Biotechnol., 8: 187-200.

[90] Forsman, B., J. Komen and I. Virgin. (2011). A decade of bioscience development in eastern Africa: the BIO-EARN program 1999–2010. Sida: Stockholm

[91] www.bioinnovateafrica.org

funded regional initiatives aimed at strengthening biotechnology capacity building, research and product development in agricultural, industrial and environmental biotechnology in eastern Africa.

2.2.5. Biosafety and intellectual property rights

African countries have made steady progress in developing national biosafety frameworks in line with the global governance instrument and the Cartagena Protocol on Biosafety (CPB). For instance, Zimbabwe's biosafety Act is an enabling one, but no trials are taking place; Uganda has developed a good level of research and regulatory capacity, but it has no biosafety legislation to move from research to commercialization. In Egypt there has been an official ban for genetic engineering-based biotechnology products since 2012. In Africa, some of the existing regulatory frameworks have taken an extreme precautionary approach limiting the development and deployment of genetic engineering-based biotechnology research and innovation.

Countries of the African Region operate within a multi-layered IP regulation and governance landscape. The Paris Convention for the Protection of Industrial Property (1883) and the TRIPS Agreement (1994) regulate the global IP framework within which African countries operate. Most African countries (40 out of the 47) are members of the WTO and are Parties to the TRIPS Agreement, which provides a minimum standard for the regulation of intellectual property[92].

2.3. Status of biotechnology research for development landscape in Ethiopia

With the race towards sustainable economic development, biotechnology plays a role in the economic, social and environmental policy decisions. As shown in the foregoing discussion, globally, the potential economic contributions of biotechnology are being exploited at an accelerated rate with a likelihood of creating a new economy along with wealth and skill requiring jobs. Countries that have taken the lead benefit most and Ethiopia need to move with a sense of urgency.

Recognizing the advances in modern biotechnology and contribution to bioeconomy, it is important to strategically adopt and integrate biotechnology R4D programs into the national economy. For a country like Ethiopia, biotechnology is a powerful enabling technology that revolutionizes agricultural production and productivity, healthcare, industrial processing and environmental sustainability.

[92]Motari, M., Nikiema, J-P., Kasilo, O.M.J., Kniazkov, S., Loua, A., Sougou, A. and Tumusiime, P. (2021). The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. BMC Public Health (2021) 21:490.

2.3.1. Agricultural biotechnology

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.

2.3.1.1. Agricultural biotechnology research landscape

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[93,94]. Furthermore, haploid and double haploid production protocols have been developed for some crops to speed up conventional breeding[95]. Recently BETin has started to work on plant tissue culture, molecular breeding, and 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 trials. In addition, genome editing of *Brassica carinata* to improve its oil quality and quantity is being conducted

[93] Abraham, A. (2009). Agricultural biotechnology research and development in Ethiopia. *African Journal of Biotechnology* 8 (25): 7196-7204.

[94] Dugassa, G. and Feyissa, T. (2011). *In vitro* Production of Virus-Free Sweet Potato [*Ipomoea batatas* (L.) Lam] by Meristem Culture and Thermotherapy. *SINET: Ethiopian Journal of* Science 34 (1): 17-28.

[95] http://www.eiar.gov.et/index.php/agricultural-biotechnology-research

in collaboration with Addis Ababa University and Swedish University of Agricultural Sciences (SLU). Research activities in molecular genetic diversity, Quantitative Trait Loci (QTL) mapping, association mapping and marker assisted selection (MAS) that potentially 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.

Recognizing the increasing impact of emerging new breeding technologies such as genetic engineering and genome edition, the Ethiopian government has taken required steps to increase domestic crop production to support the agricultural productivity through official approval for environmental release and authorizing cultivation of genetically engineered (GE) cotton in the commercial farms. Furthermore, the revised Biosafety Proclamation, in addition to cotton, has also opened the door for legalized confined field trials (CFTs) of insect resistant and drought tolerant maize through the WEMA project. This is the first food crop to obtain CFT approval since the 2015 revised Biosafety Proclamation. The Striga Smart Sorghum project initiative is also one of the most important experiment on one of the cereal crops in terms of human consumption, production and cultivated area coverage in the country.

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)[96]. Research on embryo transfer technology was conducted by ILRI in on zebu cattle[97,98]. 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[99]. Moreover, characterization of indigenous livestock populations has been carried out using protein polymorphism, SSR, SNP and whole genome sequencing. Accordingly, genome-based researches have been conducted for high-quality beef[100], thermotolerance[101], trypanotolerance[102] and ecological adaptations[103] in indigenous livestock species.

[96] NAIC (National Artificial Insemination Center) (1995). NAIC at a Glance. Ministry of Agriculture, National Artificial Insemination Center, Addis Ababa, Ethiopia.

[97] Tegegne A (1991) Embryo Transfer at ILCA: The first calf is born. ILCA Newsletter 10:1-2.

[98] Azage Tegene has had pioneered embryo transfer in Africa using Boran cattle breed in the 90's

[99] Tegegne A. (2016). On-farm hormonal oestrus synchronization in mass insemination of cows for smallholders in Ethiopia. Presented at ILRI Institutional planning meeting, Nairobi, October 4-7, 2016. Nairobi, Kenya.

[100] Taye M, Kim J, Yoon SH, Lee W, Hanotte O, Dessie T, Kemp S, Mwai OA, Caetano-Anolles K, Cho S, Oh SJ, Lee HK, Kim H, 2019b. Whole-genome scan reveals the genetic signature of African Ankole cattle breed and potential for higher quality beef. BMC Genetics 18:11.

[101] Mekonnen YA, Gültas M, Effa K, Hanotte O, Schmitt AO. Identification of Candidate Signature Genes and Key Regulators Associated With Trypanotolerance in the Sheko Breed. Front Genet. 2019 Nov 14;10:1095.

[102] Taye M, Lee W, Caetano-Anolles K, Dessie T, Cho S, Oh SJ, Lee HK and Heebal Kim H, 2018. Exploring the genomes of East African Indicine cattle breeds reveals signature of selection for tropical environmental adaptation traits. Cogent Food & Agriculture 4: 1552552.

Animal vaccines have also been produced at a 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[104] in collaboration with overseas laboratories. For livestock disease diagnosis, ELISA, PCR and cDNA probe-based techniques have been used at NAHDIC, Sebeta.

With regard to biofertilizers, efficient isolates of indigenous *Rhizobia* and mycorrhizal-based biofertilizers have been identified and characterized as soil inoculant for faba bean, chickpea, field pea and fenugreek[105]. Large-scale production of the selected isolates and trials have been conducted at farmers' field level in different parts of the country. A superior strain *Bradyrhizobium japonicum* was produced at large scale and being used by farmers in soybean growing areas of the country. Similarly, research on biocide-based activities have been conducted on the screening and identification of local as well as introduced biocontrol agents (fungal and bacterial) to control crop diseases, insect pests and weeds in Ethiopia although only few of them passed through field trials and none has yet been commercialized. The indigenous microbes, *Beavaria bassiana* and *Metarihizium anisiphole*, were reported to be the most promising biopesticides for the control of locusts, grasshoppers and storage pests[106]. Although a series of local research activities have been conducted in the formulation and development of biofertilizers and biocides, none of these products has been commercialized.

2.3.1.2. Agricultural biotechnology research manpower

A number of scientists educated abroad have studied biotechnology and related subjects and gained laboratory skills in specialized areas such as molecular biology, tissue culture, genetic engineering, bioinformatics and biosafety. Currently, some of these scientists are teaching and conducting research in various HLIs and agricultural research institutes in the country (Fig. 17). In the research institutes, there are more MSc holders compared to the PhD holders that might have an implication on the quality of the research conducted by the institutes. On the other hand, it could also possibly indicate presence of staff turn-over from the regional and national research institutes.

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[103] Kim K, Kwon T, Dessie T, Yoo DA, Mwai OA, Jang J, Sung S, Lee SB, Bashir Salim B, Jung J, Jeong H, Tarekegn GM, Tijjani A, Lim D, Cho S, Oh SJ, Lee HK, Kim J, Jeong C, Kemp S, Hanotte O, Kim H, 2020. The mosaic genome of indigenous African cattle as a unique genetic resource for African pastoralism. Nature Genetics 52: 1099–1110.

[104] Vaccine was developed by Professor Tilahun Yilma, California Davis, USA

[105] Asfaw, H., Angaw, T. (2006). Biological Nitrogen Fixation Research in Food Legumes in Ethiopia., pp. 172 - 176. In: Food and Forage Legumes of Ethiopia: Progress and Prospects. (Ali, Kemal, etc. eds.) Proceedings of the workshop on food and forage legume, 22 -26 Sept. 2003, Addis Ababa, Ethiopia. EIAR and ICARDA, Aleppo, Syria, p. 351.

[106] Kassa A, Stephan D, Vidal S, Zimmermann G (2004) Production and processing of *Metarhizium anisopliae* var. *acridum* submerged conidia for locust and grasshopper control. *Mycology Research* 108: 93-100.

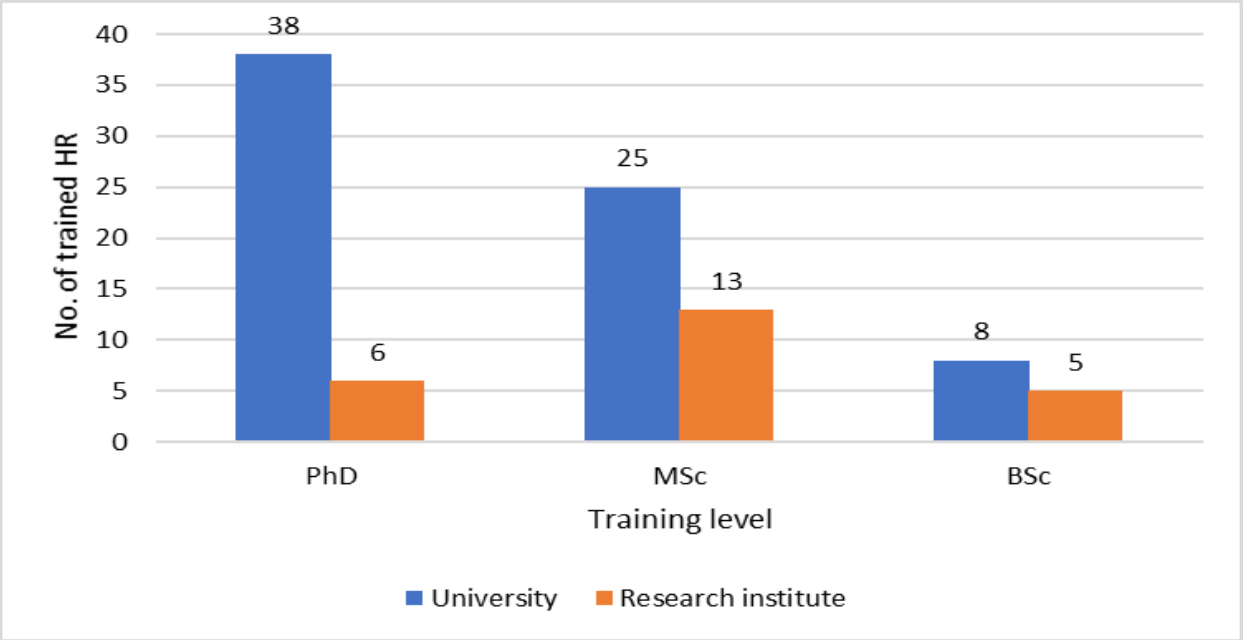


Figure 17. Human resources profile in agricultural biotechnology in the surveyed institutions (Note that the specializations in agricultural biotechnology is not properly filtered out)

Several HLIs including Addis Ababa, Hawassa, Haramaya, Jimma, Wolkite and Addis Ababa Science and Technology Universities are also strengthening their capacity in agricultural biotechnology. Regarding biotechnology education in the country, in most universities where degrees are offered in the area of life sciences, biotechnology courses are also offered. Addis Ababa University (AAU) is the first to open both MSc and PhD degree programs in biotechnology in the country followed by other universities. The biotechnology teaching and research capacity of AAU and other universities are modestly being strengthened through human resource development and acquisition of equipment through project grants. Jimma University offers an MSc degree in plant biotechnology. Currently, more than 13 universities (except AAU) offer degrees in various areas of biotechnology at undergraduate levels.

2.3.1.3. Infrastructure for agricultural biotechnology research

The National Agricultural Biotechnology Center (NABRC) at Holeta has the facilities for DNA sequencing and genotyping, protein analysis, bioinformatics, tissue culture, animal reproductive biotechnology, disease diagnosis and genetic engineering including automated as well as containment greenhouses. It has also developed a set-up and started research on mushrooms. The Center was assigned to serve as one of the nodes for BeCA-ILRI hub and has collaboration and networking with universities and research institutes both locally and internationally. In addition, the EIAR has been building its biotechnology capacity at its

various research centers such as Debre Zeit Agricultural Research Center, Melkassa Agricultural Research Center, Jimma Agricultural Research Center and Ambo Agricultural Research Center (Table 1 and Fig. 18).

Plant tissue culture laboratory facilities are available at regional agricultural research institutes (ARARI, SARI, OARI), accompanied by an automated temperature, light and humidity controlled green houses at Adami Tulu Agricultural Research Center. Figure 19 and Table 2 also provide infrastructure present in the surveyed HLIs.

The current status of availability of wet-lab facilities can be evaluated as modest in Ethiopia. However, those facilities are present at different institutes and some of them are not functional and are outdated. Some of the equipment (e.g. sequencing machine) are heavy/expensive machines, and yet duplicated. Responsive system to acquire the necessary supplies on time and instituting an experienced high level laboratory technologists working on these equipment will help to mitigate such problems.

Table 1. Availability of major equipment and facilities in research centers (shaded cells indicate presence)

Facility	**EPHI**	**BETin**	**MARC**	**STERP**	**NVI**	**SARI**	**Areka AR (Arek research center is unde SARI**	**ATARI**	**ARARI**	**AHRI**	**EIAR**
Biobank						■				■	
Liquid nitrogen plant	■									■	■
Bioinformatics										■	■
Data Management				■	■			■		■	■
Electrophoresis set (vertical/ horizontal)	■	■		■	■	■			■	■	■
Microfuge	■	■		■	■	■			■	■	■
Temp. regulated centrifuge	■		■	■	■	■		■	■	■	■
Ultracentrifuge	■			■	■	■	■	■			
Hood Class I	■	■	■	■	■	■	■		■	■	■
Biosafety hood class II	■	■		■	■	■		■	■	■	■
Fume hood	■	■		■	■	■	■	■	■	■	■
Rotary shaker	■	■		■	■	■		■	■	■	■
Ultrasound homogenizer											
Phase-contrast microscope								■		■	
Microtome and/or Cryotome										■	■
Micropipette (single and multichannel)	■	■	■	■	■	■	■	■	■	■	■
Other Basic facilities	■	■	■	■	■	■	■	■	■	■	■

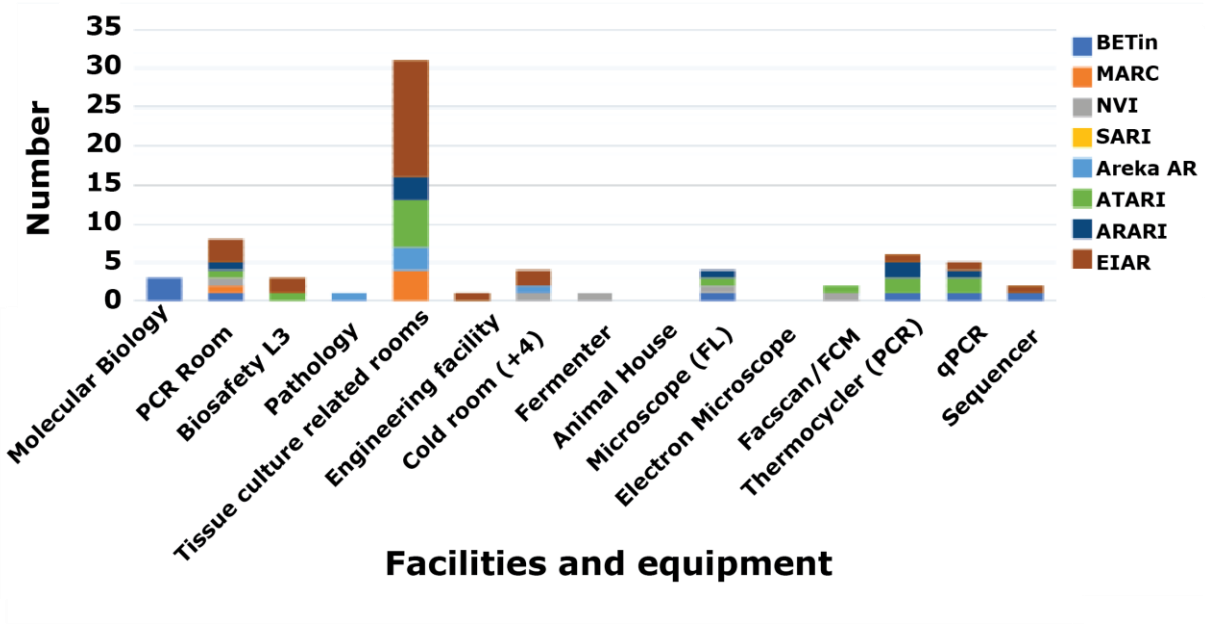


Figure 18. Available facilities (equipment and infrastructure) in research institutions

Table 2. Availability of major equipment and facilities in universities (shaded cells indicate presence)

Facility	AAU	AASTU	HU	AU	DBU	JU	ASTU	BDU
Biobank	■						■	
Liquid nitrogen plant	■						■	
Bioinformatics	■	■			■		■	
Data Management	■						■	
Electrophoresis set (vertical/ horizontal)	■	■	■	■	■	■	■	
Microfuge	■	■	■		■	■	■	■
Temp. regulated centrifuge	■	■		■		■	■	■
Ultracentrifuge	■				■	■	■	■
Hood Class I	■					■	■	
Biosafety hood class II	■		■	■			■	■
Fume hood	■	■	■	■	■	■	■	■
Rotary shaker	■	■		■		■	■	■
Ultrasound homogenizer	■	■			■		■	
Phase-contrast microscope	■	■		■				
Microtome and/or Cryotome	■			■			■	
Micropipette (single and multichannel)	■	■	■	■	■	■	■	■
Other Basic facilities	■	■	■	■	■	■	■	■

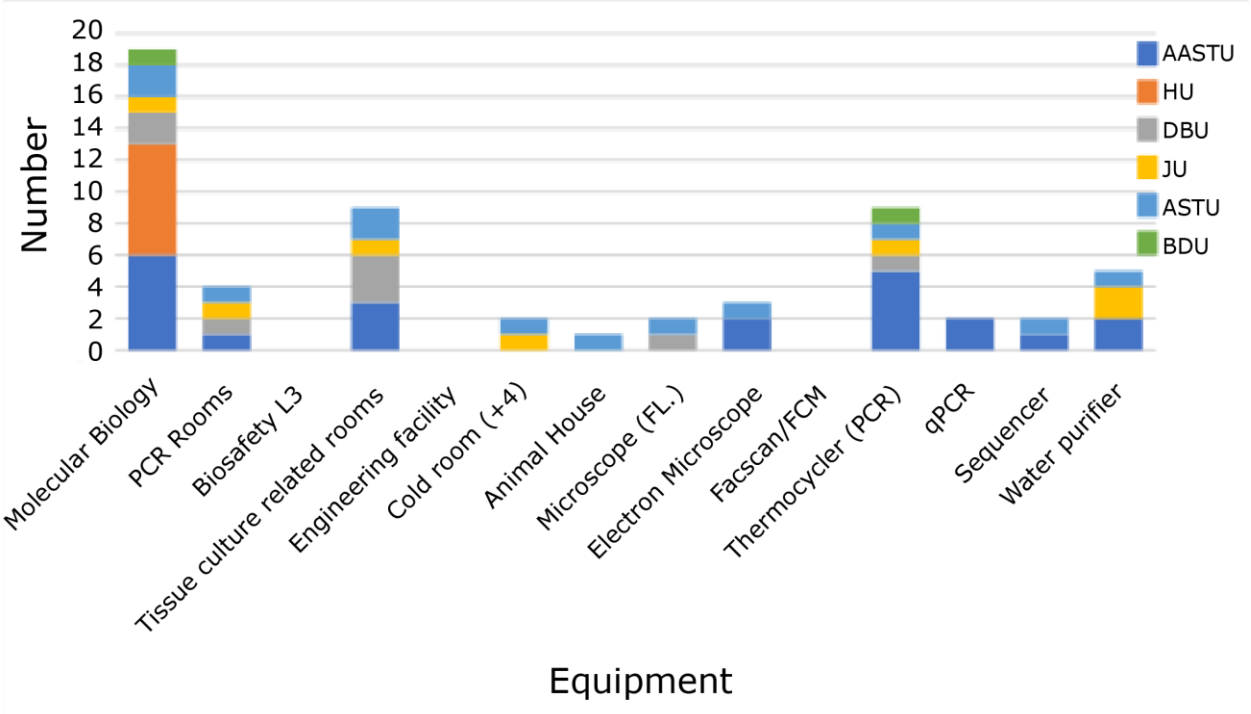


Figure 19. Available facilities (equipment and infrastructure) in higher learning institutions

2.3.1.4. Financial resources for agricultural biotechnology research

The main funding source for the agricultural biotechnology research in higher learning and research institutions is from the government as capital and regular budget. There are also research activities that are supported by donors. In most cases such project activities are collaborative projects with foreign institutions.

