GOVERNING EMERGING TECHNOLOGIES OF GLOBAL SIGNIFICANCE IN THE DEVELOPING COUNTRIES: THE CASE FOR SYNTHETIC BIOLOGY REGULATION IN KENYA

BY

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DECLARATION

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ABSTRACT

Technologies with transnational impact can no longer be relegated as 'mundane artefacts' in International Relations (IR). Two recent events validate this assertion. In 2014 world found itself in stress and confusion due to unprecedented Ebola attack. Very recently the novel COVID-19 threatened the very existence of mankind. In both events synthetic biology (SynBio) techniques saved the world, by enabling scientists to study and imitate the genetic make-up of the viruses and create a vaccine. Despite such immense value of SynBio, the field remains dominated by developed nations. Additionally, effective global governance of SynBio requires proper regulation in all countries including developing countries like Kenya. Against this backdrop, and motivated by the fact that despite the Government of Kenya (GoK) commissioning a synthetic biology (SynBio) project in 2020 in line with her Vision 2030, it remains blurred the extent to which Kenya's current biotechnology regulatory frameworks are sufficient to the regulation of SynBio, this study explored Kenya's biotechnology regulatory environment. Study specific objectives explored: Kenya's biotechnology-related policy frameworks; biotechnology-related legislations; the extent to which the theme of Science, Technology and Innovation (ST&I) is embedded into selected national development plans (NDPs) and; key expert stakeholders' perceptions and expectations on the adoption of SynBio technologies in Kenya. A conceptual framework derived from the concept of national power as used in International Relations and the theory of adaptive anticipatory governance guided the collection, analysis and interpretation of findings. Exploratory sequential mixed-method design was utilized. Study locations were Nairobi, Kisumu, Kakamega, and Kisii Counties and on Zoom, Google Meet and Gmail platforms. Study population composed 83 purposively sampled experts stratified into academia, research, industry, medical, and policy, governance and regulatory and media & communication sectors. Data collection was done through documentary analysis of 6 policies, 8 legislations, and 5 NDPs; survey questionnaires, 4 Focus Group Discussions (FGDs), and 22 key informant interviews (KIs). Quantitative data was analyzed through simple descriptive statistics while qualitative through thematic analysis. The study established, a) while the biotechnology development policy 2006 and Biosafety Act 2009 are the main policy and legislations, respectively, governing biotechnology in Kenya, their scopes do not however cover biosecurity, ethical, social and economic issues that come handy with SynBio regulation; b) Kenya Vision 2030 and the Big Four Agenda place ST&I at the core of national development, but the ST&I theme is not emphasized in other NPDs and the place of biotechnology in these two key NDPs and other relevant NDPs is not properly spelt out; c) there is above average national capacity to adopt and implement SynBio in terms of requisite human expertise (90%); further, key regulatory and research institutions were rated above average: NACOSTI-86%; NBA-60%; KALRO-67% and KEMRI-60% except for NEMA-46%. These findings lead to the conclusion that Kenya has a robust biotechnology regulatory system but to optimally gain from SynBio technologies, the biotech governance frameworks will have to be tailor-made to cover the unique SynBio regulatory issues. The study thus recommends to the GoK and concerned stakeholders to ensure the establishment of clearly spelt-out SynBio policy, legislation and an overarching NDP. The findings of this study thus revealed the extent to which current biotech governance in Kenya can regulate SynBio. Such evidence is relevant to IR debates insofar as it will inform debates around global governance of SynBio. The evidence is also locally relevant as it showcases to policy makers and other concerned stakeholders the underlying limitations to utilizing SynBio as an engine to revitalizing Kenya's bio-economy, and consequently assert herself as a regional SynBio powerhouse. Such include political economy challenges emanating from an almost fully donor-funded approach which permeates current biotechnology development in Kenya.

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LIST OF ABBREVIATIONS AND ACRONYMS

A*STAR	Agency for Science Technology and Research
ABS	Access Benefits Sharing
ABTs	Aichi Biodiversity Targets
ACB	African Center on Biological Diversity
ACC	African Conservation Centre
ACTS	African Centre for Technology Studies
AHTEG	Ad-hoc Technical and Expert Group to the Convention of Biological Diversity
APHIS	Animal and Plant Health Inspection Service
ASAL	Arid and Semi-Arid Land
ASCU	Agricultural Sector Coordination Unit
ASDS	Agricultural Sector Development Strategy
ASS	African Sub-Saharan
ATLC	Agri-Tech Leadership Council
BWMD	Biological Weapons of Mass Destruction
BWTC	Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and Their Destruction
CAADP	Comprehensive African Agricultural Development Programme
CBD	Convention on Biological Diversity
CBI	Confidential Business Information
CDC	Centers for Disease Control
CFRB	Coordinated Framework for Regulation of Biotechnology
CIS	Climate Information Services
CoG	Council of Governors
COPs	Conference of Parties
COVID-19	Corona Virus Disease

CTCN	Climate Technology Centre and Network
DIYB	Do-It-Yourself Biology
DNA	Double-nucleic Acid
DOE	Department of Energy
EBS	Equitable benefit sharing
EC	European Commission
EIA	Environmental Impact Assessment
EIU	Economist Intelligence Unit
ELSI	Ethical, Legal, and Social Issues
EPSO	European Plant Science Organization
ERSWEC	Economic Recovery for Wealth and Employment Creation
ESC	European Scientific Committees
EU	European Union
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FGDs	Focus Group Discussions
FOIA	Freedom of Information Act
FY	Fiscal Year
GAO	Government Accountability Office
GDP	Gross Domestic Product
GEF	Global Environment Facility
GHG	Green House Gas
GMO	Genetically Modified Organisms
GoK	Government of Kenya,
HACCP	Hazard Analysis Critical Control Point

IBCs	Biosafety Committees
IBLC	Industrial Biotechnology Leadership Council
ICRC	International Committee of the Red Cross
ICT	Communication Technology
IDIs	In-depth Key Informant Interviews
IDS	Institute of Development Studies
iGEM	International Genetically Engineered Machine
IGSC	International Genome Synthesis Consortium
IKCE	Indigenous Knowledge and Cultural Expressions
IMMYT	International Maize and Wheat Improvement Center
INLUG	Integrated National Land Use Guidelines
IPR	Institute of Primate Research
IRMA	Insect Resistant Maize for Africa
ISAAA	International Association for Agri-biotech Acquisition and Applications
IUNC	International Union for Conservation of Nature
JKUAT	Jomo Kenyatta University of Agriculture and Technology
JOOUST	Jaramogi Oginga Odinga University of Science and Technology
KALRO	Kenya Agriculture and Research Organization
KAP	Knowledge, attitudes and practices
KBBE	Knowledge Based Bioeconomy
KCDP	Kenya Coastal Development Programme
KEFRI	Kenya Forestry Research Institute
KEMFRI	Kenya Marine and Fisheries Research Institute
KEMRI	Kenya Medical Research Institute
KEPHIS	Kenya Plant Health Inspectorate Services

KFDA	Kenya Fisheries Development Authority
KIPRA	Kenya Institute of Research and Policy Analysis
KIRDI	Kenya Industrial Research and Development Institute
KIs	Informant Interviews
KLC	Kenya Land Commission
KNBS	Kenya National Bureau of Statistics
KNIC	Kenya National Innovation Centre
KPA	Knowledge, Practice and Attitudes
KWS	Kenya Wildlife Service
LMOs	Living Modified Organisms
M&E	Monitoring and Evaluation
MDGs	Millennium Development Goals
MEAs	Multilateral Environmental Agreements
MGTI	Multiplex Genome Engineering Technology
MMUST	Masinde Muliro University of Science and Technology
MoA	Ministry of Agriculture
MoAq	Ministry of Aquaculture
MPs	Members of Parliament
MSME	Small and Medium Enterprises
MSU	Maseno University
MTPs	Mid-Term Plans
MUERC	Maseno University Ethics Review Committee
NACOSTI	National Commission on Science Technology and Innovation
NAP	National Adaptation Plan
NAS	National Academy of Sciences

NASEP	National Agricultural Sector Extension Policy
NBA	National Biosafety Authority
NBC	National Biotechnology Council
NBEP	National Biotechnology Enterprise Programme
NBR	National Biodiversity
NCCAP	Kenya National Climate Change Action Plan
NDC	Nationally Determined Contribution
NDE	National Designated Entity
NDPs	National Development Plans
NEMA	National Environmental Management Authority
NFNSPF	National Food and Nutrition Security Policy Implementation Framework
NIH	National Institute of Health
NRF	National Research Fund
NTI	Nuclear Threat Initiative
NTPS	National Tourism Protection Service
NTRA	National Tourism Regulatory Agency
NTRI	National Tourism Research Institution
NTTA	National Tourism Training Agency
OECD	Organization of Economic Development
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy (OSTP)
PBSD	Potato Brown Streak Disease
PE	Policy Environment
PIC	Prior Informed Consent
PPP	Public Private Partnership

PPP	Public-Private Partnership
R&D	Research and Development
RAM	Risk Assessment and Management
RNA	Ribonucleic Acid
RRI	Responsible Research and Innovation
SASS	School of Arts and Social Sciences
SBLC	SynBio Leadership Council of the United Kingdom
SBRWG	SynBio Roadmap Working Group
SBSTTA	Subsidiary Body on Science Technology and Technical Assistance
SDGs	Sustainable Development Goals
SDSS	School of Development and Strategic Studies
SE	Stakeholders' Engagement
SEA	Strategic Environmental Assessment
SGS	School of Graduate Studies
SIG	Special Interest Groups
SMEs	Small and Medium Enterprises
SPS	International Sanitary or Phytosanitary
SRA	Strategy for Revitalizing Agriculture
ST&I	Science Technology & Innovation
STC-FN	Stakeholders' Technical Committees for Food and Nutrition
STS	Science and Technology Studies
SWAP	Sector-Wide Approach
SynBio	Synthetic Biology
TAPIC	Transparency, Accountability, Participation, Integrity and Capacity
TCEs	Traditional Cultural Expressions

TWN	Third World Network
UDHR	Universal Declaration on Human Rights (19948)
UHC	Universal Health Coverage
UK	United Kingdom
UN	The United Nations Organization
UNCED	United Nations Convention on Environment and Development
UNEP	United Nations Environmental Programme
UNESCO	United Nations Educational, Social and Cultural Organization
UNFCCC	United Nations Framework Convention on Climate Change
UNODA	United Nations Office of Disarmament Affairs
UNSC	United Nations Security Council
UNSCR	United Nations Security Council Resolution
UoN	University of Nairobi
USA	United States of America
USDA	United States Department of Agriculture
USDOE	US Department of Energy
USEPA	US Environmental Protection Agency
WEF	World Economic Forum
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WSH	Workplace Safety and Health
WTO	World Trade Organization

OPERATIONALIZATION OF CONCEPTS AND VARIABLES

Synthetic biology: *the design and engineering of biologically-based parts, novel devices and systems as well as the redesign of existing, natural biological*[1] *systems.* In Kenya, producing such cutting-edge products will require the availability of an adaptive anticipatory governance frameworks for the innovation to catapult the achievement of Kenya's Vision 2030. It is important to note here that as an emerging yet disruptive technology, there is not an already agreed definition of SynBio.

Others have emphasized that SynBio is not a technology or technique as such, but a discipline that incorporates knowledge from several other disciples such as medicine, virology, bioinformatics, among others, to produce novel devices and systems. The study adopted the definition above which perceives SynBio as a technology. However, to stay informed with definition of SynBio as a disciplinary field, and to try to limit the enquiry for that matter, the study adopted the concept SynBio technologies (interchangeably with SynBio products and components) implicating that the study was interested in the regulatory and development issues of SynBio results/outcomes (technologies, products, components, or tools {Keiper & Atanassova, 2018; Synthetic Biology Leadership Council [SBLC], 2016).

Regulation: ensuring that both *processes* and *products* that involve SynBio are properly governed to avoid cases of breach of biosafety, biosecurity/dual-use, biological diversity, bioethical and potential socio-economic impacts as well as to realize optimal exploitation of the benefits of the technology for enhancement of national science capabilities and sustainable livelihoods of Kenya. For these to be achieved, this study's premise is that there must be in place, a clear policy, clear legislation, clear national development plan in terms of their provisions for SynBio research and development, and potential risks areas.

Regulatory environment: The policies, legislations, national development plans that are currently applied in the regulation and development of biotechnology or are in one way or another relevant

[1] Modified from one the most common definitions of the field including as adopted in the Synthetic Biology Roadmap Coordination Group [SBRCG] (2012, p.5) definition by the UK Government.

to the regulation and development of Kenya's bioeconomy, and as such, would form the basis for regulating SynBio.

Policy environment: The selected policy documents relevant to SynBio, that is, policies that regulate Kenya's biotechnology and bio-economy more broadly.