2.3.1.5. Institutional synergy and collaboration

The situation analysis showed that there have been encouraging research and innovation activities in agricultural biotechnology in Ethiopia implemented by various national and regional higher learning and research institutions. In spite of the long history of the agriculture research in the country, the overall status of agricultural biotechnology research and innovation activities and their product development could be evaluated as insufficient. In addition, the institutional synergies and collaborations among the various national institutions can be considered as loose. This has its own impact for the little contribution of the agricultural biotechnology to the national agricultural production and productivity.

2.3.2. Health biotechnology

2.3.2.1. Health biotechnology research landscape

Based on data from the surveyed institutes, a relatively higher number of health biosciences-related research activities are present in Ethiopia. Site visits of some of the health research institutions indicated that most of the health research activities were focused on epidemiological studies using conventional and molecular approaches. Research on neglected tropical diseases, malaria, tuberculosis, viral diseases and antimicrobial resistance as well as traditional medicinal plants research are among some of the ongoing research activities at EPHI. The Institute has also a national experience in production of vaccines against rabies virus and cell culture-based safety assessment of vaccine production against Rabies virus. Similarly, research on TB, leprosy, leishmania, cell culture-based antibody development and SARS-CoV2 diagnosis are undertaken at AHRI. Project-based research activities such as traditional medicine (AAU, JU and DBU), zoonotic diseases (ALIPB, College of Veterinary Medicine, AAU and JU), and nanotechnology-based drug delivery (ASTU) are among the activities involving biosciences.

COVID-19 pandemic has opened opportunities for building the capacity of RT-PCR based detection in various laboratories of universities and research institutes under the logistic support by EPHI. This has been instrumental in control and prevention of disease transmission. To develop local capacity, there are research and development projects being carried out at several institutes like BETin, IoB-AAU, AHRI, CDT-Africa-AAU.

2.3.2.2. Health biotechnology research manpower

From the survey made, the number of MSc and PhD trained manpower in universities was higher than research institutes (Fig. 20). Institutions like AHRI, EPHI, BETin and APHI have a modest number of manpower in this sector but very few of the surveyed institutions have staff with postdoctoral research experience. Nevertheless, universities and research institutions have contributed to health biotechnology research outputs which are reflected in the number of publications. In addition, some universities such as AAU has MSc as well as PhD programs in health biotechnology in addition to related biomedical sciences. AAU have played significant roles in training manpower at MSc and PhD levels. Universities and research institutes have contributed to health biotechnology research outputs which is reflected in the number of publications.

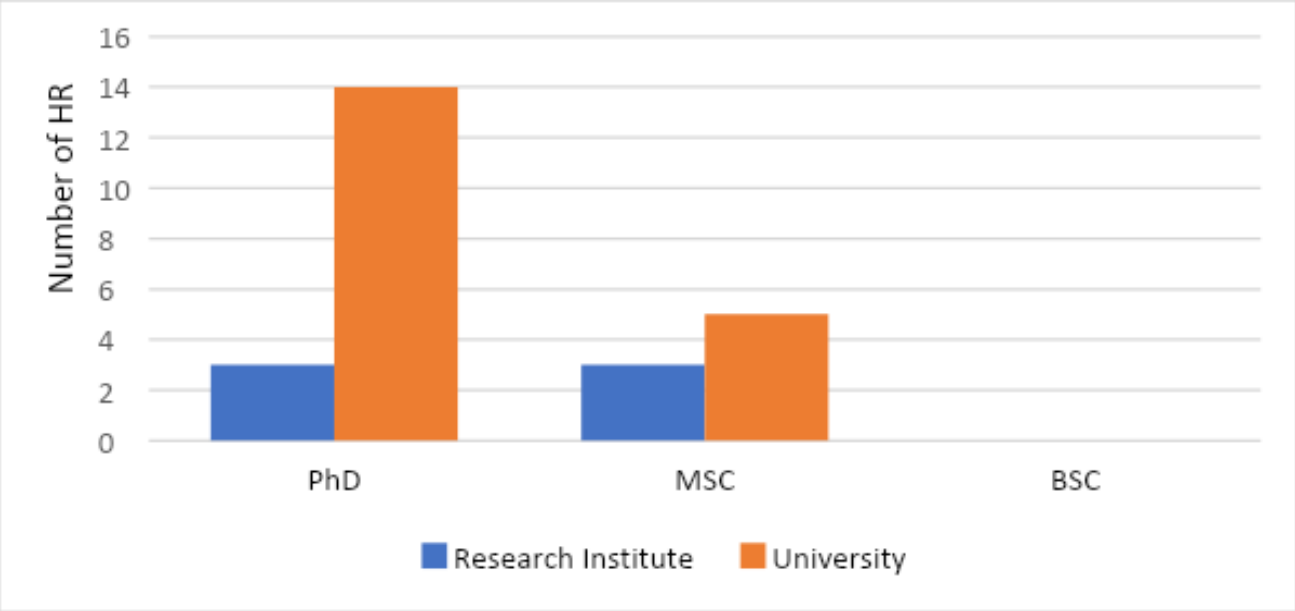


Figure 20. Human resource capacity in the health biotechnology sector

2.3.2.3. Health biotechnology R4D laboratory infrastructure

Based on the survey made, there are only limited facilities in universities and research institutions. This is reflected on the capability to convert outputs to products. On the other hand, some universities and research institutions possess facilities such as sequencers, ultracentrifuge and flow cytometry that can be used by the other institutions on a shared basis. Basic laboratory facilities are modestly distributed across the universities and research institutions (Fig. 21). However, functional major equipment are concentrated in few of them, with less common utilization. It has been noted that laboratory infrastructure built with standard design and safety levels are hardly existent. Such laboratories with standard design are needed in all the sectors of biotechnology in order to comply with international standards.

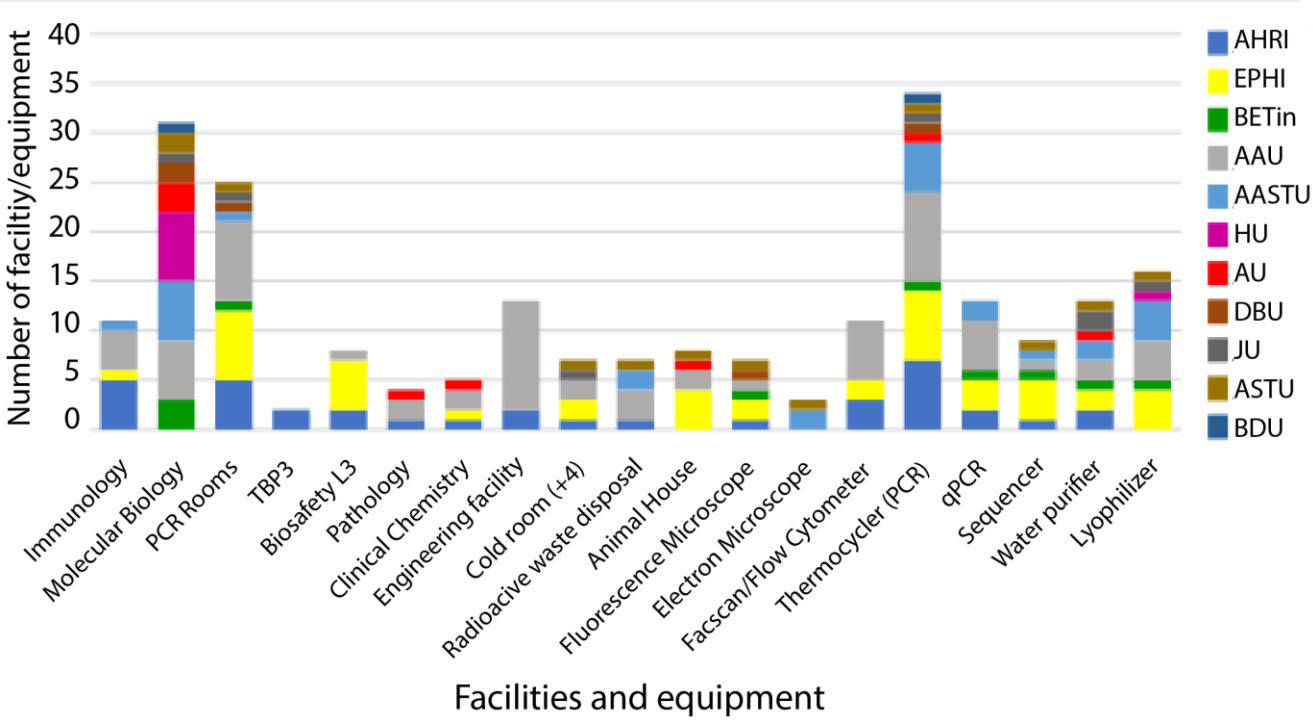


Figure 21. Research infrastructure available in universities and research institutes in 2021

2.3.2.4. Financial Resources for health biotechnology research

Government financial support is the major source of research funds in both the universities and research institutions. However, few universities and research institutions also solicit funding from foreign funders as well (Fig. 22). The funding system is erratic and very low which is one of the major problems for the development of the health biotechnology sector research program. The available limited funds from the government budget is also constrained with the procurement procedures, hence limiting its efficient and timely utilization.

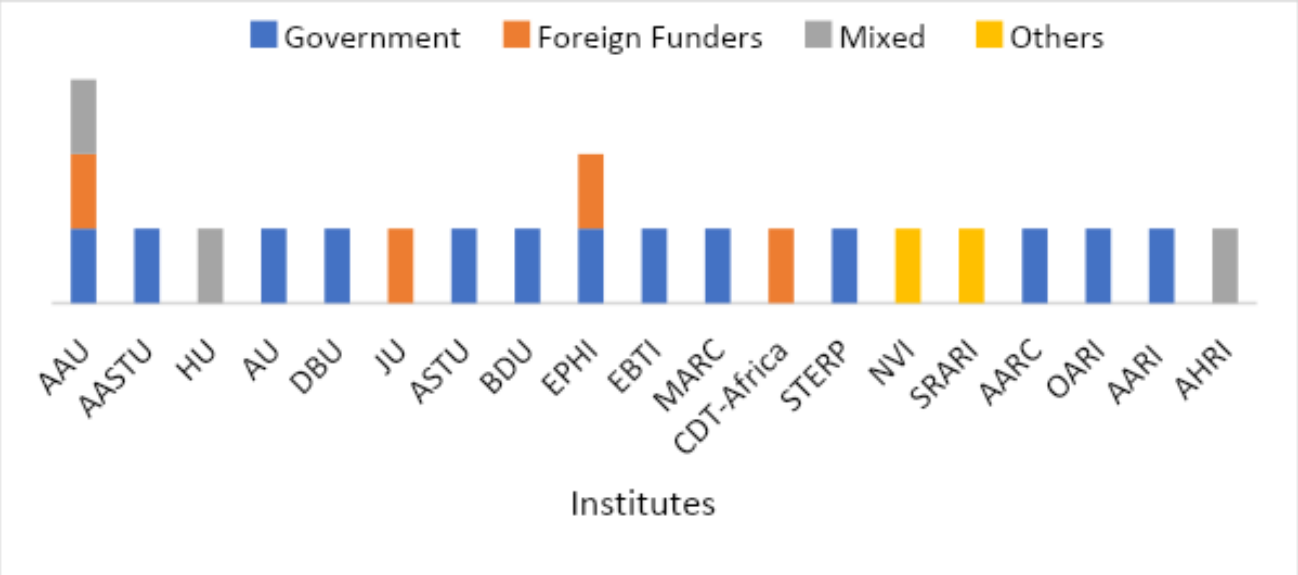


Figure 22. Source of funding in the surveyed universities and research institutes

2.3.2.5. Institutional synergy and collaboration

From the survey and detailed interviews, collaborative action in developing inter-institutional links is loose. Collaboration and co-hosting of research facilities and research grants is missing in most institutions. Co-supervision of graduate students and collaborative research among HLIs and research institutes exist. Entrepreneurship for bio-based pharmaceutical products is not well developed. However, there are a few linkages between higher learning and research institutes in terms of product co-development.

2.3.3. Industrial biotechnology

2.3.3.1. Industrial biotechnology research landscape

The situation analysis has shown that conventional biotechnology research is being conducted using culture-dependent, fermentation-based, biochemical and molecular biology techniques. Limited industrial biotechnology research and innovation activities are conducted in HLIs (AAU, Gondar University, and AASTU), and research institutes (NABRC-Holeta, EBI and EPHI). The majority of the research activities encompass laboratory-based screenings and characterizations of bacterial, yeasts, algal isolates for the production of bio-based products such as bulk enzymes, proteins, biofuels, bioactive compounds, and probiotics. In this regard, a few higher learning and research institutions such as Jimma University, AAU, Gondar, and NABRC are conducting various research activities in bioprocesses to improve the nutritive value of traditional fermented foods and beverages. A few research works have been made by NABRC and other higher learning institutions on identification of starter culture/lactobacillus, yeast/ for improving fermentation of dairy products.

Furthermore, researches have been conducted by AAU and AASTU to identify various microbial enzymes such as protease, amylase, cellulase, pectinase and phytase from extreme environments for use in leather, textile, food/feed, detergent industries, and in construction biomaterials[107]. AAU has formulated a dry form of crude protease enzyme and executed a successful small pilot scale trial for dehairing process in tanneries[108]. Regardless of these research attempts, none of these enzyme candidates have been scaled-up for commercial use in bio-based industries in Ethiopia due to partly the loose linkage between industries, research institutes and universities.

According to the information obtained from the Ethiopian Customs Commission in the current survey, the amount of enzymes imported by the country increases by an average of 25% per year with import cost of 54.521 million ETB per annum (Fig 23). This trend is expected to increase due to the expansion of agro-processing and bio-industries[109].

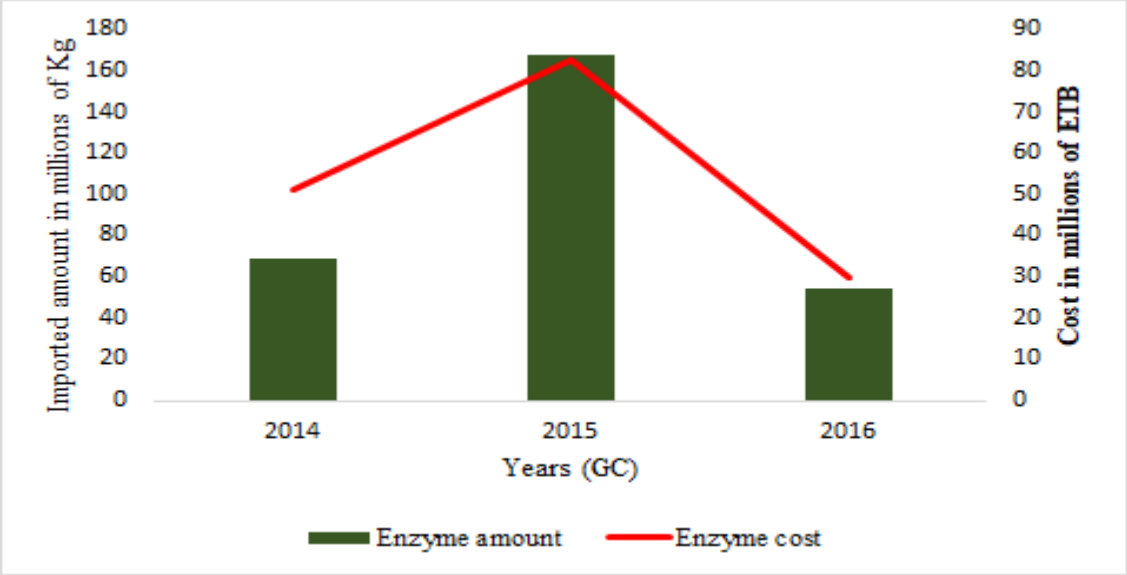


Figure 23. Annual amount and costs of imported enzymes in Million Birr[110]

Research is also underway by AAU and AASTU to improve the fermentation process and the yield of bio-ethanol production through identification of potent yeasts from local environments in collaboration with

[107]Shimelis Admassu, Endashaw Bkelle, Abraham Aseffa, Endale Gebre,Tewdros Bekelle andBelete Geda. (2015). Ethiopian Industrial Biotechnology Research and Development Roadmap. Addis Ababa, Ethiopia, Amharicversion, pp.99.

[108] Berhanu Abebe (2014). Dehairing protease production and evaluation of the efficacy of protease products of relevant downstream processing http://etd.aau.edu.et/handle/123456789/7525

[109]Shimelis Admassu, Endashaw Bekele, Abraham Aseffa, Endale Gebre, Tewdros Bekelle and Belete Geda. (2015). Ethiopian Industrial Biotechnology Research and Development Roadmap. Addis Ababa, Ethiopia, Amharicversion, pp.99.

[110]Shimelis Admassu, MesfinTafesse and Debebe Worku(2021). Industrial Biotechnology Enormous Potential for Growth and Investment in Africa: Bio-based markets, Unpublished data.

Metehara and Fincha sugar factories and National alcohol and liquor factory. Although there are such research activities in yeast production and bioconversion to develop bio-industries in the country, none has been scaled-up for use in commercial production. Thus, the country is currently importing a large amount of yeast. The survey data showed that Ethiopia imported up to 23.82 million kilograms of yeast from 2014 to 2018, with an average of 4.76 million kilograms per year. The total amount of imported yeasts from 2014 to 2018 is estimated to be ETB 16.3 billion with an average of ETB 3.2 billion spent annually on the purchase of the various yeasts (Fig. 24). This trend is expected to increase with the expansion of agro-processing and other bio-based industries.

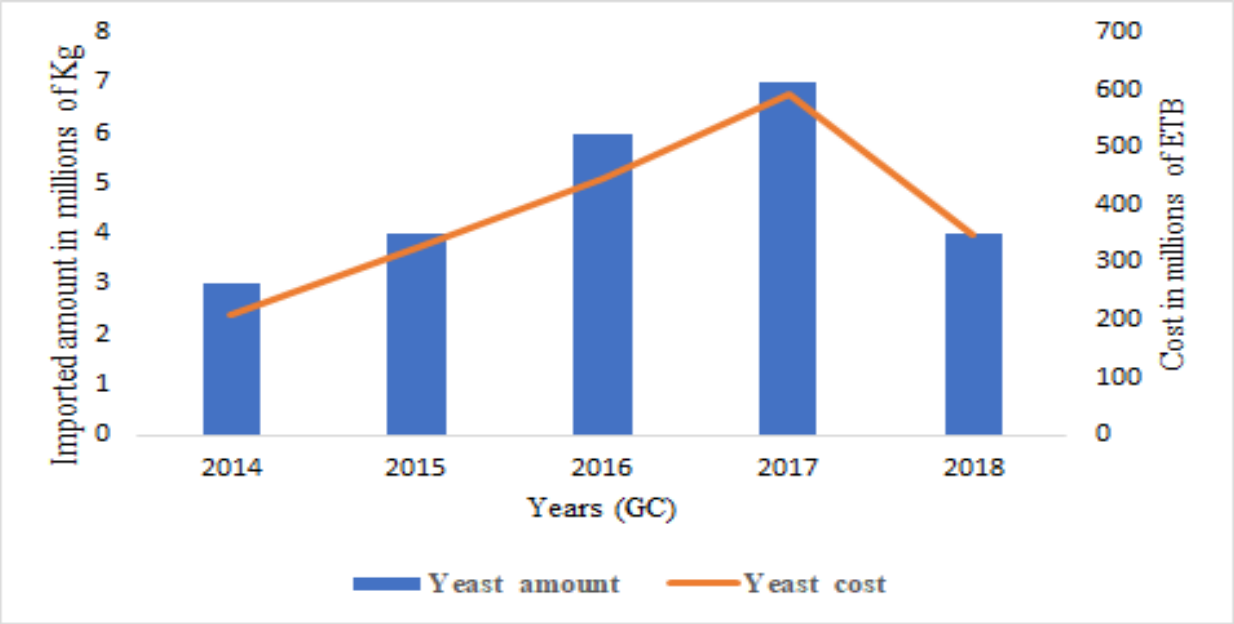


Figure 24. Annual costs of imported yeast between 2014 - 2018

In addition, researches on biomaterials like bio-blocks, bio-plastics, biopolymers (starch, lactic acid and PHA) are being conducted at AAU and AASTU but have not yet reached pilot and large-scale production. In addition, BETin in collaboration with AAU is currently conducting research on microalgae for mass production of protein food supplement (spirulina) for use in nutraceuticals, pharmaceuticals and food.