Stakeholders' engagement: the involvement of a wide range of key stakeholders in biotechnology and SynBio research in Kenya. The stakeholders are broadly categorized into government, industry and academia. Because SynBio is new research domain in Kenya, the premise of the study was that the most important stakeholders to inform the policy makers and regulators are Kenyan experts in biotechnology or SynBio. Study unit of analysis was key experts drawn from six sectors (academia, media & communication, medical, research, industry, policy governance & regulatory bodies) key to generating evidence on regulatory gaps for adoption and implementation of SynBio.

Capacity. "Aptitudes, resources, relationships and facilitating conditions necessary to act effectively to achieve some intended purpose" (United Nations [UN], 2018). For this study the purpose being effective regulation and development of SynBio for achievement of national goals; key among which national power and sustainable livelihoods.

Public policy: Study adopted Anyebe (2018) who conceives as *actions, intensions and actual programs explicitly laid out by the government to facilitate effective and efficient reactions to public demands* which can be best provided through the adoption of SynBio. The study will be constrained to those policy documents whose intentions and programs are relevant to the regulation of SynBio technologies.

Public legislation: an Act of Parliament of Kenya enacted upon recommendation by a policy or a Sessional Paper relevant to the regulation of SynBio technologies and published by the Kenya National Council on Law Reporting.

International regimes: Are those global pieces of governance that are relevant to the regulation of SynBio because they have been domesticated by nation-states/Kenya to guide biotechnology and GMO-specific activities and products, and would constitute the building blocks for regulating SynBio.

Biotechnology; modern and traditional biotechnology: the study adopted these concepts as operated by Kingiri & Hall (n.d.): "…we use the term biotechnology to mean the manipulation of living organisms to produce goods and services useful to humans. However, we make a distinction between traditional (or conventional) and modern biotechnologies. The traditional approach allows the development of new products (such as seed varieties) by the process of selection from genetic material already present within a species, while the modern (transgenic) approach develops products (such as seed varieties) through insertion of genetic material from different species into a host plant. These products are known as genetically modified organisms (GMOs)."

National Development Plans (NDPs): selected nation-wide and sector-based development plans that are meant to bolster the bioeconomy through Science, Technology & Innovation [ST&I]. The scope of this study (objective 3/chapter six) was to explore the extent of embedding of the theme of ST&I in selected NDPs with an aim of ascertaining whether those provisions are enough ground for mainstreaming SynBio in NDPs or not.

Science, Technology & Innovation: The whole set of activities/research, inventions and innovative ideas and products which are based on digital or automated techniques. These are also frequently called emerging technologies or research and development [R&D]. Nations, including Kenya have accepted the significance of such emerging technologies as ICT, nanotechnology, and bioinnovation. Advanced countries like UK have considered SynBio as top 8 most significant technologies, and as being at the "innovative heart of national bioeconomy" with the capacity to solve "growth and job" creation challenges (SBLC, 2016). Refers to official statements in government policies, laws, and NDPs as well as programmatic activities that place ST&I at the innovative heart of national development planning, and actual development activities.

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CHAPTER ONE

INTRODUCTION

1.1.Background of the Study

This chapter of the thesis highlights the background and dynamics of the subject studied, the study objectives, questions, academic and empirical significance of the study, scope and limitations encountered during the study, theoretical and finally conceptual frameworks adopted and the rationale behind their adoption.

1.1.1. Science, Technology and Innovation in International Relations

> The importance of technology in global affairs is visible to the naked and uninitiated eye. Yet International Relations (IR) still lacks a more systematic and critical attention to the role of technological infrastructures in contemporary global governance dynamics (Mayer & Acuto, 2014, p. 662).

The claim above quite captures the state of affairs of IR in light of the field's ability to consider technology, especially those that have a transnational and/or global dimensions, hence portend high impact on the conduct of global affairs. However, Mayer & Acuto (2014), like Herrera (2006) discern a sharp paradox in this state of affairs where systematic studies of the role of technology in and between states is sidelined to the state of 'mundane artefacts', and subsequently relegated to the peripheral contours in the disciplined analysis of global politics (Mayer & Acuto, 2014, p. 663). Crucially, the paradox is crystallized by the fact that despite the continued placement of especially transnational disruptive technologies 'in the everyday experience of world politics, there are no purely 'social' relations that might be dissociated from technological mediation by, for instance, satellite positioning, oil pipelines, or vaccination response mechanisms' (p. 662), akin to the one experienced in 2014 when Ebola hit Africa.

In very recent times the better part of 2019-2021 COVID-19 shifted world' attention and challenged the traditional concerns of IR such as high politics, to a dire need for a technology that was able to detect the genetic make-up of the novel COVID-19 so as to manufacture an antidote and save the world. Scientists not politicians, technology for health and medical purposes, not for war, became the core concerns – matters of world existential threats. The new realities of the

contemporary complex interdependent globalized world implies that IR has been pushed to go beyond her disciplined discipline and consider technology beyond 'mundane artefacts' and agents of states, but also as analytical category and agents in international relations, in their own right (Hererra, 2003; Hererra, 2006; Mayer & Acuto, 2014; Musembi, 2022). Mayer & Acuto (2014) thus argues for a technology 'turn'[2] in IR and suggests that in such a quest, the field must engage in an 'interregnum' (p. 664) with most particularly Science and Technology Studies (STS) in order to move science, technology and innovation (STI) from the peripheral contours of IR discourses to the field's center. This thesis is a step toward the vision of IR. The thesis explored biotechnology regulatory gaps in light of synthetic biology regulation.[3] Proper regulation of SynBio in Kenya is key to global concerns around the technology, which is largely seen as not only very promising and revolutionary across several sectors of the bioeconomy, but also marked by varied uncertainties, begging, particularly, questions as to the robustness of regulatory instruments applied to its precursor, Genetically Modified Organisms (GMOs).

Effective 'anticipatory global governance' (Berten & Kranke, 2022) for a highly promising yet disruptive technology like SynBio is particularly a matter of concern for international institutions as to the uncertainties of 'present futures' that SynBio serves to such current global frameworks as the Convention on Biological Diversity (CBD), its protocols such as Kualar Lumpur, Nagoya, and Cartegena protocols, as well as other international regimes including Biological Weapons Conventions as well concerned United Nations recommendations and Resolutions. Simply put, the essence of studying a technology of the stature of SynBio in IR, within the context of a quest for its effective regulation in a developing country like Kenya, is step toward treating transnational and disruptive technologies as analytical categories in IR worth studying, due their capacity as agents in their own right to change the course of international relations (the practice) and politics. COVID-19 sets SynBio acutely aside (more of which in the following paragraphs.