A few institutions such as AHRI, NARDIC, EPHI, and NVI are conducting research activities on vaccines, drugs and diagnostics. Despite this, most of the vaccines that are being used in our country are imported. According to the Ethiopian Customs Commission[111], the total import of vaccines from 2014 to 2018 was nearly ETB 24 billion for human vaccines and 144 billion for veterinary vaccines. This rate is expected to increase by 30 percent annually.

[111]ECC (2021). Ethiopian Customs Commission (ECC). Customs Management System Ethiopia, Electronic Customs Management System (eCMS) data source. Customs data analysis and dissemination team, strategic plan and project administration directorate, Ethiopian Customs Commission (ECC), Addis Ababa, Ethiopia.

The current survey shows that the number of publications output by professionals from industrial biotechnology related research activities in the last five years are marginal. Nevertheless, advanced biotechnology research that employs modern and emerging biosciences such as gene expression, gene editing, systems and synthetic biology, and nano-biotechnology, bioprocess technologies are very limited.

2.3.3.2. Industrial biotechnology research manpower

The survey showed that there are limited trained professionals in research institutions, universities, and industries in the areas of biotechnology and other related bioscience fields at all levels. Among the 42 institutions surveyed, there are about 110 biotechnology professionals from which professionals' specialization in industrial biotechnology accounted for only less than 8%. This shows the dire need for training programs to develop competent and skilled critical mass in the area of advanced bio-sciences that support bio-industries in the country.

2.3.3.3. Infrastructure for Industrial biotechnology research

The survey conducted in AHRI, AAU, AASTU, ASTU and Gondar University showed that there are few dispersed research facilities for bio-based product development using bioprocess platforms. These include molecular and microbial biotechnology facilities such as PCR, qPCR, culture and shaker incubators, bench-top fermenters, lyophilizers, simple centrifuges and microscopes. A few modern equipment such as electron microscopes at AASTU, sequencers at AHRI, AASTU, EBI, NGS, BETin and NAHDIC, primer synthesizer at AASTU are in place. The level of infrastructure for industrial biotechnology research in various HLIs, research institutes and industries is not exhaustive and not suitably organized to execute collaborative and cutting-age industrial biotechnology research.

2.3.3.4. Financial resources for Industrial biotechnology research

Generally, the funding allocated for industrial biotechnology research activities in HLI and research institutes is inadequate to conduct advanced research and scale-up activities. Most Universities have internal research grant schemes (around ETB 2.5 million per project) to support research activities on a competitive basis. At a national level, the Ministry of Technology and Innovation (MiNT) is currently granting (up to ETB 5 million per project) to support mega research projects that aim at national priority and lead to industrial bio-based product development. A few such national research projects have been and being conducted in few HLI and research institutions such as AASTU and AAU on enzymes and bio-ethanol; Gondar University on yeast fermentation products and biodiesel; NABRC on bacterial starter culture; and AAU- Institute of Technology on baker's yeast and bio-refinery. An average of ETB 15,000 and 50,000 is allocated for MSc and PhD research respectively. Very limited international (including

continental, regional and global) funds go to industrial biotechnology research and innovation at BETin, AAU, AHRI, NABRC, NHADIC and EPHI. From the survey, it was observed that private sector-funded research for bio-industry is limited. The capital budget that goes to the bio-industry's research and innovation should be improved to advance the national bio-based economy. The capital investment to promote pilot and demonstration activities that motivates entrepreneurs and start-ups should be primed.

2.3.3.5. Institutional synergy and collaboration

The survey showed that synergy and collaborations between most of the educational and research institutes and bio-industries are too weak to conduct research and innovation in industrial biotechnology. There are a few collaborative research projects jointly conducted in universities and industries. The current funding initiatives by BETin and MiNT in promoting collaboration with HLIs, research institutes, industries and end-user sectors are encouraging.

2.3.4. Environmental biotechnology

2.3.4.1. Environmental biotechnology research landscape

A survey conducted on the status of environmental biotechnology research landscape in Ethiopia in selected higher learning and research institutions, as well as industries showed that existing environmental biotechnology-related research and innovation activities are very few, accounting for 13% of the biotechnology related activities and are confined to limited universities and research institutes (Fig. 25).

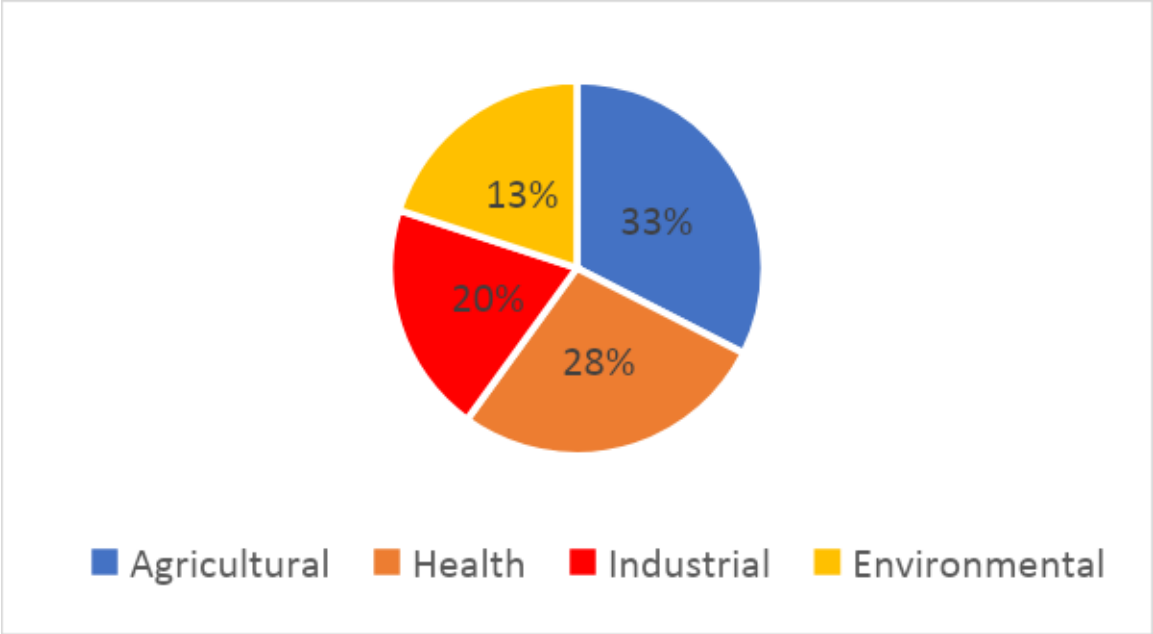


Figure 25. Percentage distribution of environmental biotechnology related research activities in universities, research institutes and industries

The survey clearly showed that environmental biotechnology related research activities in HLIs, research institutes and the industry sector is extremely limited as compared to agricultural, health and industrial biotechnology research activities in the country (Fig. 26).

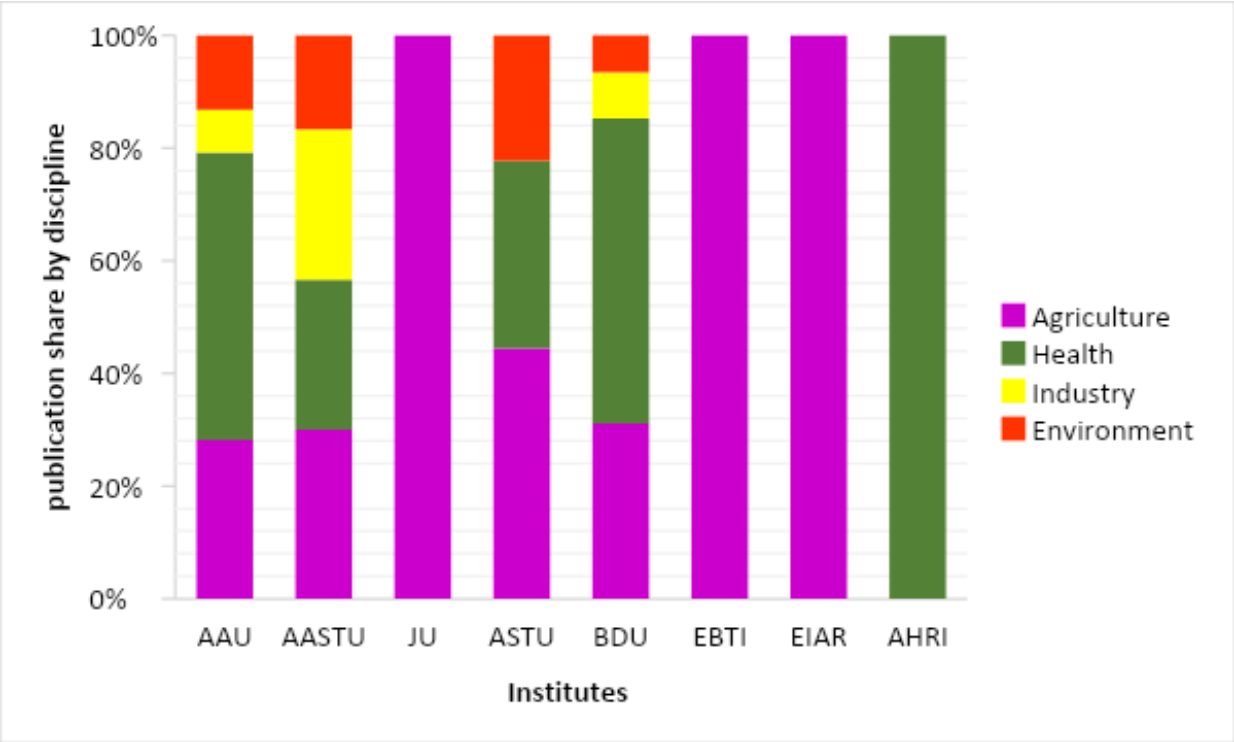


Figure 26. Environmental biotechnology research activities in universities, research institutes and industries

With regard to the existing limited activities, environmental biotechnology research has been initiated at AAU aiming at developing efficient treatment technologies for high-strength industrial wastewaters with the support from the Swedish International Development Agency (Sida) through BIO-EARN followed by pilot testing and demonstration during the Bio-Innovate Program in collaboration with Modjo Tannery. Similarly, pilot- project focusing on nutrient recovery from wastewater with the support of the National Academy of Sciences (NAS) through USAID has been carried out to produce nitrogen and phosphorus in the form of struvite and demonstrate to the relevant stakeholders for technology adoption. A spin-off of the wastewater-derived struvite project has led to urine-derived nitrogen and phosphorus recovery supported through collaborative initiatives as well as national support, with assessment of the public health risk[112]. A good size of research outputs have been generated as described below.

- Biological wastewater treatment using microorganisms and selected plants species,
- Bioaugmentation of bacteria in nitrogen and sulfur removal in sulfide- and chromium-laden tannery wastewater,
- Efficient and tolerant native plant (*Phragmites karka*) to remove pollutant residues from tannery wastewaters,
- Pilot-scale biological integrated wastewater treatment and biogas production using an up-flow anaerobic sludge blanket technology,
- Biodegradation using microorganisms to degrade toxic compounds such as dyes from the textile industry,
- Molecular tracking of pathogens in biological wastewater treatment systems,
- Novel fluidized bed bioreactor technology for the production of struvite from domestic wastewater and human urine,
- Microbial fuel cell production, and
- Molecular survey of drinking water distribution systems and improved water sources in urban centers.

Moreover, some of the preliminary environmental biotechnology research related initiatives also include screening of wetland plants for phytoremediation potential (AASTU); organic fertilizer (compost/ vermicomposting) (AAU, HU, DBU, BETin and NBRC-Holeta); biofuel (biogas and bio-biased products from biowaste/agricultural biomass (AAU, HU, EEFRI and BETin), microbial and micro-algae-based remediation of industrial wastes, wetland plants for watershed management and bamboo tissue culture for re-afforestation of lowland degraded areas (EEFRI and EIAR).

[112] Stephen Nayfach, Simon Roux, Rekha Seshadri et al., (2020). A genomic catalog of Earth's microbiomes. Nature Biotechnology, DOI: 10.25982/53247.64/1670777

With reference to the limited number of institutions working on environmental biotechnology research, the technologies generated seem encouraging and a lot can be generated if appropriate support is provided. Even though environmental biotechnology research and product development is non-existent in industries except some research partnerships with universities, assessment of some agro-process industries[113] showed that they all have keen interest in the applications of environmental biotechnology for use in cleaner processes as well as for waste management and environmentally friendly industrial development in Ethiopia. Very few of them with installed biological wastewater treatment systems are observed to have low removal efficiency mainly due to shortage of trained manpower to operate the systems. Some key products/technologies emphasized by almost all the industries are enzyme technologies, waste management technologies and production and use of biodegradable packaging materials. Even though Bio-based technologies have competitive advantages for effective management of wastes and increasing the efficiency of agro-process industries including the municipalities, only very limited waste management technologies are being applied in the country.

In terms of research publications, the number of publications emanating from environmental biotechnology-related research has been very limited compared to agricultural and health biotechnology for the last five years (Fig. 27).

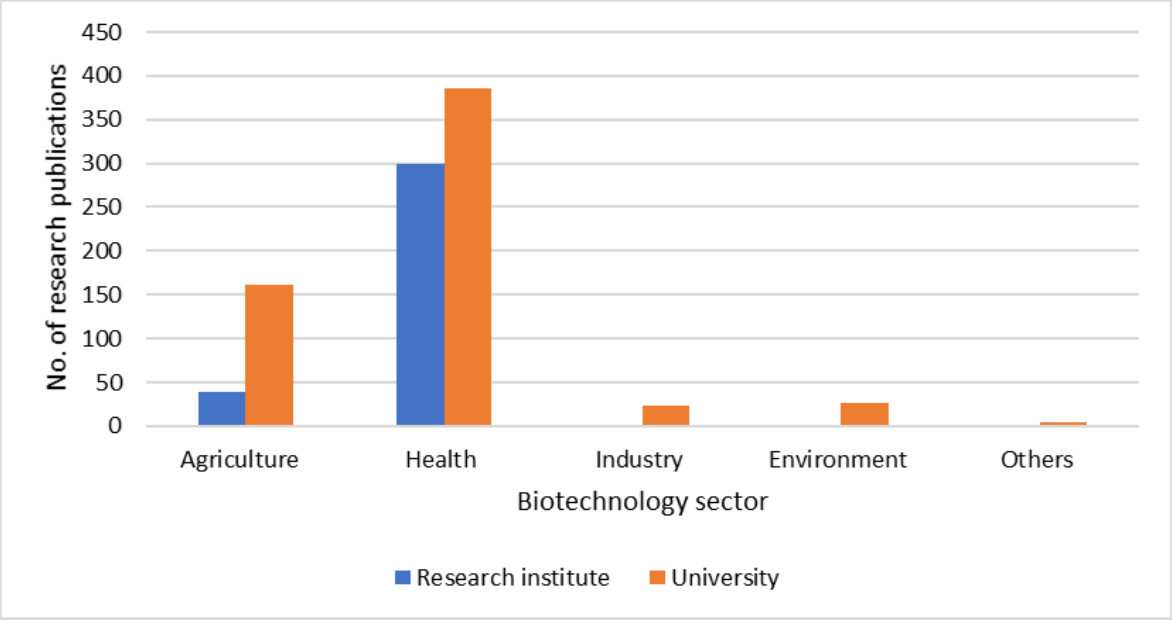


Figure 27. Publications from biotechnology related research activities in the last five years (Note that publications were based on broader biosciences)

[113] Such as leather, textiles, dairy, brewery, food processing, sugar enterprises, pulp and paper, integrated agro-industrial parks

2.3.4.2. Environmental biotechnology research manpower

The survey showed that the manpower with requisite skills and level of training is very limited. While the status of skilled manpower in agricultural and health biotechnology research is relatively better, the situation in industrial and environmental biotechnology is alarming. Out of the 114 professionals engaged in biotechnology research, 20 are trained in different areas of environmental biotechnology. With respect to level of education and specialization, PhD holders are only 17% of the total out of which 55%, 14% and 14% are in agriculture, health and industry, respectively. Environmental biotechnology research personnel are extremely limited to higher learning institutions indicating that much needs to be done in training of environmental biotechnology professionals at various levels (Fig. 28).

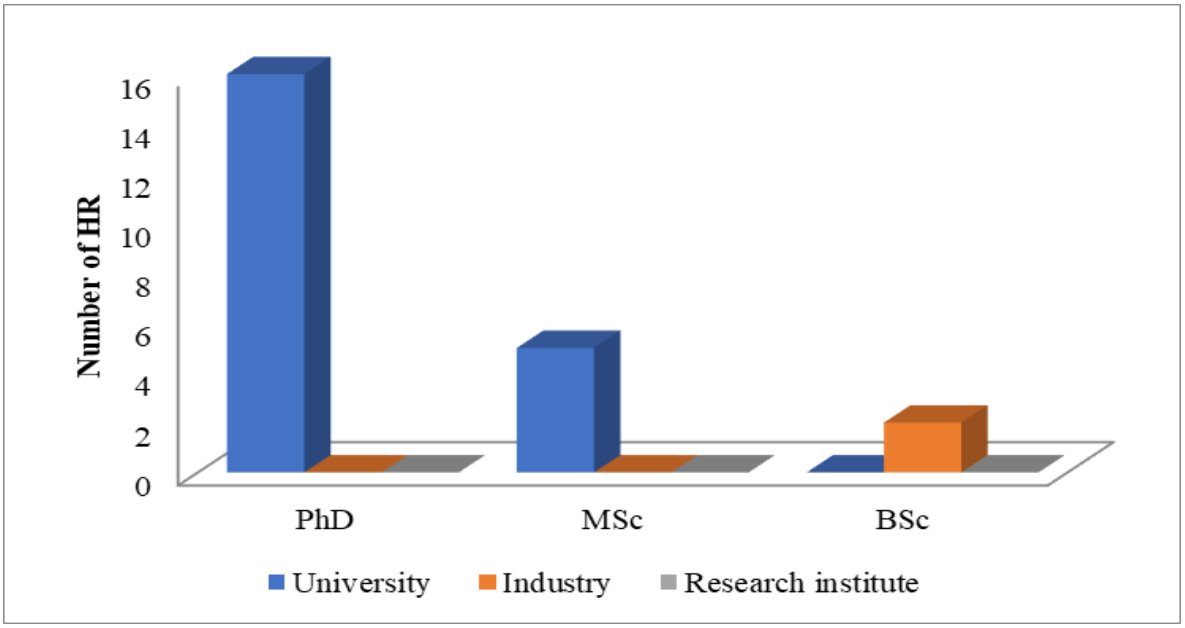


Figure 28. Trained manpower in biotechnology based on the collected data in the institutions and industries

2.3.4.3. Infrastructure for environmental biotechnology research and innovation

Currently, the infrastructure for environmental biotechnology research is on a shared basis, either with industrial biotechnology or with the other biotechnology research wings. It was shown that the level of existing facilities is not complete enough for carrying impactful environmental biotechnology research activities. Moreover, they are scattered and in most cases duplication of expensive equipment (PCR, sequencing, electron microscopes) is observed. Establishment of a shared platform for the wise use of the expensive facilities is not practiced at all and there is a dire need to acquire more equipment without taking the problem of duplication of resources into consideration.

2.3.4.4. Financial resources for environmental biotechnology research

The survey showed that the current research funding for higher learning and research institutions are mainly from the Government in the form of capital and regular budget on an annual basis where catering for research activities is also included in the capital budget. In addition to government funding, sources from donor partners and collaborative research with international organizations were also available as demand-driven projects. Statistical information on the financial allocation for research in general and biotechnology in particular hardly exists in the country. Moreover, private sector-based funding for environmental research and innovation activities in the country is not practiced at all.

2.3.4.5. Institutional synergy and collaboration

The situation analysis on the status of environmental biotechnology research for development in Ethiopia indicated that the existing environmental biotechnology related research and innovation activities are limited both in number and in scope, with scattered efforts of project-based activities in HLIs, and development organizations. There is loose synergy and coordination among the various actors. The public-private partnership (university and research institutes linkages with industries) is weak, thus hampering product development, scaling and wider application of environmental technologies in the country. On the other hand, with the rapid development of industrial, agricultural, commercial and service sectors, coupled with growth of population and urbanization in Ethiopia, the country is facing tremendous challenges of resource depletion/environmental degradation and pollution. At present the scientific and technical capacity in the field of environmental biotechnology dealing with the changing environmental issues is low and or non-existent in Ethiopia.