[2] They go futher to show evidence that unlike other 'turns' in IR, technology is historically, within the IR theory (including in major Realist works such as the *Twenty Years Crisis, Politics Among Nations, The Structure of International System*), approaches (poststructuralism, Liberalism and Feminism), and evidentially in state practice, justified (p. 664).

[3] A technology Kenya has expressed intensions to adopt by commissioning a study dubbed National Research Fund for Synthetic Biology (SynBio).

1.1.2. Synthetic Biology: An Emergent, Promising yet an Uncertain Technology Frontier

The merging of the biological, digital and physical worlds, or what is commonly called the 'fourth industrial revolution' has made it possible for scientists to invent highly disruptive scientific technologies, hitherto, not imaginable (Moniz, 2020). Synthetic biology (SynBio) is one such innovations and is perceived as the latest and most novel of all biotechnological innovations ever invented by mankind. Simultaneously, it is also thought of as the bioinnovation accompanied by the greatest regulatory uncertainties (Trump, 2017; Akpoviri, 2018; Secretary to the Convention of Biological Diversity [SCBD], 2021). Though closely related to, and advances from GMO technologies (Trump, 2017; Keiper & Atanassova, 2020), the technology goes beyond those previously used in the construction of Living Modified Organisms (LMOs)/GMOs (Trump, 2017; Keiper & Atanassova, 2020). The CBD's Ad-Hoc Technical Expert Group (AHTEG) on SynBio, buttresses this notion, thus: "SynBio is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems" (AHTEG, 2015, quoted in Third World Network [TWN], 2017, p. 1).

The Presidential Commission on the Study of Bioethical Issues reiterate this understanding, thus: "applying standardized engineering techniques to biology and thereby create organisms or biological systems with novel or specialized functions". Trump (2017) argues that such high-end "research is aimed at selectively altering genotypic (genetic) information to trigger a desirable shift in an organism's phenotype, or physical characteristics" (p. 1). This way, SynBio enabling technologies present novel techniques that can enable researchers to, it is argued, have the ability "to substantially alter the genotype of viruses, prokaryotes, and eukaryotes, who may go on to interact with the natural environment" resulting into breakthroughs in fields spanning from drug and medicine, energy, food security, environmental stability and more (Trump, 2017; Marris & Calvert, 2018; SCBD, 2021; Jayanti, 2020; Supan, 2014).

As a result of the highly specialized nature of synthetic biology materials, SynBio has attained the status of world's top ten most significant technologies (Bojar, 2018), ranked at position two in

2012[4], albeit its utility being largely confined within technologically-advanced countries. The technology offer innovative methods for engineering new biological systems or re-designing existing ones for beneficial purposes (iGEM, 2016, p. 1; Moniz, 2020; UK Parliamentary Office of Science and Technology, 2015; Keiper & Atanassova, 2018; Trump, 2017; Andy, 2020). SynBio technologies are expected to deliver specialized applications with a wide usage across multiple sectors of the bioeconomy such as healthcare, agriculture, manufacturing, and the environment (Bojar, 2018; Wesseler & Demont, 2011). Advanced countries like the USA have gone ahead to innovate and utilize the technology within and beyond bioeconomy. Gronvall (2015) reports that USA main intention in the post-2015 with bio-innovation was to deepen the countries utility of SynBio as a means to attaining national strategic interests, including security through export of high-end products and creation of friends to promote USA long-term goals with SynBio innovations. Most importantly, literature (Jayanti, 2020; Gronvall, 2015; Bojar, 2018; Wesseler & Demont, 2011; Trump, 2017) shows that a critical element that has enabled USA and her equals in the fields of SynBio such as UK, has been the fact that these countries have been able to recast their biotechnology regulatory environment including primarily the legal, policy and development blueprints as well as technical and sectorial formations to ensure SynBio technologies are adopted and utilized maximally, albeit common oppositions (see, e.g. Supan, 2014 for an analysis of how the USA regulatory system still needs further tightening for proper regulation of what he calls 'synthetically modified organisms' [SMOs]).

The potential and actual benefits of SynBio as well as the need to regulate it, has therefore become a key area of global discussion (AHTEG, 2015, quoted in Third World Network [TWN], 2017). According to Long (2021) and Gronvall (2015) the indispensable role of SynBio technologies both as a means of national power and national (human) development has pitched the technology as the new avenue for realizing national objectives, and consequently for international competition – with countries able to produce for domestic and international use, gaining enormous leverage as they are able to export such high-value products to consumer countries, increase their Gross Domestic Product (GDP), and continue to subdue small states that will depend on them for health, agricultural high-value products whose production is possible, thanks to SynBio. This has made developing countries, including middle income countries like Kenya be attracted to the technology,

[4] Haselof (2013): http://forumblog.org/2012/02/the-2012-top-10-emerging-technologies/.

first to ensure that they use it to move toward sustainable livelihoods of their populations and secondly to gain independence through increase industrial use of biotechnology, and reduce loan and other forms of dependence on developed economies. Kenya's aspirations for the utilizing science, technology and innovation (ST&I) is particularly very key, as she elaborates in her Vision 2030. For her the greatest question is whether these aspirations have been put into place, if not how they can be put into place, and whether there are the requisite environment for such.

Consequently, the primary challenge for new comers like Kenya in their move to adopt and implement SynBio is whether they possess the requisite regulatory frameworks (Reagan et al. 2022; Trump, 2017). Accordingly, the literature asserts that countries with unclear frameworks for regulating SynBio should assess the current frameworks based on adaptive and anticipatory governance framework principles (Trump, 2017; Calvert & Marris, 2018). According to Trump, (2017) and Keiper & Atanassova, (2018) advanced countries have been able to reap maximally from SynBio due their ability to ensure that existing genetically modified organisms (GMOs) regulatory frameworks – the precursor of SynBio - are aligned to the SynBio regulatory issues. Recently, Reagan et al. (2022) have shown in their analysis of Africa's preparedness to adopt SynBio that, although it is a fact that SynBio holds the key to unlocking sustainable livelihoods in Africa's Sub-Sahara (ASS), that cannot be attained without existing GMOs governance frameworks adopted to SynBio. Particularly, Reagan et al. (2022) have shown that Kenya and USA, the leading African countries in terms of GMOs development, stand a better chance to adopt and implement SynBio because what remains is for them to understand the existing gaps in GMOs governance frameworks in order to adapt them according to SynBio development and regulatory issues.

The rest of the parts of this thesis are arranged as follows: section 1.1.2 and 1.1.3 of the background premises this study on the field of international relations (IR) and highlights the regulatory lacunas that surround SynBio technologies based on existing scholarly debates on the subject matter-informed by research objectives - respectively. Chapter two presents the literature review, chapter three contains the study methodology, chapter four, five, six and seven contain the study findings. Final chapter, eight, entails the summary, conclusions and recommendations of the study.