2.3.5. Status of biosafety and IP regulation in Ethiopia

2.3.5.1. Biosafety systems in Ethiopia

Ethiopia is party to the United Nations Convention on Biodiversity (CBD) and the Cartagena Protocol on Biosafety (CPB), all of which are the integral part of the law of the land, according to the Ethiopian constitution. Ethiopia ratified the Cartagena Protocol on Biosafety in 2003 as Proclamation No. 362/2003. The Protocol provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to the rapidly growing global biotechnology industry. Accordingly, the Ethiopian Parliament enacted the Biosafety Law in 2009 (Biosafety Proclamation No. 655/2009)[114]. The

[114] Federal Negarit Gazette of the Federal Democratic Republic of Ethiopia, Biosafety Proclamation No. 655/2009, 9th Sept, 2009, Addis Ababa.

proclamation was amended in 2015 as and Biosafety (Amendment) Proclamation No. 896/2015[115]. The amendment was necessitated because of the precautionary and non-functional nature of the preceding law.

The Environment Forest and Climate Change Commission (EFCCC), now EPA, is designated as the competent authority. EPA closely works with other regulators such as EBI, FDA, and Ministry of Agriculture. In making regulatory decisions, the Authority is supported by the National Biosafety Advisory Committee (NBAC) which was established by Minister of Council Regulation No. 411/2017.

The fundamental provisions of the Ethiopian Biosafety Law are:

- No person may engage in any transaction destined for release of modified organism to the environment without obtaining an advance informed agreement (AIA) from the EPA[116],
- Any person who intends to engage in any transaction destined for release of modified organisms to the environment shall submit to the Commission an application prepared in accordance with this Proclamation and directives issued by EPA.
- Any applicant intending to obtain an AIA shall comply with requirements set in the regulations and directives issued by EPA.

The Biosafety (Amendment) Proclamation No. 896/2015 includes a new Article 6(4) "Special Permit", to support research and teaching under contained use. According to the article, "Any person who is conducting research in a contained use shall take all necessary measures to completely avoid the risks that may arise from the transaction". In addition, no person may establish a confined field trial of any GM plant in this country without obtaining a special permit from the Regulator based on proclamations and applicable directives. Contained use is governed by Directive No. 05/ 2016 issued to determine a special permit for the contained use of modified organisms in research and/or teaching with the view to effectively preventing their contact with, and their unintended impacts on human, animal and the external environment.

2.3.5.2. Intellectual Property Rights (IPRs)

Ethiopia is not a party to WTO and UPOV, to strictly adhere to international agreements. However, there are several IPR regimes that are in conformity with TRIPS agreement. The laws and regulations that are currently under operation and related to biotechnology developments include:

- Trademark registration and protection proclamation No. 501/2006

[115] Federal Negarit Gazette of the Federal Democratic Republic of Ethiopia, Biosafety (Amendment) Proclamation No. 896/2015, 14th August, 2015, Addis Ababa.
[116] According to the restructuring in October 2021, the EPA is the competent authority for biosafety issues

- Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006.
- Plant Breeders' Right Proclamation No. 481/2006
- Copyright and neighboring rights protection proclamation No. 410/2004.
- Research and conservation of cultural heritage proclamation No. 209/2000; and
- Council of Ministers regulations no. 273/2012 on trademark registration and protection;
- Inventions, minor inventions and industrial designs council of Ministers regulations No. 12/1997.

In Ethiopia, while patent applications are handled by the Intellectual Property Office (EIPO), implementation of the Plant Breeder's right is under the jurisdiction of the Ministry of Agriculture. According to the EIPO, there has been no filing of a single patent application remotely connected to biotechnology products. Further, there will be no provision that hinders biotechnology development as EIPO is considering the patentability of microorganisms in its law which is under revision in preparation to ratifying the Budapest Treaty. Therefore, the impact of the existing IPR regulation on biotechnology development in Ethiopia may not have been tested but it is not as negative as it was conventionally perceived by researchers and product developers.

The Plant Breeders' Right (PBR) law and the derived regulations equally apply to varieties developed through both conventional breeding and genetic engineering methods. In practice, however, implementation of PBR in Ethiopia is operational only for hybrid varieties. However, the implementation on varieties of self-pollinated crops is extremely difficult as farmers can use own-saved seeds, which is a disincentive for the private companies. Therefore, GM-crop varieties do not pose unique challenges different from conventional varieties of self-pollinated crops.

2.3.6. Existing gaps in biotechnology research in Ethiopia

While the world reaps the benefits of biotechnology, in Ethiopia critical gaps exist in actualizing bioscience innovations that resulted in a low capacity to invest in biotechnology. Based on the current survey, the following gaps were identified in the four biotechnology sectors including biosafety and IPR.

- Insufficient resources in the different areas of biotechnology reflected in manpower, infrastructure and finances,
- Limited government investment in leveraging biotechnology in all the sectors. Consequently, funding has become a big impediment to a successful biotechnology R4D in Ethiopia,
- Minimal awareness and interest to invest in biotechnology by the private sector. This has led to loss of opportunities in job creation and economic growth,

- Limited attention given to biosciences in general and biotechnology in particular as a sector that can hugely contribute for sustainable development,
- Limited number of innovation centers that are required to promote not only innovations but also entrepreneurship in biotechnology,
- Challenges in revamping of infrastructures for cattle multiplication centers, establishment of facilities for laboratory animals, clinical trials, field stations to leverage biotechnology-based interventions in the respective biotechnology fields of animal biotechnology, health biotechnology and plant biotechnology,
- Weak institutional linkage, and the prevailing tendency of the existing institutes to work in isolation,
- Limited implementation capacity for the existing enabling policies that render biotech development from taking off.
- Presence of limited bio-entrepreneurial skills and knowledge in Intellectual Property (IP) management issues,
- The curriculum in many of our institutions does not effectively prepare and deliver the skills needed for students to turn research findings into marketable products,
- Limited incentivizing mechanisms to researchers and academicians.

2.4. SWOT analysis for the development of biotechnology R4D in Ethiopia

This section highlights some of the Strengths, Weaknesses, Opportunities and Threats in biotechnology for development in Ethiopia as summarized in Table 3 below:

Table 3. SWOT analysis for biotechnology research for development in Ethiopia

Strengths	Weaknesses	Opportunities	Threats
● Presence of a considerable number of universities and research institutions ● Existence of several ongoing innovative research and development programmes ● Availability of valuable indigenous knowledge ● Expansion of postgraduate programs for supply of qualified and skilled researchers ● Presence of different national policies and roadmaps as benchmark to support the biotechnology R4D ● Government commitments and initiatives that supports biotechnology R4D in Ethiopia such as; ➔ Home-grown economic reform ➔ Establishment of industrial parks ➔ Green legacy initiatives ➔ Irrigation expansions and **የ በ ታ የ ጣ ኮ ኖ ስ ን ዴ** ➔ Urban agriculture **'የ ሌ ሙ ት ሩ ፋ ት'** ➔ **ገ በ ታ ለ ሃ ገ ር**	● Poor implementation of policies promoting R4D, innovations and incubation ● Existence of complicated procurement system ● Absence of incentivizing policies for private industries engaged in knowledge-based economy, R4D and innovation ● Inadequate infrastructure, logistics and market linkage ● Challenges in sustainable raw material supply and production ● Underutilization of genetic resources ● Low attention for commercialization of research outputs ● Limited engagement of private sector in bioeconomy ● Limited standards and regulatory frameworks for biobased products ● Limited availability of the state-of-the-art laboratories in the area of biotechnology ● Limited number of highly skilled manpower in the area of biotechnology ● Limited capacity for lab equipment maintenance and repair ● Existence of fragmented activities and weak integration among organizations ● Limited capacity to transfer, adapt and utilize advanced technologies ● Insufficient budget, incentives and fund for R4D, innovation, incubation, & commercialization ● Limited societal awareness and acceptance of biotechnology ● Dependency on international donations ● Failure to meet stringent international quality standards	● Presence of abundant and diverse biological resources ● Growing industrial sector with high demand ● Expansion of agro-industrial parks ● Recognition of biotechnology as the engine of economic growth. ● High market demands for value-added export products ● Commitment of the government to foster biotech R4D ● Existence of local and international collaborators for biotechnology R4D; ● Ethiopia's being a diplomatic hub fosters international cooperation ● Geographical location advantage for international market ● Presence of a large number of trainable youths' population ● Completion of the Great Ethiopian Renascence Dam (GERD) ● Presence of new international economic cooperations like BRICS; African continental free trade area (AfCFTA)	● Conflicts (national and international) ● Increasing inflation rate ● Shortage of foreign exchange ● Climate change ● Environmental degradation ● Emerging and re-emerging diseases like COVID -19

PART III. NATIONAL BIOTECHNOLOGY R4D PROGRAM (2024-2034)

3.1. Program overview

The Biotechnology R4D Program is a national initiative by the Ethiopian Bio- and Emerging Technology Institute, Ministry of Innovation and Technology aiming at promoting biotechnology research and innovation. The Program addresses the technological and societal challenges in building the bio-economy of the country in the next ten years taking into account longer-term time horizons, with increased emphasis on the sustainable use of natural resources, competitiveness, socioeconomic and environmental issues. It considers and aligns with the national priorities in science, technology and innovation, Vision 2030, Ten Year Perspective Development Plan, the Biotechnology Roadmap and sectoral plans, Homegrown Economic Reform Agenda, and AU Agenda 2063. The Program envisions a country with a system that supports biotechnology research and innovation as a driver for sustainable bioeconomy development. .

The National Biotechnology R4D Program is designed and organized with due considerations of strategic programmatic areas that are both critical to economic and social development and national security and in dire need of biotechnology research and innovation support. The strategic programmatic areas are designed within the premises of:

- areas desirable for breaking up bottlenecks and for enhancing the sustainability of national economic growth,
- areas that are desirable for securing enabling technologies and for improving core agricultural, health, industrial and environmental competitiveness,
- areas that are enviable for addressing major public good R4D issues and boosting the potential in providing public services, and
- areas that are required for the development of technologies designed to enhance the capability in ensuring national security.

In order to unlock the innovation potential of biotechnology while minimizing adverse socioeconomic and environmental impacts, the Program is designed to respond to transforming Ethiopia into a knowledge-based and innovation-led bioeconomy with the guiding principles as described below.

3.2. Guiding principles for the formulation of National Biotechnology R4D Program

The National Biotechnology R4D Program will be guided by the following principles in the design and implementation processes:

- Alignment of the biotechnology R4D Programs with STI policy, the National Ten-Year Development Plan and imperatives, including job creation, rural transformation; agro-processing sector development, human resource development, ultimately leading to knowledge and innovation-led bioeconomy of the country,
- Demonstrating transparency, accountability and inclusiveness through creating a favorable research environment and multidisciplinary team approach,
- Enhance competitiveness of biotechnology research and innovation through exchange of up-to-date scientific information,
- Increase our understanding on climate change and adaptation measures for increasing productivity and environmental sustainability,
- Use latecomer advantage in transfer and adoption of knowhow and technologies from countries with rich experiences,
- Forge partnerships and networking with national, regional and international organizations to foster biotechnology research and innovation in the country,
- Establish a viable public-private partnership in biotechnology research and innovation to deliver scalable technologies,
- Focus on those areas where there is (or is likely to be) a comparative advantage in biotechnology research and innovation,
- Build new programs that will harness existing national scientific and technological competencies,
- Review the Programs constantly in light of national priorities and international trends in biotechnology development, and
- Import substitution and export promotion of biotechnology products and foster expansion of bio-based commercial products and market potentials.

3.3. Goal and objectives

Goal: Harnessing biotechnology innovations in agriculture, health, industry and environment for knowledge- and innovation-driven bio-economy

3.3.1. Objectives

General objective

The general objective of the Program is to promote research and innovation activities at national and regional levels towards building an effective biotechnology R4D base in the country.

Specific objectives

The National Biotechnology R4D Program aims to achieve the following specific objectives:

1. Strengthen technical competencies and institutional capacity for biotechnology research and innovation in agriculture, health, industry and environmental sectors
2. Enhance effectiveness of biotechnology research and innovation in addressing priority areas of the biotechnology sectors for bioeconomy development of the country
3. Promote competitiveness through fostering innovation, value addition, industrial development and entrepreneurship in synergy with research, academia and industrial actors
4. Establish and enhance national, regional and international collaboration and partnerships in biotechnology research and innovation

3.3.2. Program outputs

1. Institutional capacity strengthened and supported for biotechnology research and innovation in the biotechnology R4D sectors
2. Biotechnology research and innovation base strengthened for improved agricultural production and ensuring food and nutrition security
3. Biotechnology research and innovation base strengthened for the production of biopharmaceuticals, therapeutics and diagnostic tools for improved health care systems in the country
4. Improved production efficiency and competitiveness of industries for the manufacturing of bio-based commercial products
5. Enhanced bioprocesses for waste management, resource recovery, bioremediation, monitoring environmental pollution as well as biodiversity and bioprospecting
6. Biosafety and IPR systems in place to enable the development of biotechnology research and innovation in the country
7. Biotechnology research and innovation platform in place involving academia, research institutes ,industries and the private sector
8. Viable collaboration and partnership in biotechnology research and innovation established and enhanced at national, regional, continental and international levels

3.3.3. Program outcomes

1. Increased visibility of biotechnology research and innovation
2. Improved food and nutrition security, employment and livelihood
3. Improved health care and human wellbeing, and quality of life

4. Enhanced green environment, eco-friendly industrial development and environmental sustainability
5. Improved and increased competitiveness of bio-based industries for product quality, safety, employment generation and wealth creation
6. Flourished biotech spin-offs and start-ups in agriculture, health care, industry and environment

Theory of change for National Biotechnology R4D Program (intervention logic) showing outputs-outcomes with Program goals and the vision of the country's development plan is summarized in Figure 29.

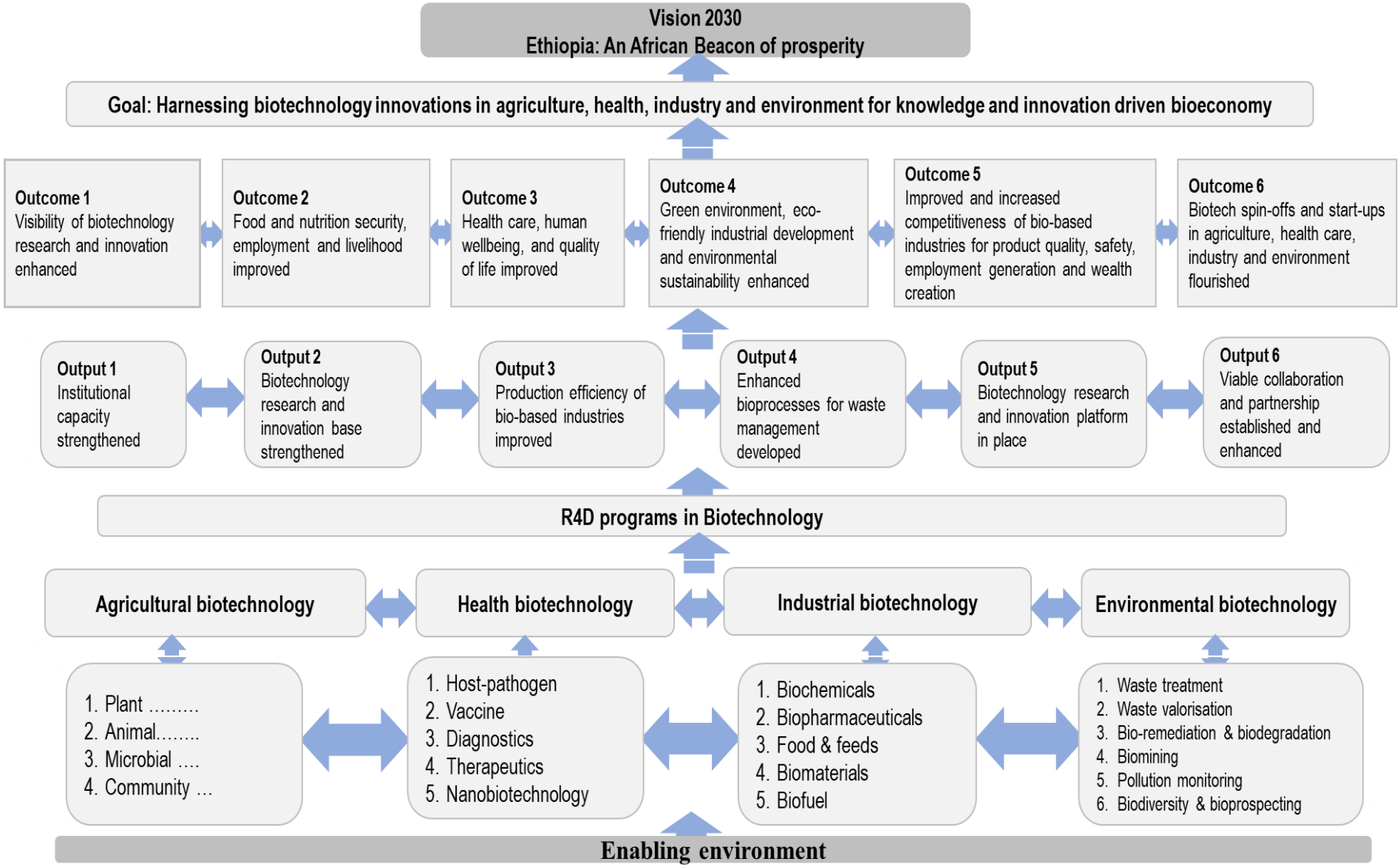


Figure 29. Biotechnology R4D Program intervention framework

3.4. Biotechnology R4D Program

R4D programmatic areas for addressing agricultural, health, industrial and environmental problems of the country with the support of new discoveries and technological advancement in biotechnology are described below.

3.4.1. Agricultural biotechnology

The production and productivity constraints on crop, animal and microbial products for food and nutrition security and sovereignty as well as for the inputs in agro-industry, export commodities and products will be considered as priority agricultural biotechnology R4D Program focus areas. Product oriented research activities are also considered as target research activity within the identified Program focus areas. The R4D Program focus areas for agricultural biotechnology are described below.

3.4.1.1. Plant biotechnology R4D Program

Three plant biotechnology R4D programmatic areas are identified for the implementation period as described below:

Programmatic R4D focus area 1: Plant molecular genetics and biotic and abiotic stress resistance/tolerance

Programmatic R4D for characterization of food and nutrition security, high market-value, forest trees and other indigenous crops using molecular tools for identification and selection of parental breeding materials as well as for designing and management of conservation strategies of these crops shall be considered. The construction of high-density genetic maps for identification of markers linked to specific traits to be used in Marker Assisted Selection (MAS) and Marker Assisted Breeding (MAB), and development of diagnostic tools for different pathogens of crops shall be given due research attention. The host-pathogen interaction studies at molecular level will also be given due consideration. These technologies will be used in combination with modern technologies such as -omics and digital image management.

Programmatic R4D focus area activities:

- Molecular characterization of genetic diversity of food security crops such as maize, barley, wheat, sorghum, rice, teff, banana, potato, root and tuber crops. In addition, other important

indigenous genetic resources like coffee, enset, pulses, oil crops and spices for yield and quality improvement

- Enhancing variety improvement through developing molecular marker for various traits such as disease and pest resistance, drought tolerance, and other stress or quality traits of the above crops
- Molecular characterization and identification of forest tree genotypes
- Molecular based monitoring of host-pathogen interaction dynamics for effective disease and pest control
- Development of molecular diagnostic techniques for important pathogens of crops, medicinal and agro-forestry plant species

Programmatic R4D focus area 2: Plant cell and tissue culture

This programmatic R4D focus area for accelerating breeding of crops through production of homozygous plants within a short period of time using anther and microspore culture, and production of fertile hybrid plants from wide crosses through embryo rescue shall be applied. Development and optimization of micropropagation protocol for high market value and industrial crops for mass production of disease-free planting materials and forest tree species for mass production of superior genotypes shall be considered. In addition, development of different crop varieties through *in vitro* screening will be given research attention.

Programmatic R4D focus area activities:

- Haploid and double haploid lines development for shortening the time for pure lines preparation for breeding in important crops including food security crops, oil crops, industrial and export crops
- Improvement of seed quality through disease cleaning, indexing, mass propagation of registered and promising varieties, and propagation of high market value crops such as citrus, apple, date palm and spices, raw materials for agro-industries or industrial crops exemplified by sugarcane and pineapple as well as conservation for wider use of endangered indigenous species
- Development of *in vitro* propagation protocols for high quality and disease-free planting materials in clonally propagated and difficult species to propagate high market value and industrial crops as well as medicinal and aromatic plants
- Mass propagation of superior forest tree genotypes for commercial farming and industrial raw materials

Programmatic R4D focus area 3: Genetic engineering and genome editing

Programmatic R4D that significantly improves the desired traits of important crops through genetic engineering to produce novel crops needs special attention. The introduction and adoption of GM crops shall be considered as the short-term research activities following the biosafety protocols whereas local development of the technologies shall be considered in the long-term. Moreover, the fast-growing genome editing research that requires the same infrastructure as that of genetic engineering shall be given special attention.