1.1.3. Science Technology and Innovation as a Source of National Power

In the field of International Relations (IR), the ability of a country to develop, use, and dominate the production of, and international trade in, high value commodities, sophisticated technologies and innovations has been recognized by both Realists and Idealists and commentators on Idealism (Morgenthau, 2007; Strange, 1994) as one of the determinants of national power. Some contemporary foreign policy analysts have expanded this view and argued that in the post-Cold War era, the more technologically advanced a nation-state is, the more the relative power it possesses on the arena of global politics (Hudson, 2014; Alden & Aran, 2017). The significance of breakthrough technologies and innovations to national development and as a measure of national power is exemplified by the enormous shares of national Gross Domestic Product (GDP) that technologically advanced countries have apportioned to ST&I or Research and Development (R&D) (United Nations, 2015). For example, the UK government currently spends 1.7% of its GDP on R&D and aims to upscale to 2.4% by 2027 in a bid to achieve her "science superpower" vision possible only through an "innovation-led economy", wherein SynBio is considered to be at the heart of the bioinnovation (Long, 2021; European Union, 2017). The USA, the global leader in spending on R&D and funding of global R&D projects, has sustainably increased its annual spending on R&D and today spends 105 times compared to 1955. The country allocated about $627 billion on non-defense R&D and $672 on defense-related R&D in 2021 and aims to increase this each financial year (FY) (Congressional Research Service, 2021; American Association for the Advancement of Science, 2021).

Synthetic biology (SynBio) is the latest bioinnovation and has become the new determinant of national development promising to revolutionize the blue economy (Bojar, 2018; WEF, 2016; Secretary to the Convention on Biological Diversity [SCBD, 2021]). SynBio "is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacturing and/or modification of genetic materials, living organisms and biological systems" in order to produce systems and products whose usages are highly targeted (Third World Network [TWN], 2017, p. 1). Its ability to create novel devices and systems for a wide range of applicability has led some scientists to say that SynBio is the missing link to arriving at the "fifth industrial revolution" and the attainment of sustainable livelihoods in Africa's Subs-Saharan countries (Reagan et al., 2022).

Being the latest bio-innovation and perhaps the most promising of global (ST&Is), SynBio has become the new determinant of "real national power" (Treverton & Jones, 2005; Wesseler & Demont, 2011) due to its ability to deliver potential benefits across a wide range of applications: national security, health and medicine, human enhancement, energy, food and nutrition and so on (Wellhausen & Mukunda, 2009; UK Parliamentary Office of Science and Technology, 2015, p. 1; Keiper & Atanassova, 2018; Wikmark et al., 2017). On this note, Randy Rettberg, the founder of the International Genetically Engineered Machine (iGEM) declared: "Synthetic biology or biotechnology in general is the world wide web (www) of the last century" (iGEM, 2016, p. 1).

The COVID-19 pandemic has recently vindicated Rettbert's sentiment. Right in the onset of the COVID-19 pandemic, scientists were able to study the DNA-make-up of the Corona Virus and synthetize a vaccine based on SynBio-enabling technologies. Such breakthroughs, reports Andy (2020) were hitherto unimaginable. From an IR's standpoint therefore, SynBio technologies have been the new ground for contemporary national power. Suffice to say that countries like USA whose scientists and health systems were not only able to create the vaccine for domestic use but also as an emergency item for international trade, have saved both the lives of their citizens and asserted their national power as what we can term "COVID-19 superpowers". We have witnessed for example, dependency of a greater magnitude from developing countries on such COVID-19 super powers. This worsened debt crises in most developing countries (WHO, 2021). It is the UK and USA who dominate the global SynBio market which has been on an upward trend. For example, "the global SynBio market was estimated to be valued at USD 6.8 billion in 2020 and is projected to grow at a compound annual growth rate of 23.9 % from 2020 to 2025*"* (Secretary to the Convention on Biological Diversity [SCBD], 2021). Placing these countries and other key players at a comparative advantage in global politics of SynBio.

Kenya is heading towards SynBio technology adoption in a bid to leverage her stature and become like the UK, US, to assert her national power in the global science space and attain sustainable livelihoods of her citizens in line with her Vision 2030. Kenya formally launched a Synthetic biology (SynBio) research project dubbed National Research Fund for Synthetic Biology Project in 2020. Through the project, the country aims to integrate SynBio as a component of her Science,

Technology, & Innovation (ST&I) in order to bolster the transformation of her bioeconomy (ISAAA, 2020). Based on the lessons that SynBio technologies have played in the science transformation of bioeconomy of countries like Singapore, China, UK, and USA (Trump, 2017; Keiper & Atanassova, 2018; Reagan et al., 2022); upon successful adoption of SynBio technologies, Kenya will not only keep, increase, or demonstrate her national power as a rapidly industrializing middle-income science-driven economy, but will also be better placed to improve the livelihoods of her population and attain her Vision 2030. However, the country does not have any policies, laws, national development plans customized for the regulation of synthetic biology technologies.

The foregoing observations begs the question as to whether Kenya's current biotechnology development and regulation landscape, is capable to facilitate the aimed adoption and implementation of SynBio technologies in an adaptive governance environment. This therefore, requires an empirical study to ascertain the preparedness of the current biotechnology regulatory environment. Unfortunately, there is no study that has been geared in this direction. This study thus attempted to fill this gap through four objectives. The first objective explored relevant policies, the second explored relevant legislations, and the third identified gaps in relevant national development plans. The fourth and final objective explored the perspectives and expectations of expert stakeholders on current biotechnology gaps across certain thematic areas.

1.1.4. Regulatory Uncertainties of Synthetic Biology Technologies

The need to regulate SynBio is an issue of global governance – a key issue domain in International Relations - of emerging technologies. This exemplified by the fact discussions around the regulation of SynBio have not only original at the inter-scales, but are driven primarily by international institutions and transnational processes. Effects on adoption, trade, research, and other activities concerned with SynBio have transnational connotation. Hence, while instructions are seeking to harmonize regulatory frameworks of countries and push for putting into place such frameworks in new spaces like Kenya, effective global governance of SynBio is also seen as very dependent on the existence of clear governance frameworks at the national scales. The need to regulate SynBio properly is twofold: firstly, it is an anticipatory endeavor to put mechanisms for mitigating any uncertainties emerging from potential risks of the technology. Secondly, it is an

avenue for countries to streamline the technology into national development goals and ensure that the technology is used optimally to transform how national businesses are transacted across the bioeconomy sectors.

For countries to make the most gains out of SynBio technologies, there has to exist regulatory mechanisms that will facilitate smooth and seamless technology adoption, implementation and further development and applications. It has been asserted that nations must have a clearly spelt policy, law, and a development plan to facilitate technology adoption in an adaptive anticipatory governance environment (Reagan et al., 2022; Trump, 2017; Keiper & Atanassova, 2020). Small wonder, therefore, the countries (such as UK and USA) which have been able to identify the current biotechnology regulatory gaps in their existing biotechnology regulatory frameworks and adapted them to SynBio regulations have been at the forefront in terms of gains from the global market of SynBio innovations (SCBD, 2021).

Discussion on SynBio technologies have occupied high profile international substantive discussions by states and non-states especially since 2010. Such forums have included among others, the Conference of Parties (COPs), and Meetings of Parties (MOPs). The technology's global significance is exemplified by the formation of specialized expert forums such as the CBD's Ad-hoc Technical Expert Group (AHTEG), and Subsidiary Body on Science Technology and Technical Assistance (SBSTTA); central forums through which regulatory concerns about SynBio and its technologies have been debated and deliberations made (SCBD, 2017; 2019). Such discussions have centered around questions on applicability of Genetically Modified Organisms (GMOs) regulations to SynBio technologies and the need thereof for states to adapt (or define fresh regulations) existing biotechnology frameworks to the regulation of SynBio technologies (Trump, 2017; Keiper & Atanassova, 2020; Akpoviri, 2018; SCBD, 2021). Clearly it has emerged that certain SynBio products and components do not fall under the global conceptualization of GMOs and thence GMO regulatory mechanisms may be insufficient to regulate such advanced SynBio research, products and components (Trump, 2017; Keiper & Atanassova, 2020; iGEM, 2020; Reagan et al., 2022).

Currently, the AHTEG is revising the 2015 CBD Technical Series on SynBio (AHTEG) with a view to position SynBio within the existing CBD and other relevant regulatory regimes. The theme

being stressed is the need to assess the current national biotechnology regulatory environment, particularly of developing countries, yet to adopt or in their early post-adoption stages to establish their robustness in light of facilitating adoption, implementation, and use of SynBio (SCBD, 2021). This has also been the SynBio theme of the COPs 13, 14 and 15. Together, the two bodies, AHTEG and COPs have not only asserted the lack of robust national regulatory frameworks, but have also questioned the extent to which CBD, its Nagoya and Cartagena Protocols are well placed to govern SynBio at the global stage (*Ibid*).

The UK's Parliamentary Office for Science and Technology (2015) reinforce this understanding that initial products of SynBio may not challenge current GMOs regulations and directives, but as research and development continues and more advanced and complex products emerge, existing regulatory frameworks may be inadequate. Accordingly:

> The anti-malarial drug artemisinin, the flavouring vanillin and other applications that may have a range of potential benefits such as pollution control, bioremediation, and reducing the dependence on non-renewable resources. Such products may fall within the scope of existing regulations and risk assessment frameworks for genetically modified organisms (GMOs), food, chemical and medicines. However, there is a debate as to whether existing regulations will be appropriate for potential future applications in this rapidly emerging field (UK Parliamentary Office for Science and Technology, 2015, p. 1).

Keiper & Atanassova (2018) argue that regulating SynBio technologies is due largely to the conflict between highly hyped potential benefits and the lack of evidence on the extent of its potential risks. On one hand, "research is aimed at selectively altering genotypic (genetic) information to trigger a desirable shift in an organism's phenotype, or physical characteristics" (Trump, 2017, p. 2). This way, SynBio enabling technologies present novel techniques that can enable researchers "to substantially alter the genotype of viruses, prokaryotes, and eukaryotes, who may go on to interact with the natural environment" resulting into breakthroughs in fields spanning from drug and medicine, energy, food security, environmental stability and more (Trump, 2017, p. 2). On the other hand, proper regulation of SynBio will not only enable formulation of favorable policies on SynBio R&D to bolster the bioeconomy, it will also ensure that possible risks to

health, environment and other vulnerable factors that SynBio components and products may portend potential risks.

SCBD (2021, p.6) adds that the most important regulatory concern about SynBio is to ensure the "adequacy of existing regulations, to deal with current and anticipated components, organisms and products of SynBio as well as the social and ethical implications of SynBio". Trump (2017) further assert that "ultimately, scholars have described how SynBio risk assessment capacities and governance requirements should be iteratively reviewed and improved as more quantitative information comes available (p. 3). These perspectives point to the need to review GMOs and biotechnology regulatory environment in order to establish the levels of sufficiency of those frameworks to regulating SynBio-specific issues (Trump, 2017; GenOk-Centre for Biosafety, 2016; European Environmental Agency [EEA], 2015; Keiper & Atanassova, 2020; United Nations Environmental Programme [UNEP] & SCBD, 2017; Moniz, 2020; Bernaert, 2020).

Marris & Calvert (2018), (Trump 2018) and Reagan et al. (2022) assert that the need for a systematic review of current biotechnology regulatory regime is necessary to provide insights that should inform policy makers on gaps on biotechnology and GMOs regulations; policies, laws/legislations and other pieces of regulations such as NDPs. For Kenya, where the technology is yet to be adopted, the need to review current biotechnology regulatory environment is even more urgent, especially owing to the fact that the Government of Kenya at the time of writing this thesis proposal has committed resources to the development of two pioneer SynBio technologies through the NRF SynBio Project [5](ISAAA, 2020). As the policy component of the said study, the main task of this study is to review the sufficiency of current biotechnology regulatory regimes for adoption and implementation of SynBio technologies. The aim of this particular study is informed by the discussions which led to the project[6] and global developments going on at the CBD and AHTEG all of which have highlighted the need to explore policies, legislations and any other

[5] The NRF Synthetic Biology Project, which this study is part, aims to produce synthetic biology –based biosensors and rapid diagnostic kits to be used in improve agriculture and health sectors in Kenya, respectively. The Project should end in 2022 during Kenya is expected to adopt these SynBio tools.

[6] The policy component of the NRF SynBio Project follows after discussions help in Nairobi on 29th of March whose resolutions was that if the Government of Kenya wants to sustainably adopt and implement SynBio technologies, there is need to assess the policy, legal and development plans and institutional mandates which are currently regulating biotechnology (and broadly Kenya's bioeconomy) (see NACOSTI, 2017).

concerned frameworks to the biotechnology governance (SCBD, 2021). In this study biotechnology regulatory frameworks: policies, legislations, and national development plans (NDPs) will be analyzed through the perspective of the gaps therein that may hinder smooth adoption and implementation of SynBio technologies. This will be achieved through analysis of purposefully selected biotechnology-related policies, legislations and NDP documents. The study will reinforce such analysis with biotechnology expert perspectives on the regulatory gaps and opportunities.