Programmatic R4D focus area activities:

- Introduction and adaptation of proven genetic engineering and genome editing technologies for biotic and abiotic factors such as disease and pest resistance, drought or heat resistance for the improvement of feed, food and industrial consumption as well as export crops
- Development of genetic engineering and genome editing technologies and adoption of new techniques such as cisgenesis to improve different qualities such as increasing biomass in sugarcane, cotton and bamboo and improving oil content in Ethiopian mustard, noug, sesame and other oil plants
- Genetic engineering and genome editing technologies of selected forest tree genotypes for improvement of different traits including pulp, timber and fiber quality

3.4.1.2. Animal Biotechnology R4D program

Successful animal production and productivity improvement program is achieved by designing well-framed national policy directives that could facilitate the effective implementation of animal feeds and nutrition, animal health, and genetics and breeding R4D programs. In this section, six animal biotechnology R4D programmatic areas are identified for the ten-year implementation period.

Programmatic R4D focus area 1: Animal genetics, genomics and breeding

Animal genetics and breeding programs require functional farming and breeding facilities that help to pool out the required phenomic and genomic information of individual animals including the pedigree. The quantitative data that will be generated using the facilities will help to provide evidence about the animals in the farming sites (farms, multiplication centers, ranches and at on-farm) that will later be used for objective evaluation of the animals for informed decision making. The genomic-based breeding value of animals for relevant traits will be evaluated; potential candidate genomic regions, genes, and QTLs, for

various production and fitness traits will be identified, and thus genomic selection and prediction and marker-assisted selection will be implemented in the breeding programs. The following research areas have been identified in this programmatic R4D focus area.

Programmatic R4D focus area activities:

- Establishing/strengthening genetics and genomics platforms/hub
- Establishing data center for poultry and ruminant livestock species
- Exploring genomic potential and employing genomic and marker-assisted selection in cattle, sheep, goats and poultry
- Genome editing in small ruminant and poultry
- Development of molecular markers for tracing animals and animal products
- Molecular characterization of camel and equine genetic resourcess

Programmatic R4D focus area 2: Reproductive biotechnology

Reproductive biotechnology plays a significant role in the livestock sub-sector by improving the reproductive rate, production and productivity of the animals, and disseminating the improved technology for wider use within a short time. Artificial insemination, sexed semen, estrus synchronization, multiple ovulation and embryo transfer are the tools applied in reproductive biotechnology to disseminate improved genotypes for the production and productivity of livestock species. In Ethiopia, these technologies have been employed at different levels. However, the improved genotypes were disseminated randomly in various parts of the country, and yet have had loose screening procedures in terms of production grade, genome background and health. In this programmatic R4D focus area, the following activities are identified.

Programmatic R4D focus area activities:

- Mapping dissemination areas of the improved genotypes (dairy, sheep, goats and poultry)
- Screening of the improved genotypes in-terms of productivity, adaptability and health (dairy, sheep, goats and poultry)
- Improving performance of the local breeds through cross-breeding (dairy, sheep,and goats)
- Artificial insemination, estrous synchronization, multiple ovulation and embryo transfer, in vitro and in vivo fertilization, and sexed semen as tools for wider use
- Develop and optimize estrous synchronization protocols
- ***Programmatic R4D focus area 3: Animal feeds and nutrition***

There is scarcity of livestock feed in Ethiopia. The available feed resources are low in nutritional quality. Low quality feeds, such as feeds having high fiber content, are difficult to be digested by monogastric animals unlike the ruminants. Fibrous feeds of low digestibility account for the major proportion of feeds accessible to most ruminants under smallholder farmers in Ethiopia. The low quality and quantity of the animal feeds has mainly contributed for the low body weight gain, low milk and meat production, low off-take rates, low conception and parturition rates, long parturition interval, and high mortality and morbidity losses of the livestock species. On the other hand, the high cost and low availability of good quality animal feed is a critical challenge severely limiting livestock productivity.

Programmatic R4D focus area activities:

- Manipulating the animal rumen ecology or microbes in ruminal livestock species (cattle, sheep and goats)
- Feed improvement and value addition such as feed additives
- Genetic selection for feed efficiency in dairy breeds
- Identification of high yielding and stress tolerant (drought, cold, pests and diseases) forage species/varieties using molecular tools

Programmatic R4D focus area 4: Animal health

Biotechnology for animal health has been developed in transgenesis, disease prevention, diagnosis, treatment and control. Advanced biotechnology-based diagnostic methods such as immunotechnology, recombinant DNA and nucleic acid-based technologies have helped identify disease causing agents, thus contributing to control programs. In this R4D programmatic focus area the following activities have been identified.

Programmatic R4D focus area activities:

- Geographical mapping of distribution of animal diseases and parasites
- Development of diagnostic kits
- Development of vaccine for selected animal diseases

Programmatic R4D focus area 5: Apiculture

Ethiopia maintains substantial comparative advantage as one of the major global exporters of eco-friendly honey and bee-wax to export destinations. It is imperative that traditional beekeeping practices in high potential production areas are transformed into market-orientated and streamlined operations, and the bottlenecks in the established value chains are overcome to maintain the country's status. Given the huge

potential the apiculture farming can support the national economy, very little/no research effort has been performed particularly to uncover the available genetic resources in the country. As a result, the genetic resources of honey bees have not been dealt with using molecular techniques. In this apiculture programmatic focus area the following activities are identified.

Programmatic R4D focus area activities:

- Molecular identification and characterization of honeybee subspecies in Ethiopia
- Improving genetic transformation rates in honeybees through functional genetic studies
- Produce pesticide resistant honeybee colonies through genome editing/Engineering of symbionts
- Biomedical research in honeybees
- *In vitro* cultured honeybee embryonic cells cultivation
- Establishing queen breeding program

Programmatic R4D focus area 6: Fish and aquaculture

Fisheries and aquaculture offer ample opportunities to reduce hunger and improve nutrition, alleviate poverty, generate economic growth and ensure better use of natural resources. In Ethiopia, the fish gene pool is believed to be very wide following the wide range of agro-ecologies found in the country. However, very little efforts were exerted to identify the available fish genetic resources using molecular techniques. Because of the limited infrastructure and resources, and insufficient well-trained human power, the available fish resources in the country have remained untapped. The following programmatic focus area activities are indicated below.

Programmatic R4D focus area activities:

- Identification of fish genetic resources using molecular approaches
- Genetic improvement and genome editing in fish such as tilapia and catfish

3.4.1.3 Microbial biotechnology R4D program

Research and innovation activities in soil-microbial biotechnology and mechanisms for bridging research and industry interface are provided for the improvement of these developments. The microbial biotechnology programmatic area identified focuses on growth promotion using improved microorganisms with nitrogen fixation, transformation and phosphorus solubilization for increasing agricultural productivity. Additionally, bio-based technologies for pathogen protection, pests and weed control are described below as follows:

Programmatic R4D focus area 1: ***Agricultural microbial biotechnology for the production biofertilizers and biopesticides***

Programmatic R4D focus area activities:

- Biochemical, physiological and molecular characterization of microbes for soil fertility, food and feed processing and biological control improvements
- Microbial improvement through classical and modern techniques for various microbial products
- Metagenomics for characterization and strain improvement
- Development of biofertilizers for better soil fertility, higher crop yield and quality improvement
- Development of biopesticide against economic diseases, insects and weeds for improving crop and livestock production (yield and quality) and improve environment
- Inoculum production and scale up and commercialization

3.4.1.4 Community biotechnology in the agricultural system

Agriculture is an integral part of both the physical and social environment in which it is practiced. Agricultural system whether "primitive" or "modern" is simply a distinctive type of man modified ecosystem and has structure, function, equilibrium and change as its property and interacts with the natural ecosystem. Ethiopia should consider the advantages of agricultural biotechnology along with the neglected and various scale of indigenous knowledge as several potential applications such as adaptation of diverse crops to marginal environments, control of diseases, efficient biological nitrogen fixation, and biological control agents that replace the use of chemical pesticides benefiting resource-limited farmers.

Programmatic R4D focus area 1: ***Agro ecological community genomics research programs and agro-ecosystems dynamics***

Programmatic focus area activities:

- Identifications of dominant plant/animal in the various agro-ecological setups and their economic importance
- Population genetic variation of agriculturally important traits of dominant plant/animal in the various agro-ecologies and their economic assessments
- Comparative community genetic diversity of agro-ecologies in terms of fitness, adaptation of bioresources, productive constraints and ecological fragility

Programmatic R4D focus area 2: ***Climate change variability, phenomics and epigenetics***

Programmatic focus area activities:

- Selection of genes of agricultural importance and study their products in various species in each agro-ecology with the variable climatic conditions
- Mapping framework that links genes to ecological interactions, to produce more precise insights into the genetic architecture of complex traits for each agro-ecology.
- Effect of competition on the phenotype of selected species of each agro-ecology under isolation or co-occurrence
- Estimate phenotypic plasticity of selected genotypes that result in specific phenotypic properties in concert with complex and changeable environmental influences
- Community genomics /metagenomics/ecological/environmental genomics to describe organizational level above that of population, community and ecosystem of each agro-ecologies to understand what genes/genomes and their variants do at higher level of ecosystem organization
- Agroecology-based food types vs human genomic variants differentiations
- Agricultural food metabolizing enzymes variations of various human population groups in the various agro-ecologies
- Categorization of environment and the rate of change in environmental gradients of variables with its own action and reaction system particularly in the present era of climate change where environment can be limiting, compensating and trigger depending on genomic reaction at various developmental stages
- Phenomics for optimum conservation of natural resource management particularly under the present habitat fragmentation, gene flow, detrimental effect of inbreeding depression and other detrimental factors.

3.4.2. Health Biotechnology R4D Program focus areas

In this section, health biotechnology R4D program focus areas and mechanisms for bridging research and industry interface are provided. Seven health biotechnology R4D programmatic areas are designed to guide in the areas of vaccine development, drug discovery, diagnostics, therapeutics and application of nano-biotechnology.

Programmatic focus area 1: Pathogen biology and host-pathogen interaction

Modern technologies such as NGS, analytical tools such as mass spectrophotometry and GC, advanced microscopy, and immune-imaging technologies are being employed for pathogen biology and host-pathogen interaction studies. This has led to high throughput approaches of -omics (genomics, transcriptomics, proteomics, metabolomics, and metagenomics) and pathogen-related studies. These platforms generate data from the pathogens through whole genome sequencing, gene expression during

host-pathogen interaction and immune response, and systems biology of the metabolic pathways from pathogens and host. Furthermore, the metabolic demand of potential pathogenic organisms may still remain unknown and this hinders appropriate interventions to be designed. Therefore, this programmatic focus area provides pathogen specific sequence information and candidate targets to be used in diagnostics and therapeutics .

Programmatic R4D focus area activities:

- Deciphering information of pathogenicity and disease-causing mechanisms
- Metabolic characterization of pathogens using culture-independent approaches
- Omics-based approaches for non-infectious health problems

Programmatic R4D focus area 2: Vaccine development and production

Considering the fact that conventional vaccines could not work for all types of health problems, research for vaccine design approaches has been practiced greatly and has shown promising results. Vaccine design such as nucleic acid- and protein-based approaches, adjuvants delivery systems are available. Therefore, this research program focus areas primarily start with local capacity followed by vaccine development. The currently proposed focus area activities are as follows:

Programmatic R4D focus area activities:

- Vaccine development
- Vaccine production and improvement technologies
- Scaling and commercialization of effective vaccines

Programmatic R4D focus area 3: Diagnostics

Diagnostics of various types of infectious and non-communicable diseases offer paramount importance to disease control and management. The following activities are recommended for this focus area:

Programmatic R4D focus area activities:

- Development of immunological and molecular diagnostics
- Develop point-of-care diagnostics
- Molecular-based biomarker development

Programmatic R4D focus area 4: Therapeutics

Appropriate and effective therapeutics against the diverse health problems requires the development of novel therapeutics and discovery of antimicrobials including immunotherapeutic; phage therapy; gene therapies; gene editing using CRISPR-CAS system, siRNA therapeutics, antisense DNA, synthetic drugs, stem cell therapies and regenerative medicine.

Programmatic R4D focus area activities:

- Discovery and development of drugs using predictive bio-analytics, computational drug design, and synthetic biology
- Screen lead compounds for drug development and discovery
- Development serum albumin production and purification system
- Antibody, cytokines and biosimilar productions

Programmatic focus area 5: Traditional medicine

Giving attention to research on standardization of the use of traditional medicine contributes to health sector development and reduces dependence on imported and costly medications. Thus, screening of promising plants from claimed practices, published peer reviewed as well as grey literature, confirmatory preclinical studies is recommended to hasten the development of marketable phytomedicine.

Programmatic R4D focus area activities:

- Prospecting for active compounds from medicinal plants
- Drug development and production
- Scaling up of traditional medicine preparations

Programmatic focus area 6: Stem cell and gene therapy

Stem cell research is an emerging area of modern medical biotechnology. In recent years, the use of stem cells involving cell-based and gene therapy is a focus for modern medical biotechnology for diseases with no efficient curative or preventive measures.

Programmatic focus area activities:

- Stem cell therapy for non-communicable diseases
- Cancer immunotherapy using hematopoietic stem cells
- Genetic diseases treatment
- Regenerative medicine
- Drug screening for precision medicine

Programmatic focus area 7: Nano-biotechnology for diagnostics, therapeutics and Vaccine delivery

Nanobiomaterial can considerably improve the diagnosis and treatment of many diseases. It can be engineered for example to recognize cancer-specific receptors at the cellular levels and to deliver anticancer drugs into the cancerous tissue. Nanoparticles are used to bypass the natural barriers during drug delivery. Moreover, nanomaterials can increase drug distribution and retention. Therefore, there is a need to be a part of the global development to benefit from the huge market of biomaterials opportunity in the sector of diagnostics and drug delivery systems. The following activities are recommended for this focus area:

Programmatic R4D focus area activities:

- Bionanomaterial synthesis vaccine delivery
- Bionano-carrier cargo- for targeted drug delivery
- Bionano-carriers for diagnostics

3.4.3. Industrial biotechnology R4D program focus areas

The R4D programs of industrial biotechnology are aimed at developing the production of innovative bio-based products and bioprocesses in a cost- and eco-friendly manner. Seven industrial biotechnology R4D focus areas are identified to address the country's gaps in bio-industry development using new discoveries and technologies.

Programmatic R4D focus area 1: Industrial enzymes

The development of the existing laboratory-scale screening and improvements of various enzymes and microbial strains could continue in research institutions, with the discovery and development of new enzymes for bio-industry applications. To this end, the areas for national enzyme R4D should involve nationwide systematic exploration of potential enzymes from microorganisms inhabiting extreme environments, guts of wood eating organisms and municipal and industrial waste streams. The R4D should also consider the latest developments in protein engineering and site-directed evolution to tailor-make enzymes with new activities and/or for new process conditions and wide industrial applications thereby alleviate the issues associated with enzyme stability and higher sensitivity to factors such as higher temperature and pH.

Programmatic R4D focus area activities:

- Bioprospecting of extremophiles

- Development of industrial enzymes from non-extremophiles
- Efficient enzymes for bio-conversions of renewable feedstocks
- Scale-up and bio-manufacturing of industrial enzymes

Programmatic R4D focus area 2: Yeast and other industrial microbes

This programmatic area focuses on the production and utilization of yeast and other microbial biomass at industrial scale, targeting the screening of suitable yeast and bacterial strains from a wide range of environment and their improvements through mutagenesis and metabolic engineering, among others. These will enable the manufacturing of commercial key yeast products such as compressed and dry yeasts.

Programmatic R4D focus area activities:

- Identification of efficient yeast strains
- Improvement of yeast performance
- Scale-up of yeast biomass production
- Characterization and scale up of starter culture bacterial and fungal strains

Programmatic R4D focus area 3: Biopharmaceuticals

This program focuses on the production of active pharmaceutical ingredients (APIs) using biocatalytic synthesis, recombinant expression systems and enzymes, tissue-culture platform technologies such as fermentation products, development of by-products including antigens, biocatalysts, as well as plant-based production of proteins, downstream process development, assay development and diagnostics are included. Research activities and profiling of the traditional medicine practices and constituents of herbal remedies of Ethiopia are also focused.

Programmatic R4D focus area activities:

- Development and scaling-up of novel drugs and vaccine
- Development and scaling-up of nano-medicine for therapy and diagnostics
- Development and scaling-up of *in vitro* diagnostics and biosensors
- Development and scaling-up of biomaterials, cell-based therapy and regenerative medicine
- Optimizing and Scale up for biomanufacturing of vaccines, diagnostics, and therapeutics

Programmatic R4D focus area 4: Food and additives

This program focuses on manufacturing of functional food additives which are classified into different functional classes such as acidity regulators, antioxidants, colors, emulsifiers, preservatives, stabilizers, flavors, flavor enhancers, bulking agents, sweeteners, and thickeners. The country has a diverse cultural heritage in fermented food, food additives and beverages which could be developed into commerce through industrial biotechnology and development.

Programmatic R4D focus area activities:

- Development of technologies for traditional fermented foods, additives, beverages and wild indigenous foods
- Impact of traditional fermented foods on the composition and function of human gut microbiota
- Biomolecule identification and characterization of functional food additives
- Optimizing and scale-up of bio-foods and additives production

Programmatic R4D focus area 5: Biocosmetics and personal care products

This research and development program focuses on bioprocessing for the extraction, purification and efficacy evaluation of bio-based ingredients of biocosmetics and personal care biochemicals. Ethiopia has the potential in the production and export of biocosmetics and healthcare products due to indigenous knowledge and biodiversity the country is endowed with.

Programmatic R4D focus area activities:

- Development of indigenous technologies in biocosmetics
- Biochemical profiling of nutraceuticals
- Development, optimization and scale-up of bioprocessing technologies for biocosmetics

Programmatic R4D focus area 6: Biomaterials

This program focuses on the development and production of biomaterials such as biopolymer and bio-plastics such as polylactic acid (PLA) and polyhydroxyalkanoates (PHA) that can be organically recycled using industrial anaerobic digestion and/or composting.

Programmatic R4D focus area activities:

- Bioprospecting of efficient microorganisms for biomaterials production
- Screening of efficient microorganisms for large-scale applications for PHA accumulation for the production of bioplastics/PLA/ from biowaste.
- Optimization of feedstocks and bioprocessing technologies for PLA and PHA production

- Scale-up of the production of bioplastics and biopolymers

Programmatic R4D focus area 7: Biofuel

This program focuses on the production of biofuels such as bioethanol, biobutanol, and biodiesel from renewable biomass and bio-waste feedstocks. Bio-based processes under research and development for commercial production of biofuels are majorly associated with effective pretreatment, enzymatic hydrolysis, and fermentation processes. Discovering of diverse and new biomass feed stocks, novel strains of microorganisms and enzymes identified from wide diverse local environments for commercial production of biofuels including bio-ethanol, bio-butanol, and bio-diesel are also focused.

Programmatic R4D focus area activities:

- Bio-prospecting microorganisms for bioethanol, biobutanol and biodiesel production
- New alternative carbon sources of feedstocks/raw material substrates for bio-based products
- Plant metabolic engineering for improved bioconversion processes
- Scale-up the production of bio-ethanol, bio-butanol, and bio-diesel

3.4.4. Environmental biotechnology R4D Program focus areas

In this section, environmental biotechnology R4D Program focus areas for the coming ten years in Ethiopia are described. Research and innovation activities in environmental biotechnology and mechanisms for bridging research and industry interface are provided for the improvement of these developments. Seven environmental biotechnology R4D Programmatic areas are identified. R4D programmatic areas for addressing the country's environmental problems with the support of new discoveries and technological enhancement in environmental biotechnology are described below as follows:

Programmatic R4D focus area 1: Bioprocesses for wastewater treatment

Programmatic R4D for improving and developing biological processes and technologies for the efficient removal of inorganic and organic pollutants from wastes and wastewater; advanced processes for treatment of recalcitrant industrial effluents and micropollutants (heavy metals), microbial communities and dynamics in wastewater treatment processes require due attention. R4D programs aiming at the development of processes and technologies to support sustainable industrial development and, in

particular, to minimize any possible negative environmental impact that may result from industrial development shall be promoted and supported.