The need to review current national biotechnology policies, legal provisions and national development plans has been identified beyond the CBD and its processes. For example, pointing to the national needs to review the existing regulatory policies, legal provisions and concerned national plans at national and regional scales by the Group of 20 rich countries (G20), Kolodziejczyk & Kagansky (2017) argued that "there are numerous aspects of SynBio that require urgent action" (p. 3). They aver that "while there is a sort of steady increase in the market share of SynBio, largely owed to constant research and development (R&D)", three critical actions must be taken including "systematic and efficient education, communication and policy development…" (p.3) this advisory follows from their observation that "most of the currently used SynBio regulations have been adopted from policies and legislations developed for other technologies, GMOs, and hence are often incapable of addressing the full extent of the field" (p. 3). They pointed out, specifically, that the G20 countries were using regulations developed for GMOs which had become outdated as SynBio in its current development had more 'superior' tools than its GMO 'prototype' (p. 6). As Kenya prepares to adopt and implement two pioneer SynBio innovations, biosensors, and rapid diagnostic kits, at the end of the National Research Fund (NRF) SynBio Project (ISAAA AfriCentre, 2020), there is an empirical justification to explore her biotechnology and GMO-specific policies and legislations and identify gaps that may hinder successful adoption of SynBio.

There are mainly four areas of regulation that the literature focus on: biosecurity, biosafety, bioethics, and bio-social and economic impacts of SynBio (Marris & Calvert, 2018; TWN, 2017; Wikmark et al., 2017). Whether these regulatory areas must be in place before adoption or whether adoption can go as countries innovate an adaptive anticipatory regulatory environment is an issue

where consensus is yet to be achieved. International non-governmental environmental organizations (EINGOs) emphasize the former, while governments advocate for and practice the latter. For example on the 13th of March 2012, a group of 100 civil society groups working on environmental-related objectives or with a special interest in emerging technologies, spearheaded by three main organizations: Friends of the Earth, the International Centre for Technology Assessment, and ETC Group issued jointly the *Principles for the Oversight of SynBio* which is a call to a worldwide moratorium to the release and commercialization of SynBio organisms until proper and functional risk measures are put into place. Governments through platforms such as AHTEG, COPs, and synthetic biology developing institutions continue to advocate the need to adopt SynBio technologies by countries while at the same emphasize that an adaptive governance framework should be put into place to ensure all aspects of the technology are properly governed for health and environmental safety and for maximum national economic gain (Kingiri & Hall, n.d.; Reagan et al., 2022; World Economic Forum [WEF], 2015; WEF, 2019, 2020; UNEP & SCBD, 2017; SCBD, 2021; Kolodziejczyk & Kagansky, 2017; Wilson International Centre for Scholars SynBio Project, 2013; Hart Research Associates, 2010; LIS Consult & SynBio Project Initiative, n.d.; Pauwels, Stemerding & Vriend, 2011; Trump, 2017; Jayanti, 2020).

Biosecurity has been perceived largely within the notion of 'dual-use dilemma'[7] (Rodemeyer, 2009) or sometimes called Do-It-Yourself Biology[8] (DIYB) (Pauwels, Stemerding & Vriend, 2011). Dual-use relates to fears that SynBio may result in unintended harmful consequences, for example, that SynBio applications may be used as toxins and biological weapons of mass destruction (BWMD). From this perspective, the advent of SynBio if not properly regulated may pose terror threats greater than the famous 9/11 attacks executed on USA territory (Pauwels, Stemerding & Vriend, 2011). Pauwels, Stemerding & Vriend (2011) report that a 2008 USA Report of the Commission on the Prevention of Weapons of Mass Destruction stated that "terrorists are more likely to obtain and use a biological weapon than a nuclear weapon" (p. 15). These fears were reaffirmed by a recruiter of al-Qaeda terrorists by the name Abdallah Fahd al-

[7] Science is primarily used to benefit humanity, but particular scientific technologies can be misused, presenting scientists and others with an ethical quandary known as the dual-use dilemma (Rodemeyer, 2009).

[8] This refers to "Dual use" concerns raised by synthetic biology, whereby research with legitimate scientific purpose may be misused to pose a biologic threat to public health and/or national security, threatens to undermine public confidence'' (CBD Series on Synthetic Biology, 2021, p. 12).

Nafisi who revealed that they were in possession of best "scientists, chemists, and nuclear physicist" hence USA fears were not farfetched. (*Ibid,* p. 15). These statements were a reflection of what the USA Central Intelligence Agency had discovered in 2002, a DIYB laboratory in an al-Qaeda camp furnished with lab manuals 'and written orders for *anthracis* and *botulinum* cultures' (Pauwels, Stemerding & Vriend, 2011, p. 16). Kenya has in place the Biosafety Act (2009) and Biotechnology Development Policy. According to Mugo et al. (2017) and Pamela (2006) these instruments do not regulate the security aspects of biotechnology. While this has not impacted much on biotechnology development, synthetic biology will obviously raise a lot of questions as to whether Kenya has the capacity to deter negative aspects of dual-use. Such anticipations require a review of the law and policy, and related development plans as when as to gather further evidence through expert opinions survey that will help in generating necessary evidence toward the formulation of a synthetic biology policy or strategy.

Biosafety as a governance issue include the immediate impacts of the systems, the research process, and the products, and components of SynBio it produces on the developers' health and the larger environment (Trump, 2017). These include fears that synthetically modified organisms (SMOs), may exhibit abilities for horizontal gene transfer where artificial genetic information may be transferred to the environmental organisms posing unintended impacts on them. Under biosafety, questions about the possible risks the technology may have to human health, that is, for example to laboratory people working in SynBio labs; as well as the effects these products and systems may have on the environment are the key issues being debated. Mitigation measures proposed for biosafety include bio-containment.

Bio-containment measures used for the GMOs have been proposed to deal with risks for example to contain SynBio organisms with confined selves and control releases to the environment or to layout protocols that can help laboratory scientists avoid possible negative impacts (SCBD, 2021; UNEP & SCBD, 2015). But yet still there are fears that have been expressed concerning the capacity of GMOs bio-containment guidelines especially with the notions that containing SynBio products may require post-laboratory approaches because these products may have biological impacts on the environment even when their safety have been proved (Trump, 2017; UK Parliamentary Office of Science and Technology, 2015) unlike GMOs. There is therefore need to

explore the relevant Kenya's regulatory documents, and understand the perspectives and expectations of experts within the limitation of SynBio regulation, which goes beyond GMOs technology.