Programmatic R4D focus area activities:

- Screening and enhancing microbial consortia in biological wastewater processes for the treatment of municipal and industrial wastewaters
- Screening and enhancing emergent plants for nutrient, heavy metals and emerging contaminants removal
- Developing and optimizing bioprocesses involving efficient microbial consortia and emergent plants for the treatment of wastewater from point- and nonpoint-sources
- Pilot-testing and scale-up of bioprocess technologies for wider use by municipalities and industries

Programmatic R4D focus area 2: Valorization and resource recovery from biowastes/biomass and climate change mitigation

Research and innovative approaches for value addition and resource recovery from agro-process biowastes and organic wastes of municipal origin, transforming it into clean energy, nutrients and other valuable biomaterials such as bioethanol, methane, biohydrogen, biopolymers and raw materials for other value products using technological clusters are highly encouraged and supported. The use of constructed wetlands and algal based ponds can favor the recovery of nutrients in the form of biomass. Coupling waste management with resource recovery thereby promoting circular economy and climate change mitigation is a very attractive solution to existing problems that requires innovative methods that can be adopted easily by agro-processing industries such as Integrated Agro-Industrial Parks (IAIPs), sugar, pulp and paper, coffee, and food processing industries.

R4D for the development of appropriate technologies such as efficient microorganisms for biowaste conversions, and promoting efficient, small-scale biogas production systems are critical. Implementation of this research and innovation activities will lead to expansion of biogas use by industry and local consumers.

Programmatic R4D focus area activities:

- Screening and enhancing microbial consortia for efficient resource recovery from biowastes.
- Develop and optimize bioprocesses for resource recovery and value addition to biowastes and wastewaters.

- Innovative clusters of technologies for valorization of sugar cane processing byproducts and coffee processing wastes for climate-smart industrial development.
- Piloting and scale-up for industrial-level resource recovery and value addition.

Programmatic R4D focus area 3: Bioremediation of contaminated environmental sites

The key to successful bioremediation is to harness the naturally occurring catalytic capability of microbes to transform environmental pollutants. Microbial-based R4D in bioremediation technologies (bio stimulation, biotransformation, bio stabilization and biofiltration) can be employed to extract, eliminate and/or bind toxins in the forms that are not harmful to the environment. Phytoremediation (phytoextraction, phytodegradation, phytotransformation, phytostabilization, and phytovolatilization) involving algae and plants can also be applied for remediating contaminated environments. Microalgae are used to eliminate nitrogen and phosphorus, and emergent plants are used to extract heavy metals from industrial effluents.

Novel environmental biotechnologies can be applied for the remediation of groundwater; biotreatment of water resources polluted by pesticides, pharmaceuticals and other micropollutants; remediation of trace element-contaminated land; as well as efficient emergent plants for cleaning and polishing of contaminated sites. The development of new methods for the bioremediation of existing sites that are already heavily contaminated and for the reduction of energy consumption and carbon dioxide emissions will also be promoted. To accelerate the degradation process to treat large volumes of waste, bio-augmentation can also be used in situations where there exists low volume degradative species in situ for successful bioremediation. R4D programs targeting screening for efficient microorganism for efficient biodegradation and bioremediation capabilities will also be supported and promoted.

Programmatic R4D focus area activities:

- Bioprospecting microorganisms of extreme environments for clean-up of pollutants
- Screening and enhancing microbial consortia for bioremediation
- Microbial seed-based bioaugmentation development for bioremediation
- Screening and enhancing emergent plants for understanding functional metabolic pathways in nutrient, heavy metals and emerging contaminants removal
- Developing microbial packages for application in bioremediation of organic pollutants
- Piloting and scale-up for commercial applications

Programmatic R4D focus area 4: ***Biodegradation of recalcitrant pollutants using efficient microorganisms***

Organic compounds which are naturally occurring (biogenic) are biodegradable while man-made (xenobiotic) compounds may be biodegradable, persistent or recalcitrant. These organic compounds include persistent organic pollutants (POPs)-DDT, PAH, PCBs, etc. Genes coding for some enzymes essential for the biodegradation of a number of organic compounds are plasmid-borne and efficient microorganisms can be constructed to degrade these recalcitrant wastes. R4D programs aiming at generating efficient and adaptive microorganisms and scaled bioprocesses for biodegradation of recalcitrant pollutants will be promoted and supported.

Programmatic R4D focus area activities:

- Screening for microbial consortia capable of biodegradation of persistent organic pollutants
- Screening and enhancing emergent plants in nutrient, heavy metals and emerging contaminants removal
- Developing microbial packages for application in biodegradation of recalcitrant organic pollutants
- Piloting and scale-up for commercial application

Programmatic R4D focus area 5: ***Microbial processes for recovery of precious metals from ores (biomining)***

Given the rich mineral resources the country possesses, employing environmental biotechnological innovations can greatly assist the recovery of precious metals (Cu, Ni, Zn, Ag) from ores. This process could also alleviate environmentally polluting approaches to the mining industry. Biomining is the use of specific microorganisms for degrading minerals that in turn facilitate the recovery of target metals (Cu, Ni, Zn, Ag). Environmental biotechnology R4D for bio mining of metal ores and recovering precious metals from mining industrial wastes are encouraged and supported.

Programmatic R4D focus area activities:

- Screen microorganisms with the metabolic capability for recovery of precious metals and treatment of mine wastes
- Enhance the metabolic efficiency of candidate microorganisms for biomining
- Developing microbial packages for application in biomining and mine drainages
- Piloting and scale-up candidate microbes for commercial application in the mining industry

Programmatic R4D focus area 6: ***Bioindicators and biomarkers for environmental pollution monitoring***

Environmental biotechnology has been applied for the development of biomarkers and biosensors that improve bio-monitoring of environmental changes along with the treatment processes and bioremediation sites. Environmental biotechnology research and innovation activities will include development of biosensors and molecular probes for monitoring pollutants in wastewater treatment processes, bioremediation sites and contaminated environmental sites. R4D programs aiming at developing reliable molecular and analytical diagnostic methods are encouraged and supported.

Programmatic R4D focus area activities:

- Developing molecular markers for the detection and monitoring of pollutants and transgenic organisms in the environment
- Developing molecular markers for monitoring key microbial sub-communities in wastewater treatment and bioremediation sites
- Developing biosensors, bioindicators and biofluidics for monitoring of environmental pollution
- Developing prototypes and commercialization of biosensors

Programmatic R4D focus area 7: ***Biodiversity and bioprospecting***

Given the fact that only 1% of total microorganisms of an environmental sample are actually cultivable, advancement in metagenomic studies has far increased our access to the genes of the microbial community that remained uncultured so far. It enables the exploration, conservation and ease of access to the genomic wealth contained in adverse environments and less explored biomes. In today's world where microbial processes have proved its applications for environmental management, metagenomic studies have become highly important as it gives a clue to the hidden wealth of the microbial world. The main advantage of metagenomics among many is it allows the discovery of novel genes from previously unknown microbes. Detection of such functional genes could be carried out using metabolite-regulated expression (METREX) and substrate-induced gene expression (SIGEX).

Culture-independent methods (Metagenomics, meta-transcriptomics, metabolomics and other -omic approaches) will be used for the identification of functional genes and new metabolic pathways in the microbial community for application, degradation and bioproduction. Rapid and low-cost nucleic acid base analysis will allow the classification of single species with better precision.

Programmatic R4D focus area activities:

- Microbial metabolic potential of natural, artificial and engineered environments
- Emerging plants genomic resources
- Biotechnology for conservation, prospecting, and sustainable use of biodiversity
- Create and develop genomic database with bioinformatics platforms
- Establish microbial resource centers in national Centers of excellences and regional Environmental Biotechnology R4D hubs

3.5. Implementation of biotechnology R4D Program

In part VI of this document, we have presented implementation plan, monitoring and evaluation systems to ensure that the program is properly implemented with monitoring and evaluation mechanisms that enable continuous performance assessment at program and project levels. The proposed Biotechnology Advisory Committee (BAC) with the implementing organization will develop detailed implementation plans. To support this, the program developed program results framework which will serve as a foundation for this purpose. Table 4 presents a program results framework covering programmatic area key activities, output outcome as well as performance indicators with implementation timelines and indicative budget along with responsible institutions.

Table 4. National Biotechnology R4D Program Results Framework (2024 - 2034)

Program/Key Activities	Outputs	Outcomes	Performance Indicators	Implementation phase		Budget (USD in Million)	Responsibilities
				I	**II**		
Objective 1: Strengthen technical competencies and institutional capacity for biotechnology research and innovation in agriculture, health, industry and environmental sectors							
1.1 Train human resources (PhD: 565[117]) and build laboratory facilities and equipment for biotechnology research and innovation in the country	Human resources and laboratory facilities capacitated for Effective biotechnology research and innovation	Critical trained mass and facilities in use by CoE and regional hubs for biotechnology research and innovation	Number of trained human resources with skills and knowledge in biotechnology R4D; Number and qualities of facilities and equipment for biotechnology R4D	X	X	11.3	MiNT, BETin, BAC, MoF, MoPD, CoEs and regional hubs, HLIs & research institutes
1.2 Create and strengthen regional hubs for biotechnology research and innovation	Existing CoE and hubs for training, research and innovations	Platform in place for efficient biotechnology research and innovations activities	Number and qualities of CoE and hubs with required buildings incubation center and technology parks for biotechnology R4D	X	X	148	MiNT, BETin, BAC, MoF, MoPD, CoEs and regional hubs, HLIs and research institutes
1.3 Gradually increase funding for research and innovation in biotechnology	Financial resources and related investments increased	Enhanced collaboration and production of scalable technologies by the platform	Number of incubation centres and technologies generated	X	X	102	MiNT, BETin, BAC, MoF, MoPD
1.4 Proper institutional arrangement for coordinated biotechnology R4D programs	Coordination arrangement in place	Synergy and institutional collaboration for biotechnology R4D program	Functional advisory committee in place	X	X	4	STIC, MiNT
Objective 2: Enhance effectiveness of biotechnology research and innovation in addressing priority areas of agriculture, health, industry and environment for inclusive green growth of the country							
2.1. Agricultural biotechnology R4D programs: ● Plant ● Animal ● Microbial ● Community	Biotechnology research and innovation base strengthened for improved agricultural production and ensuring food and nutrition security	Food and nutrition security, employment and livelihood improved	Number of products and technologies used by the farmers, pastoralists, and agro-processors	X	X	97	MiNT, EIAR, MoA, ATI, CoEs, BETin, Regional hubs, private sectors
2.2. Health biotechnology R4D program: • Host-pathogen • Vaccine • Diagnostics • Therapeutics • Nanobiotechnology	Biotechnology research and innovation base strengthened for the production of biopharmaceuticals, therapeutics and diagnostic tools for	Health care and human wellbeing, and quality of life improved	Number of health care products produced	X	X	53	MiNT, BAC, MoH, EFDA, ESA, CoE, Regional hubs, Private sectors, BETin

[117] agriculture (200), health (120), industry (165), environment (80)

	improved health care systems in the country						
2.3. Industrial biotechnology R4D programs: • Biochemicals • Bio-pharmaceuticals • Biofoods and additives • Biofuels	Improved the production efficiency of bio-based industries in unlimited potentials to manufacture commercial products	Improved and increased competitiveness of bio-based industries for product quality, safety, employment generation and wealth creation	Number of commercialized bio-based products	X	X	80	MiNT, BETin, CoE, EFDA, Regional hubs; MoI, BAC, EIPO, VDFACA, ESA
2.4 Environmental biotechnology R4D programs: • Waste treatment • Waste valorization • Bio remediation & degradation • Biomining • Pollution monitoring • Bio diversity & prospecting	Efficient microorganisms and bioprocesses for waste management, resource recovery, bioremediation, monitoring environmental pollution as well as biodiversity and bioprospecting developed	Green environment, eco-friendly industrial development and environmental sustainability enhanced	Number of microbial consortia, products and processes used by municipalities and industries	X	X	40	MiNT, BETin, ESA, CoE, EPA, Regional hubs, BAC, EIPO, MoI
Objective 3: Promote competitiveness through fostering innovation, value addition, industrial development and entrepreneurship in synergy with research, academia and industrial actors							
3.1. Establish viable links and partnerships among academia, research and industry	Biotechnology research and innovation platform in place involving academia, research institute and industries in the countries	Visible and functional PPP	Number of R4D activities using shared platforms; Number and quality of partnerships developed	X	X	1.5	CoEs, Regional hubs; MiNT, BETin, BAC, EIC
Objective 4: Biotechnology research and innovation platform in place involving academia, research institute and industries in the countries							
4.1. Establish contacts with national, continental and international Centers of Excellences for joint research activities in biotechnology	Collaborative biotechnology R4D programs and projects; Presence of network among collaborating actors	Increased biotechnology R4D capacity for generation of scalable technologies	Number and quality of regional and international initiatives	X	X	0.25	CoEs, Regional hubs; MiNT, BETin, BAC, MoPD, MoF
4.2. Establishing contacts with continental and international funding agencies for supporting biotechnology R4D	Enhanced collaborative R4D programs and projects for generation of scalable technologies	Productive engagement by all actors	Quality of platforms created; number and Quality of R4D programs and projects	X	X	0.25	CoEs, Regional hubs, MiNT, BETin, BAC, MoPD, MoF

Key: *= PhD students shall be recruited and trained using center of excellence and/or regional hubs in collaboration with professionals from abroad, where necessary students shall spend a minimum of three months. Note: Ethiopia's GDP of 2020 = $95.6 Billion. 1% of the GDP to STI = $0.956 Billion; The estimated budget for national biotechnology R4D programs for 10 years = $537.3 million ($53.73 million annually). This will be 5.62% of the STI per year allocation.

PART IV. ENABLING CAPABILITIES FOR THE IMPLEMENTATION OF BIOTECHNOLOGY R4D PROGRAM

4.1. Creating an enabling environment

An overall enabling environment for biotechnology research and innovation needs to be created by the Government to achieve the R4D focus areas identified in the National Biotechnology R4D Program (Fig. 30). The creation of such an environment mainly involves the Government (MiNT and BETin) having evidence-based policies and programs that encourage biotechnology research and innovation in the country. MiNT and BETin require a coherent national framework for actions that directly affect the promotion of biotechnology research and innovation and STI in general. The National Biotechnology R4D Program is designed and developed in consultation with national and regional research and innovation stakeholders from the public, private, education and research, societal, international development and funding sectors.

The R4D institutional landscape in Ethiopia can be defined as a loosely connected science and technology system within a National System of Innovation (NSI)[118], with insufficient flexibility and capacity to adjust to the changing policy and technological environments. The NSI has a significant role to play in achieving the goals of promoting competitiveness and job creation and of enhancing the quality of life through the development of human resources and the promotion of knowledge and innovation-driven economic growth. Biotechnology research and innovation should be premised on a knowledge base and be sustainable.

An enabling environment also implies building a comprehensive STI research and innovation culture, strengthening legal and regulatory systems to ensure they are fit for purpose and promote innovation and IP creation and actively promote equal opportunity careers in STI research and innovation. The status of researchers must be attractive and offer better working and living conditions. The perception of the society must value the research profession. Such a conducive environment will also attract experienced and competent Ethiopian Diaspora as well as expatriates.

[118] The NSI is defined as a set of functioning institutions, organizations and policies which interact constructively in the pursuit of a common set of social and economic goals and objectives

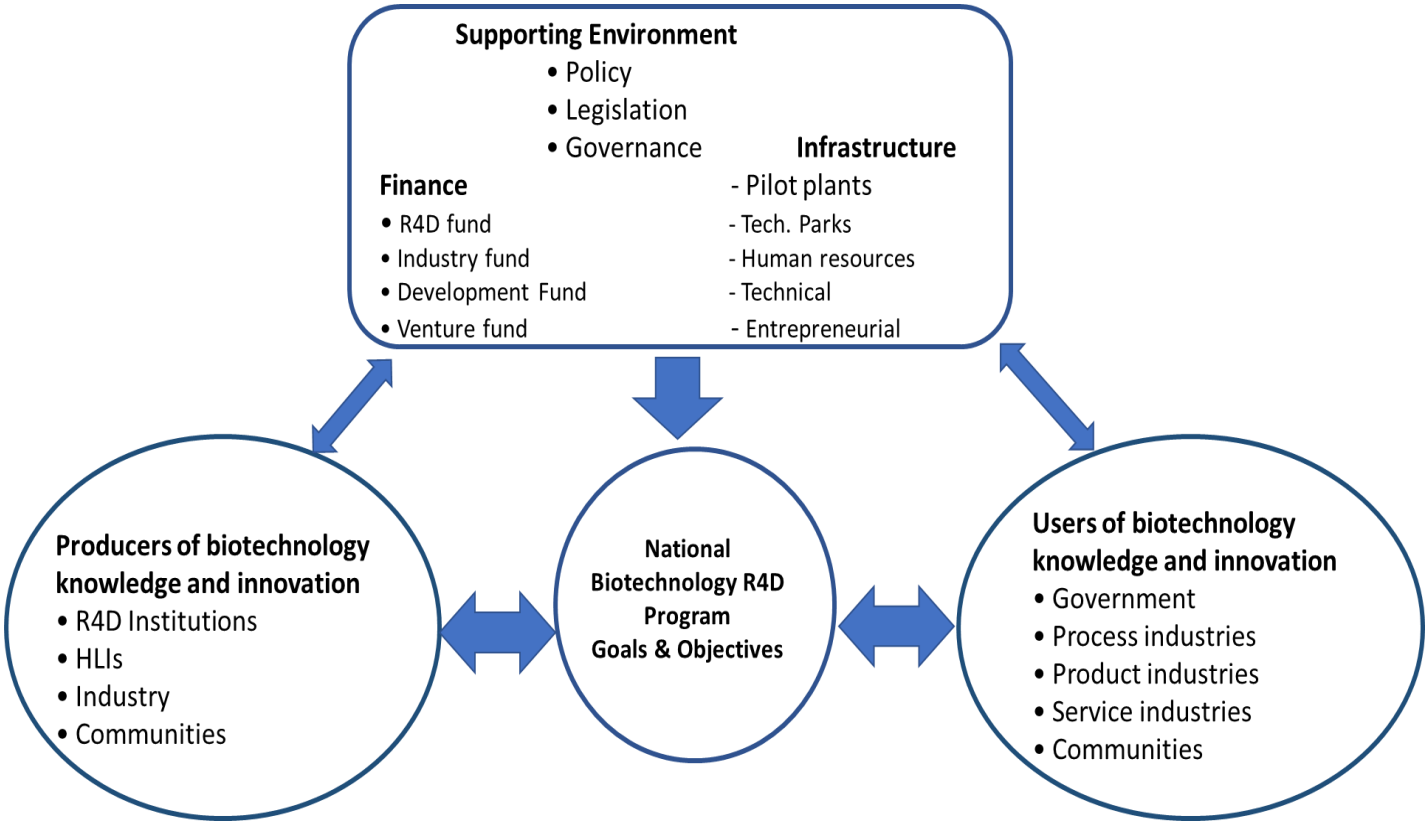


Figure 30. Overarching arrangement of the different structures involved in the national biotechnology R4D Program implementation processes within national innovation system

As shown in the previous sections, capacities to adapt and use modern biosciences in various sectors are emerging in Ethiopia. For the country to transform into a knowledge-based bio-economy that promotes inclusive bioeconomy growth much more targeted efforts are needed, including increased funding for biosciences research and innovation, policy development and access to capital and institutional reforms. These reforms are particularly needed in the public research organizations, including universities. Public research organizations[119] should be more effective in moving ideas and technologies beyond research[120]. The knowledge and bioscience technologies in the laboratories should move out into economic sectors. The private sector and other market actors such as social investors on the other hand, should also be

[119] Including federal and regional agricultural research institutes (FARIs/RARIs) and public research universities including S&T universities

[120] This applies in particular to the universities who has been structured and organized to exclusively do research and training. Public R&D institutions also need to develop structures for technology transfer, such as IP policies, IP management capacities, capacity to develop effective contractual agreements, marketing capacities and abilities to establish links with market actors.

sufficiently engaged[121] with the universities and public R4D sector in commercializing technologies. This can be made possible by promoting innovation initiatives that link academia, R4D organizations with the industry. Such efforts should be a key component in funding and implementation of this National Biotechnology R4D Program by MiNT/BETin and the Biotechnology Advisory Committee (BAC), recognizing that biotechnology research and innovation is a complex process highly dependent on functional policies, institutions, financial and human resources. The Science, Technology and Innovation Council (STIC) assisted by the BAC should facilitate the process to build functional biosciences innovation systems[122] in its effort to translate useful technologies to innovations in a sustainable manner for societal impact. Some of the required capabilities for the effective implementation of this National Biotechnology R4D Program are described below.

4.1.1. Strengthen capacity in biotechnology research and innovation

For the country to be able to conduct meaningful research and innovation activities in biotechnology, it must continue to train in modern biotechnology and enhance the skills of existing professionals with related biosciences as well as to upgrade and/or develop the required research infrastructure both at the regional and national levels. In addition, universities and research institutions and individual scientists in the country must strengthen links with other research and development partners at national, regional continental and international levels in order to lower transaction costs and improve efficiency. The BETin with support from the proposed biotechnology advisory committee[123] should facilitate and develop procedures for mobilizing existing professionals trained in related to biosciences for the implementation of the R4D Program in biotechnology. In order to create a critical mass of trained manpower and build capacity in biotechnology, training programs for new graduates and on-job skill enhancement should be initiated in Phase I of the implementation period (2024-2034). Arrangement for PhD and post-doctoral training abroad in universities and institutions with centers of excellence in biotechnology will enable the transfer of knowhow and technology. This should be coupled with building adequate laboratory facilities and equipment at universities, research institutes and/or national center of excellence(s) and regional hubs[124] for biotechnology R4D and innovation in the country. Finally, the country should also strive to build a strong and cost-effective biotechnology R4D program and capacity within universities and research institutes and effectively link with industries. This will enable the country to take advantage of the powerful tools and rapidly growing fields of biotechnology applications.

[121] To a large extent, the private sector and small enterprises dealing with agriculture and agro-processing and value chains are not investing in R4D, and are not well connected to the academia and research institutes.

[122] In the innovation system perspective (ISP) there is a shift from viewing research as the central actor to being only part of the innovation system. The argument here is that focus should not only be on technology generation but also its diffusion and adoption.

[123] Described in section 5 of the program document

[124] Described in section 5 of the program document

Some of the R4D capacity building involve:

- Human resource training and enhancing facilities[125]
- Strengthening biotechnology R4D centers/Departments within the existing Universities and research institutions
- Gradual increase in fund for research in biotechnology
- Create R4D nucleus and regional hubs for biotechnology
- Establishing contact with international excellence centers for joint research activities in biotechnology

4.1.1.1. Establishing and strengthening of bioresources center (biobank) and bioinformatics platform

The establishment of biobanks for all the biotechnological research products (from various sectors) including microbial and pathogen strains, various molecular fragments have to be envisaged for long-term storage and future use with appropriate informed consent, ethical and legal systems, with sound governance structure and operational models.

Bioinformatics is an interdisciplinary field that combines biosciences with computer science, statistics, mathematics and engineering. It is used as a tool for storing, archiving, retrieving, analyzing and giving meaning to the huge data size that can be generated from any biological material. The bioinformatics programming skills are becoming a necessity across the many facets of biosciences, owed in part to the continuing explosion of biological data aggregation and the complexity and scale of questions now being addressed through modern biosciences. The following activities are identified to be implemented and support the national biotechnology research and innovation in the next ten years:

- Establish bioresource center (biobanks)
- Establish state of the art IT and High-Performance Computing (HPC) infrastructure and training facilities;
- Create the capacity of nationally self-sufficient capacity development in bioinformatics and its applications through short, medium and long term trainings;
- Offering databases and software tools for bioinformatics;
- Establishing networks with external partners;
- Providing continuous bioinformatics support for bio-scientists in Ethiopia;
- Increasing bioinformatics awareness in Ethiopia;

[125] Facilities shall include incubation centers, technology parks, greenhouse, field stations, laboratory animal handling facilities, animal breeding facilities that include farms, ranches, multiplication centers, etc

- Providing online bioinformatics training resources for wider use.

4.1.2. Development and retention of skilled human resources for biotechnology

Apart from a good knowledge of basic molecular biology, biotechnology requires a convergence of multiple skills, including bioinformatics, information technology, related biosciences and engineering as well as business management, product development and legal issues. As no one person is likely to be able to become an expert in all these skills, specialists in the above fields will also be required. To this end, the following needs attention:

- Increase the quality of training in biotechnology
- Provide more options for professional specialization in graduate programs and explore ways to enhance the standing of biotechnology training and improve facilities at universities. The accumulation of innovation capabilities by the industry crucially depends on the availability of qualified biotechnology professionals.
- Provide more opportunities for upgrading the skills of those already in the workforce and improve the effectiveness of short-term training. An expansion of part-time tertiary training and other lifelong learning offerings would help address some of the gaps in "*soft*" and "*hard*" skills and provide a further boost to labor productivity. Overall, policy should pay attention to the effective and efficient use of available human resources in government organizations, research institutes, universities and enterprises.
- Use public-private partnerships (PPPs) to encourage the industry to take a greater part in the national effort on biotechnology education and skills development. The private sector should be encouraged to increase their investments in biotechnology research and training, to fund demand-tailored specialization or programs, and to engage in curricula development. This will not only involve biotechnology but also "soft skills".
- Turn a *brain drain* into a *brain gain*. To address some of the skills constraints, the government could make a significant effort to scout potential returnees and give them powerful incentives (in the form of special remuneration packages and/or key management positions) to return. This should be complemented by the provision of a sound working environment and reduced bureaucratic administrative procedures. If sustained long enough, this process could catalyze other developments, such as attraction of knowledge-intensive investments, improved access to global knowledge production networks, and better training and education of human resources. It is important that sufficient jobs with competitive remuneration packages be established in Ethiopia so that talented people can be attracted and retained. In addition, the training of scientists in entrepreneurial and innovative skills will be required.

- Improve pay structure and working environment in all higher learning and research institutes as well as schemes for rewarding excellence. The BAC shall establish a competitive funding system involving multidisciplinary teams from the public and private sectors with a good amount of money given to those research groups that come up with the best research and innovation ideas involving post graduate students. In addition, there should be a provision where a minimum of 10% of the project grant is directly paid to the PI(s) and Co-PI(s) of the project as part of rewarding excellence.

4.1.2.1. Establishment of career opportunities

The establishment of center(s) of excellence (CoEs) and regional hubs in biotechnology employing biotechnologists will contribute significantly towards creating career opportunities for experienced and well-trained individuals. The staffing of CoEs and the various regional hubs that involve universities, research institutes and the industry would include a management and a core group of specialists to maintain the infrastructure. Associated with the CoEs and regional hubs will be a number of program leaders and professional staff (including post-doctoral fellows) and technical staff, who will be on contract appointment and assigned to the projects. In addition, support for start-up funding would lead to an expansion of the biotechnology industry and thereby to a better absorption of young scientists into career paths in biotechnology in the country. It is also important to consider scholarships for advanced study abroad as a strategic tool for national capability accumulation. These should ideally form part of broader strategies for biotechnology development and include research, training and internship components that involve or take place in the productive sector.

4.1.2.2. Fast-tracking the human resources needs of the CoE(s) and regional hubs for biotechnology research and innovation

There is a need to establish a number of postdoctoral salary schemes competitive with those on the international market. The implementation of this strategy will also increase and stimulate the opportunities for graduate fellows, research fellows, post-doctoral fellows and offer the opportunity for them to enter the biotechnology job market.

4.1.3. Creating viable research and industry interface for biotechnology research and innovation

The generation, transfer of knowledge and technology, encompassing intellectual property, from HLIs and public research institutions into the market place is recognised as being of crucial importance in the establishment of a strong research environment and a knowledge-based economy. In Ethiopia, serious

deficits exist in the areas of awareness, identification, evaluation, capture, protection and commercialisation of ideas.

There is limited support for the commercialisation of biotechnology in the country; hence only a few biotechnology companies exist. There are a number of reasons for the failure of investment in R4D to generate commercial products. Key factors that stimulate the biotechnology industry are shown in Table 5.

Table 5. Summary of the basic foundations for the successful commercialisation of biotechnology products

Biotechnology Venture			
Research and development	**Regulatory support**	**Finance and business**	**Product development and marketing**
• Competence in research platform capable of generating competitive products, processes and/or services • Strong linkages between academic, research and private sector institutions • Access to funding	• Registration, maintenance and protection of IPR • Shared ownership of IP as an incentive for inventors to commercialize ideas • Grants and other support from government for concept development and proof of concept	• Funding for product development, testing, approval and marketing • Competent management of research and company development • Business incubation	• Market intelligence for strategic development and marketing decisions • Ability to get products through trials and regulatory agencies • Commercial skills to get the product / service to the market • Expansion capital

A two pronged approach needs to be implemented to upgrade the performance in the management and commercialisation of products and technologies from publicly funded and collaborative research. This will involve strengthening the IP/Commercialisation functions within the higher education and research institutes and supporting this, where relevant, with a central source of specialist expertise. The mix of strong local action combined with central support for resource intensive and cross institutional tasks is a model which will deliver comprehensive assistance in this key area of the knowledge economy. This should be supplemented by the development of a range of measures supported by MiNT, BAC/BETin to develop collaborative links between industry and academic researchers.

In order to create industrial opportunities for biotechnology research and innovation in the country the following strategies should be followed:

(i) Encourage linkages between the private sector and CoEs/regional biotechnology hubs:- This approach could be followed for attracting major R4D investment from national and international partners and companies in the areas of biotechnology in the country.

(ii) Create biotechnology industry in sectors that are well aligned with national imperatives, market demand and national expertise:- A primary recommendation of this strategy is the creation of R4D hubs/clusters and CoE(s) in order both to build the technology platforms required to support a biotechnology industry and to populate the new product (or service) development pipeline, which could result in new self-sustaining companies serving national and international markets. Selecting the most appropriate focus areas of each hub/cluster/CoE will be essential to the success of this strategy.

4.1.4. Bridging biosciences research and entrepreneurship

The inadequacy of a strong science base coupled with proper technology and technology incubation mechanisms as well as enabling policy that would move bioscience research and innovations along the innovation chain and to the market place has been a big hindrance in integrating technologies into key sectors like agriculture, health, environment and industry in Ethiopia. Conscious of the limited capability of the research organizations and academia in the country to move research output from the experimental set up to the marketplace, the R4D Program, in its implementation process, shall apply innovation systems approach to catalyze the translation of research outputs to innovations in a sustainable manner for impact.

For effective implementation of the Program, public research organizations (federal and regional), universities (research universities and the two science and technology universities) need to partner with the industry/private sector. This linkage improves the chances of the country benefitting from the rapidly advancing field of biosciences. In doing so, the R4D Program in biotechnology contributes towards the development of a bio-economy in the country.

For this to materialize, a multi-disciplinary and multi-sectoral approach to collaborative innovation and entrepreneurship is essential to achieving knowledge based and innovation driven bioeconomy of the country. Increasing networking and collaboration between education and research, private and public sector stakeholders will facilitate the co-creation, adaptation and commercialisation of research and innovation outputs. This will ensure biotechnology research and innovation programs that are regularly valorised for impact and alignment with national development plans as these continue to evolve. Such

commitment to national and cross-institutional coordination of biotechnology research and innovation actors will strengthen the socio-economic situation of the country through local ownership and wider utilization of research outputs and technology acquisition. Taking a systematic approach to technology transfer and knowledge sharing, co-creation and adaptation of new products, services, processes, business models and policies and commercialization of research and innovation outputs will stimulate local, regional and national innovation ecosystems[126]. This will result in better public services (including entrepreneurial innovation), the creation of new economic sectors, wider employment opportunities in the formal economy and commercialization of technologies with national relevance and global potential.

Translating biotechnology innovations into viable commercial enterprises/ into startup biotech companies in the areas of agriculture, health, industry and environment involves:

a) Develop an '*Ease of Doing Science Index*' to ensure effective use of both disbursed funds (including flexibility of fund utilization) and the researchers' time.
b) Enabling support to start-ups to propel their technology from proof of concept to manufacturing, prioritization and indigenization of technologies, self-reliance in consumables, equipment, reagents, instruments for R4D.
c) Two-pronged approach of import substitution of key reagents/products/ instruments while increasing the export of '*Made in Ethiopia'* biotechnology goods and services.
d) R4D clustering approach with flexible governance models with enhanced private sector investment and promoting co-location and co-development of market-driven interventions within academic laboratories through industry-academia partnerships.
e) Setting-up of Centers of Excellences (technology incubation centers) and Technology Transfer Offices (TTOs) to strengthen Ethiopia's IPR landscape.
f) Strengthen biotech-driven SMEs involving agro-processing industries.

4.1.5. Creating enabling biosafety and IPR regimes

Proper biosafety and IPR regulatory framework for enabling smooth and efficient implementation of the proposed Ten-Year Implementation Plan on biotechnology research for development in Ethiopia should also be worked out as follows:

- Revise the Ethiopian biosafety law to accommodate NBTs such as genome-editing and synthetic biology

[126] National Innovation Ecosystem

- Alignment and clarity of role is important among public institutions involved in biosafety regulations
- Continuous public awareness exercise is important
- Active participation in regional and continental harmonization initiatives help to share experiences
- Policy guidance and strict adherence to ethical and safety standards are critical for some of the health research and development activities proposed in this plan
- Biosafety levels of local laboratories will have to be certified and accredited for fitness to conduct genetic engineering-related biotechnology research
- Establishment of Institutional Biosafety Committee (IBC) in universities and research institutes
- The current IPR system in Ethiopia would facilitate and promote biotechnology research and product development in Ethiopia.

4.2. Mobilizing financial resources for implementation of biotechnology R4D program

The National Biotechnology R4D Program offers the country an opportunity to rapidly move towards a knowledge-based and innovation-led bioeconomy. The success of the Program depends on a number of factors, including increased R4D budgets at national and regional levels. The Government is expected to take action in allocation of at least 1% of GDP to STI as per the understanding of African Union Member States to ensure that the country maximizes ownership and responsibility for its own developmental path. For effective implementation of the Program at various levels, a strategy to mobilize domestic and alternative financial resources should be developed to accelerate implementation and reduce over-reliance on external resources.

4.2.1. National science, technology and innovation fund

MiNT and BETin have demonstrated leadership in establishing national funds for research and innovation as well as, in some cases, entrepreneurship. A number of universities have also established calls for research proposals to promote research collaboration. It is essential that all institutions adequately prioritize investment in STI research and innovation as well as entrepreneurship.

At the national level, there is a need to streamline funding for STI, and entrepreneurship into national development strategies and adapt existing STI policies to support implementation of the National Biotechnology Program. Within a national STI fund, there is also a need to establish Biotechnology

Research and Innovation Fund (BRIF) to support existing or new specialized centers for excellence that respond to the National Biotechnology Program priority areas as well as cross-institutional research and innovation collaboration addressing common challenges. These funds will drive specialized CoE initiatives, and ensure wider sustainability.

4.2.2. Biotechnology research and innovation fund

For effective implementation of the National Biotechnology R4D Program, domestic resources should be mobilized for biotechnology research and innovation. External technical and financial support should help strengthen the domestic funding base, thus supporting sustainability. Further, there is also a need to upscale the MiNT and BETin innovation fund for biotechnology research and innovation targeting R4D clusters and CoEs as a national financial instrument. To ensure that the proposed BRIF is sufficiently well endowed and functional, it is crucial that adequate financial resources are mobilized from the public and private sectors, funding communities both inside and outside Ethiopia, and actively engaging other alternative sources of funding.

New and innovative financing mechanisms should be created for effective implementation of the national ten-year biotechnology R4D Program in Ethiopia. This include:

(i) ***Provide sustainable funding for the Biotechnology R4D Program***:- A number of strategic interventions for sustainably mobilizing resources for biotechnology R4D as shown in Table 4 which include:

- Funding for the BAC, principally to cover advisory services and policy studies
- Funding for R4D hubs and CoE(s) establishment
- Program funding for R4D hubs and CoE (s). This funding scheme will be required for research and equipment that will be shared by different groups in the R4D hub and/CoE
- Strengthening the interaction between industry and academia, as well as the creation of tax incentives to encourage private sector biotechnology companies to invest in biotechnology
- Establish a venture capital fund to assist in the transfer of technology from research laboratories to start-up companies
- Funding for strengthening institutional capacity (standardized lab facilities and infrastructures of universities and research institutes) for generating scalable technologies in collaboration with industries

(ii) ***Maximize the impact of limited public resources***

- Increase the budgetary resources for funding proven/promising public support Programs, alongside measures to improve their design and implementation. In this context, consider an

(external) evaluation of ongoing programs that support business innovation, starting with a comprehensive inventory. This could be led by BETin, MoF and MoPD in consultation with R4D hubs and/CoE(s).

- Establish matching-fund mechanisms, e.g. to enhance the effectiveness and efficiency of the Biotechnology Research and Innovation Fund (BRIF) in supporting industry investment in technological innovation.
- Streamline the existing tax incentives and simplify the procurement and financial procedures of biotechnology R4D in line with international good practices. MiNT, in cooperation with MoF and MoPD, appears best suited to lead an evaluation of the tax treatment of R4D and innovation-related investment in the country.
- When deciding on priorities for building innovation capacities, seek to relate national strengths to emerging global opportunities. Consider a suitably adapted PPP pilot program for R4D and innovation that would help focus attention and resources, leverage additional resources, and improve cooperation between public research and domestic and foreign-invested business actors.

Funding for biotechnology R4D can be mobilized from the following principal sources:

- Government funding to STI (biotechnology research and innovation)
- Competitive research grant by universities and research institutes
- Biotechnology innovation and demonstration of pilot technologies fund
- Donor and international funding agencies
- Private sector
- Venture capital
- Endowment fund
- Research foundations

(iii) Enhancing international co-operation for technology transfer

Strengthening international networks could considerably improve the efficiency of knowledge generation and technology acquisition. This will leverage the existing investments and improve the efficiency of R4D institutions. CoEs and hubs need to strategically establish partners for the platforms in biotechnology: a key component of the success of the CoEs and hubs will be the creation of strong international linkages with equivalent institutions that are at the leading edge of biosciences research in their fields. It is envisaged that the proposed BAC will be responsible for the performance of hubs and CoE(s) through ongoing evaluation according to performance indicators as shown in Table 4. At least one

of these measures will relate to the success with which the relevant center has established international linkages.

Program partners: Biotechnology R4D is often characterized by a major initial capital investment in equipment. One of the objectives of the CoE(s) is to provide access for its network of users to such equipment. A priority for the Government is to ensure participation by industry at the program level within each center. It is therefore proposed that the program develop joint projects with equipment suppliers whereby the suppliers either donate or share a portion of the costs in exchange for beta testing[127] of new prototypes.

Bilateral agreements: Ethiopia has entered into a large number of bilateral agreements, some of which specifically cover science and technology cooperation. It is recommended that strong linkages be formed between programs in this biotechnology R4D and leading biotechnology institutions in countries with which Ethiopia has bilateral agreements as well as seek new ones. In addition, information on existing agreements shall be disseminated through the MiNT and BETin's internet portal for the biotechnology industry.

AU Agenda 2063: The AU Agenda 2063 recognizes Science, Technology and Innovation (STI) as multi-functional tools and an enabler for achieving continental development goals. The Agenda, further, emphasizes that Africa's sustained growth, competitiveness and economic transformation requires sustained investment in new technologies and continuous innovation in areas such as agriculture, clean energy, education, health and the environment. Biotechnology should be a cornerstone of this Agenda, the details of which need to be negotiated with AU and African partners.

[127] Beta testing refers to the testing of new prototypes or versions of products prior to market launch. The product is normally provided at no cost to the user in exchange for feedback on its performance.

PART V. INSTITUTIONAL ARRANGEMENT AND SYNERGY FOR IMPLEMENTATION OF NATIONAL BIOTECHNOLOGY R4D PROGRAM

The successful implementation of this national biotechnology R4D program primarily depends on the suitability of the chosen institutional arrangement, the capacities and complementarities of the institutions involved. Figure 31 provides a proposed arrangement of the different structures that could be involved in the national biotechnology R4D Program implementation processes. The illustration below presents relevant stakeholders/actors.

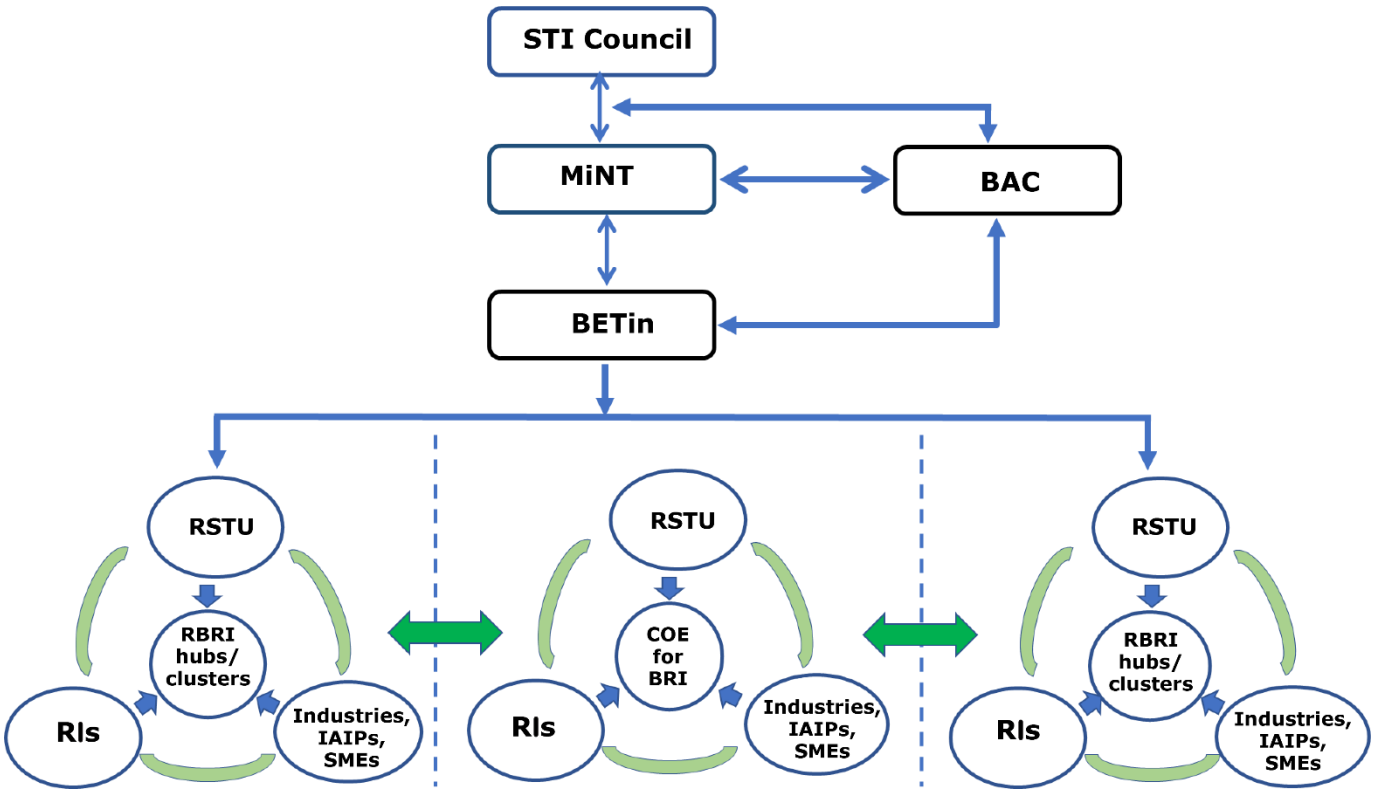


Figure 31. Proposed institutional arrangement for the implementation of national biotechnology R4D Program

Note:

- BAC- Biotechnology Advisory Committee; CoE- Centre of excellence for BRI; BRI-biotechnology research and innovation; RBRI-regional biotechnology research and innovation; RIs, Research Institutes; RSTU- research (8) and ST (2) universities, as per the differentiation of

HLIs by MoE; IAIPs- integrated agro-industrial parks; SME- small and medium agribusiness enterprises

- The Centre of Excellence for biotechnology research and innovation will serve as a bioscience and technology platform and will possess incubation facilities, technology parks, and research programs. The number of COEs addressing the four biotechnology sectors will be determined by the BETin depending on the existing realities on the ground.
- The regional biotechnology research and innovation hubs shall be created on the basis of geographical proximity, R4D specialization, and existing scientific base.
- Other comprehensive and technical universities can also collaborate with RSTU and regional hubs as well as the CoE for training, research and innovation activities where biotechnology activities are believed to contribute to both institution capacity and national development.

5.1. Development of a coordinated biotechnology R4D program implementation

The development and execution of a strong biotechnology R4D program in Ethiopia requires a detailed assessment of the current situation regarding first, second and third generation biotechnology in order to identify the existing strengths and to build on these wherever possible. In R4D Program implementation, focus on coordination between the various stakeholders, from research institutions, academia and to industry is pivotal. An effective strategy needs to promote the development and utilization of biotechnology at three levels:

- Research and technology development
- The development of research findings into products
- The commercialization of the products on national and international markets

A strong biotechnology R4D Program therefore requires not only coordination between people and institutions, but also a multidisciplinary approach involving scientists, engineers, economists, lawyers and business managers.

There are regions in the country that have a number of universities and research institutes in close proximity. Number of agribusiness enterprises (SMEs) and integrated agro-industrial parks are also being created in the various regions of the country. However, most of these do not collaborate with each other, and in most cases, there is duplication of activities among higher learning and research institutes. All require similar infrastructure and equipment, but experience difficulty in acquiring them. Among them there is often a skill-base in basic and applied biotechnology. It is necessary to identify the Center of Excellence in the biotechnology sectors and provide the necessary enabling support in order to promote collaboration and increase research and innovation efficiency while maximizing optimum use of scarce

resources. A good intervention would be to create a coordinated biotechnology Program implementation in the country.

5.1.1. Creation of a biotechnology advisory committee

The Ministry of Technology and Innovation and BETin are mainly responsible for the development of biotechnology research and innovation in the country. There is a strong need for a built-in institutional arrangement that can provide technical advisory support to the STI Council, MiNT and BETin. To this end, creation of a Biotechnology Advisory Committee (BAC) is necessary for overseeing and providing advisory services to MiNT and BETin in biotechnology development in general and the biotechnology R4D Program implementation in the country in particular.

If the country is to make a concerted effort towards the establishment of a strong biotechnology industry in Ethiopia, there is a strong need for a champion to drive this process. It is recommended that a national Biotechnology Advisory Committee (BAC) be established to ensure that this Program focuses on national priorities and promotes coordination between the different components of the national innovation ecosystem. The BAC will have representatives from a diverse group of stakeholders (academia, civil society, the research community, the industry and Government as well as specialists in the four areas of biotechnology), supported by a secretariat from MiNT/BETin. The BAC will:

- Be an advisory body appointed by the Government under the auspices of MiNT and reporting to MiNT/BETin[128]
- Oversee and provide support in the implementation of this national Biotechnology R4D Program
- Ensure that the Program implementation by the various actors is aligned with national priorities
- Identify national biotechnology priorities, in addition to those mentioned in this Program
- Identify and support the establishment of center(s) of excellence and regional biotechnology research and innovation hubs within established guidelines for the promotion of synergy in the biotechnology community
- Recommend to MiNT/BETin and other funding agencies, the appropriate programs and expenditure on biotechnology in the country
- Promote the investment of venture capital in biotechnology and the search for industrial partners,
- Support in resource mobilization for biotechnology R4D Program implementation (skills, funds and facilities)

[128] It is not clear whether BETin is to evolve as a good coordination wing or center of excellence for biotechnology research and innovation in the country. This requires deliberation by the STI council and BAC on which way to organize the Institute.

- Facilitate and advice on forging collaboration and partnerships with proper regional and international partners, and
- Establish a sub-technical advisory committee for agricultural, medical, industrial and environmental biotechnology, and biosafety.

5.1.2. Creation of centers of excellence and regional hubs for biotechnology R4D in the country

It is widely known that since its origin, biotechnology has developed around centers of excellence identifiable as biotech clusters[129]. In the biotech industry, geographical proximity plays a pivotal role in facilitating the use and transfer of technologies and tacit knowledge that are the key to successful development. Three kinds of advantages are identified in the formation of biotech clusters: (i) productivity advantages, due to the use of better specialized inputs (shared facilities, components or services); (ii) innovation advantages, due to the proximity to knowledge centers; and (iii) new business advantages, due to better circulation of information about market opportunities and potential involving private sectors. In the Ethiopian scenario, though biotechnology industry is at its very low level, through making use of latecomer advantage, creation of shared platforms for biotechnology research and innovation activities will enable to capture the above three advantages.

Research and innovation productivity in biotechnology can be enhanced through: (i) the establishment of high trust relations among academia, research institutes and the private sector within a cluster; and (ii) the exploitation of joint purchasing services as well as of shared dedicated facilities. Such an approach will result in reduction of transaction costs, minimize duplication of efforts, and increase productivity of the programmatic R4D focus areas. Moreover, shared dedicated biotechnology infrastructures (e.g. specialized labs or other facilities offered by incubators and/or science parks) help in reducing fixed costs for innovators and initial investments for new ventures, thus sustaining the growth process of the cluster. Finally, clusters themselves may represent a sort of ‘‘magneto’’ for a highly qualified workforce, thus enhancing labour flexibility within institutions and lowering searching costs for personnel. Despite the extensive efforts regarding the creation of centers of excellence, science and technology incubation centers and university and industry linkages in the Ethiopian Universities remain a ‘‘**black box’’** where the study of internal dynamics and development mechanisms is often neglected.

[129] ‘a cluster is a pronounced geographic concentration of biotechnology research and innovation activities aiming at production of a product or a range of similar products, as well as linked institutions that influence the competitiveness of these concentrations (e.g. education, research institutes, private sector, infrastructure and research programs)

Cluster or hub creation in biotechnology is actually driven by the continuous generation of new science-based biotech start-ups or dedicated biotech firms. However, this process of generation of biotech-startups is not a self-sustaining process, i.e. it is to be nurtured by a favourable environment. The key factors affecting this favourable environment are shown in Figure 32.

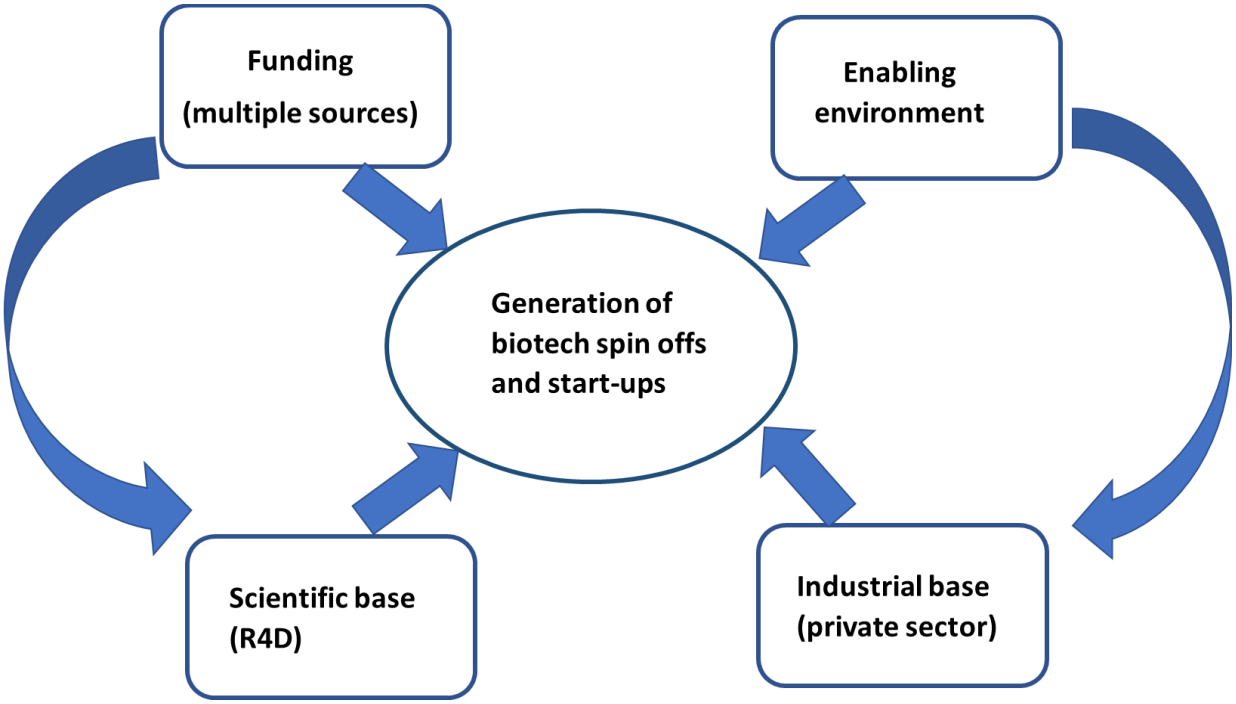


Figure 32. Creation and growth mechanisms of a cluster or hub for biotech research and innovation.

Two kinds of spin-offs can be identified: (i) academic spin-offs, in which universities or the public research centers play a major role. The idea, in this case, starts in the academic labs and a new firm is created by university people (maybe jointly with business people) in order to exploit it commercially; and (ii) industrial spin-offs from large industrial companies. In some cases, these spin-offs are planned by the corporate, which facilitates the creation of independent firms focused on biotech businesses. In the Ethiopian case scenario, the first kind of spin offs may predominate and requires nurturing by creating a supporting environment. The Biotechnology Advisory Committee will have roles in nurturing the creation of spin-offs and start-ups from the various R4D programs (agriculture, health, industry, and environment). This should be one of the performance indicators for the successful implementation of the biotechnology R4D Program towards the end of the ten-year implementation period.

The academic origin of start-up companies, moreover, facilitates the establishment of strong links and networks between industry and science. These two effects, in turn, reinforce the industrial and the

scientific base of the research and innovation base of biotechnology and therefore provide the basis for the generation of new ventures (which becomes a factor of attractiveness for financial actors).

Experiences show that there are two major forms of cluster creation: (i) spontaneous clusters, that are the result of the spontaneous co-presence of key factors; (ii) policy driven clusters, that are triggered by the strong commitment of governmental actors whose willingness is to set the conditions for the cluster creation, either as a response to an industrial crisis or as a deliberate decision to foster the biotech sector. In a few cases, both forms of cluster creation coexist, thus determining a hybrid process. It may be evident that in the process of organizing the various actors involved in biotechnology research and innovation activities into biotechnology R4D clusters in the country, some of the existing organizations can be clustered as a result of the spontaneous concentration of the key factors enabling its birth and development especially in the agricultural and health biotechnology sectors. On the other hand, in the case of creating clusters, a policy-driven approach could trigger the strong commitment of the government to set the conditions for the development of industrial and environmental biotechnology R4D clusters.

Since the biotechnology R4D capacity is extremely low in Ethiopia, wait and see approach is not an option to benefit from the latecomer opportunity. In order to leapfrog in biotechnology research and innovation, there is a strong need for a deliberate and strategic policy driven intervention in the creation and strengthening of biotechnology R4D hubs in the country. Policy-driven formation of hubs should be the result of systematic policy decisions to foster the development of biotechnology research and innovation base of the country. The intervention of the government shall aim to put in place factors enabling the birth and development of a biotechnology research and innovation base. The key aspect is to improve the entrepreneurial ‘‘attitude’’ and favor the generation of products and technologies for spinoff and startup companies.

Moreover, the concept of *policy-driven hubs* highlights that actions undertaken by public actors can actually trigger (or strongly support) the creation of essential biotechnology hubs. These actions are the only way of leveraging existing favorable conditions (industrial and/or scientific base) in order to create biotech hubs in those areas where the presence of such conditions is not so strong as to spontaneously ‘‘trigger’’ the birth process of a cluster.

Though creation of a number of CoE(s) specialized in the various areas of biotechnology in the country would be ideal, it will be prudent to at least establish a CoE for biotechnology research and innovation to provide biotechnology platforms in response to the identification of biotechnology focus areas. In the short-to-long term plan, establishing the number of CoEs in various regions of the country will be

determined based on regional specialization and identified existing capacities in terms of human, and infrastructure resources as well as concentration of biotechnology related research activities in institutions in its proximity. However, the existing R4D actors including industrial parks and agribusiness SMEs can be networked to form a regional biotechnology research and innovation hub for sharing resources and generation of technologies with societal impact. Each hub can establish more than one program, according to regional expertise and demand. The biotechnology platforms are envisaged as acting as common areas where capital equipment and specialized expertise will be shared by the biotechnology programs and industry. Two major components of the platforms have been identified as being crucial for the success of the biotechnology R4D Program:

i. ***Biological resource centers:*** are an essential component of the infrastructure underpinning biotechnology R4D. They are responsible for preserving and distributing biological materials and information. They are crucial to the exploitation and maintenance of our diverse natural heritage.

ii. ***Bioinformatics networks:*** Bioinformatics has become an indispensable part of the infrastructure required for biotechnology research. Furthermore, human resource capacity in bioinformatics has become increasingly important across the spectrum in biotechnology (agricultural, medical, industrial and environmental biotechnology). The enhancement of competency in bioinformatics has the potential to place Ethiopia at the forefront of this field.

Apart from bioinformatics and biological resource centers, which are considered to be essential facilities or technologies for CoE and regional hubs, it is recommended that each regional hub specialize in a one of a number of more specific areas of technology, which are in turn well aligned with the national imperatives, local expertise and market opportunities. Before the creation of regional hubs in biotechnology, a sounding and competent national biotechnology center of excellence (CoE) has to be established. Once such CoE(s) is established, the modalities of regional hubs can be realized in terms of national and regional benefit.

It is essential that each center also accommodates a biotechnology incubator, which in turn will be linked to a number of industries for enabling spin-off companies (Fig. 30), thereby ensuring that the outcomes of the R4D in the programs have the necessary infrastructure to support their commercialisation. The incubators are an important component of CoE and regional hubs in assisting with the commercialisation of innovations arising from a biotechnology R4D program and/or project. An incubation is necessary to ensure that the appropriate framework is in place for the support of entrepreneurs in transferring technology from the laboratory to the marketplace.

A further component of the regional hub's network is the close association with industries and investors (agro-process industries, seed companies, etc.) located in the region. The integrated agro-industrial parks, small and medium scale agribusiness enterprises operating in the region, and other multinational companies will be attracted as a result of the development of the regional hubs in overlapping areas of expertise. For instance, a manufacturer of vaccines could be attracted to CoE and regional biotechnology research and innovation hub that has a strong program in vaccine development; an industry interested in the production of biodegradable plastics will be attracted to a hub that has a strong research program in resource recovery and production of biodegradable materials.

The Regional biotechnology research and innovation hubs will be responsible for:

- The establishment and maintenance of technology platforms to be available internally and for satellite groups.
- The establishment of associated biotechnology incubators to facilitate spin-off companies and technology transfer from laboratory to commercial entities

PART VI. NATIONAL BIOTECHNOLOGY R4D PROGRAM IMPLEMENTATION MONITORING AND EVALUATION SCHEMES

1.1. Monitoring and evaluation scheme

The shortage of a built-in monitoring and evaluation (M&E) system with the implementation of the biotechnology Roadmap made it difficult to demonstrate the achievements of the Roadmap and the contribution of biotechnology in addressing Ethiopia's challenges. There has been a limited focus on assessing how biotechnology research efforts are contributing to solving the needs in agriculture, health, industry and the environment in the country.

The National Biotechnology R4D Program is a strategic intervention of the country's STI sector in support of the national development plan. The Program has adopted a cross-sectoral and multi-disciplinary approach which intends to strengthen the use of biotechnology research and innovation in addressing socio economic challenges of the country. To ensure that the Program is properly implemented, there is a need to embed in M&E mechanisms that will enable continuous performance assessment as programs and projects are rolled out by national CoE and regional hubs involving universities, research institutes and the industry as well as multiple funding agencies and the wider stakeholders.

The M&E system will:

- Facilitate learning, transparency and accountability;
- Guide the design, implementation and review of policies and programs;
- Enhance the processes of embedding biotechnology research and innovation in all development sectors (agriculture, health, industry, energy, and environment);
- Ensure appropriate biotechnology research and innovation indicators in all development sectors;
- Ensure effective communication and build trust among stakeholders;
- Strengthen knowledge generation, management and translation; and
- Support the implementation and coordination of biotechnology research and innovation programs.

The Program will be implemented by the Ministry of Innovation and Technology and Bio and Emerging Technology Institute with active involvement of research communities from the R4D institutes, academia and the private sector. At each level, programs/projects will be co-designed, validated, implemented,

communicated and evaluated. MiNT/BETin assisted by the BAC. The BAC will provide leadership to secure active participation and contribution by a critical mass of relevant public, private, education and research, societal, international development and funding sector stakeholders to co-design and implement the various flagship programs and initiatives resulting from the national biotechnology Program. BETin, BAC and program/project leaders will also coordinate the Program implementation and submit bi-annual implementation status reports to the Biotechnology Council and MiNT.

International development partner institutions will collaborate with MiNT/BETin to support successful implementation of the national biotechnology program by providing financial and technical assistance and aligning current and future programs. They will also play important multiplier roles in popularizing the importance of biotechnology research and innovation in Ethiopia's development. The private sector will work closely with public, education and research, societal, funding and national and international development agencies to support building the necessary capacities and technical competencies of research and academic institutions required to achieve the objectives of the Program.

1.2. Monitoring and evaluation implementation plan

The M&E Plan consists of a logical framework which outlines the major drivers of performance with regard to effectiveness and efficiency; which links goals, objectives and actions shall be developed by the BAC/BETin at the onset of Program roll out. The following will be undertaken to implement the M&E plan:

1. Definition of performance indicators - In consultation with stakeholders, the BAC and BETin will, as part of the M&E planning, define a set of agreed targets and performance indicators (2024-2033).
2. Tracking performance – BAC and BETin will track a minimum set of performance indicators at national level to measure achievement of priorities set in the Program. Each Program and or projects will incorporate performance indicators in their program implementation.
3. Integrated learning - Lessons learnt, good practices and unintended impacts will be systematically documented by all involved institutions to allow knowledge sharing and inform bi-annual reviews of the Program. Based on lessons learnt, multi-stakeholder dialogues will be established to ensure positive feedback into planning at national, and institutional levels.
4. BAC shall also put in place for mechanisms that all performing and funding agencies report on an annual basis their expenditure on biotechnology.
5. Constant monitoring of the impact of biotechnology expenditure, including the establishment of new companies, the creation of employment and the improvement of quality of life.