Biological diversity is a key regulatory issue in synthetic biology debates more so because synthetic biology itself emerges from within the CBD where the core business has been biological preservation, equitable sharing of biological resources. Discussions here proceed through the prism of mitigating and preventing environmental impacts of SynBio products. This follows after the fears that SynBio products and components once released in the environment where there are other organic organisms and substances may outcompete naturally occurring organisms and substances (Trump, 2017; Guston, 2014; Greer & Figueras, 2013; Douglas & Stermerding, 2014; Oye, 2012). Currently, literature points to the lack of specific modeling techniques to quantify the biological diversity threats (Trump, 2017), but much discussions lays emphasis on the need for countries to lay down governance frameworks that are preemptive/anticipatory to such challenges. The point is that national governments and even the global frameworks may be able to eliminate or mitigate such risks when they emerge both in the immediate and mediate terms.

Finally socio-economic, and religious-ethical concerns relate to the fears that by large industrial adoption of SynBio in technologically backward countries like Kenya, there is a high possibility of massive job losses in those working in traditional industries like butcheries and such set-ups because SynBio implies for example that synthetic meat can then be produced using alternative cheaper and faster production methods. It involves about impacts of established religious beliefs for example about life, God, and so on and the possibility if SynBio changing these through for example, creation of synthetic living organisms. These perspective further warrants an exploration of the policies, laws, and concerned development plans as relates to job protection and other social impacts such as religious and ethical concerns, and seek expert opinions on best ways forward.

The question that has also emerged about SynBio regulation is what form or model should be adapted. Trump (2017) and Guston, (2014) have suggested that an adaptive anticipatory governance is likely to inform regulators and policy-makers on what types of gaps exist in current biotechnology frameworks and to inform adapting such frameworks to the regulation of SynBio

technologies. Trump (2017) formulated an important gaps analytic framework from the theory of adaptive anticipatory governance of emerging technologies. This include five interrelated concepts: transparency, accountability, participation, integrity, and capacity (TAPIC). These concepts, he argues, can be useful to researchers aiming to understand regulatory gaps for SynBio, as well as to policy and decision makers aiming at revising or formulating policies, legislations and NDPs to put into place an adaptive anticipatory governance framework for adoption and development of SynBio. According to Trump (2017) such a framework is only possible if underlying gaps in biotechnology-related policies, legislations, guidelines, and other pieces of regulation such as NDPs clearly express who should do what, when where and how in the entire life cycle of SynBio products development, from research to commercialization (detailed in section 1.7).

Trump's notion of the adaptive anticipatory governance formed the basis for this exploration. Based on the 14 guiding questions (refer to Survey Tool at the appendix), the researcher developed a framework to understand the transparency, accountability, participation, integrity and capacity of selected policies, legislations and NDPs. Further exploration involved survey of expert opinions on the thematic issues concerned with SynBio regulation based on the biotechnology development and regulation landscape in Kenya. Such experts were drawn from six key sectors, an approach which is globally accepted in conducting a study aimed at providing evidence for formulating an anticipatory adaptive governance framework (Douglas & Stemerding, 2014; Roco, Harthorn, Guston & Shapira, 2020; Calvert, 2013).

Trump (2017) adds that a multi-sectorial approach based on a TAPIC framework will reinforce SynBio governance in four crucial grounds: "identify gaps in SynBio governance within a given case country, indicate where any future attempts at governance reform should be directed to address the technology's uncertainty, prioritize data needs for the technology's human and environmental health risks, and develop strategies for the technology's governance in the immediate term" (p.2). It is in the spirit of stakeholder engagement in policy-making that objective four of this study specifically explored experts' stakeholder's perspectives and expectations as regards the gaps in policies, legislations and NDPs guiding biotechnology in Kenya. Such has been in the practice in the USA (see hart Research Associates, 2010; 2013), the UK (UK Parliamentary

Office of Science and Technology, 2015; Marris & Calvert, 2018), large parts of Europe (Trump, 2017). Focus was on experts because SynBio is a grey terminology and area of practice in Kenya and only experts in biotechnology research, regulation, reporting could give needed information to answer research questions.

Proper regulation and sustainable research and development of SynBio has also been pegged on national development planning as it is on proper (TAPIC-based) policies, and legislations (Marris & Calvert, 2018). In this spirit, USA Government formulated her national development plan in the form of *National Bioeconomy Strategy* which spelt out the role of SynBio in US national development across several sectors of bioeconomy. The document followed after the Presidential Commission for the study of Bioethical Issues (2010) and highlights the mandates of institutions to deal with bioethical issues concerning SynBio. In the UK, the country has had two important national development plans, for the regulation, and sustainable research and development of SynBio, namely, the 2012 SynBio Roadmap, and the 2016 SynBio strategic plan (UK Synthetic Biology Leadership Council [SBLC], 2016; Marris & Calvert, 2018).

The Singaporean government has also defined her national development plan for SynBio and like UK and the USA, its successes in the bioeconomy and national development generally, have been linked to not only her ability to adapt biotechnology policies, legislations and guidelines to the regulation of SynBio, but also her ability to formulate a robust national plan to guide research and development of SynBio (Trump, 2017). In the third objective of this study, the explored selected NDPs in order to identify the areas of gaps and the necessary measures that may be explored to mainstream SynBio into national development programming. Experts were drawn from academia, industry, governance, policy, and regulation, medical, and media and communication. Study explored perspectives of key stakeholders on SynBio technologies and issues related to its adoption and implementation in Kenya in order to a) establish expert perspectives on the regulatory gaps in the biotechnology-related documents analyzed; b) understand current biotechnology institutional mandates, opportunities and gaps in relations to the adoption and implementation of SynBio c) understand any thematic areas which may influence adoption and implementation of SynBio based on experts experience from biotechnology research, regulation and other processes in past years.

Summarily, the foregoing discussions present the need to conduct a review of the Kenya's biotechnology regulatory frameworks in light of their sufficiency to regulate SynBio. For proper regulation of SynBio, national governments must understand the current gaps in their regulatory frameworks for biotechnology. Since biotechnology regulation in Kenya and elsewhere is guided by policies, legislations and development programs, there is need for an analysis of the level of robustness of biotechnology, policies, legislations and NDPs in Kenya, a country which aims to adopt SynBio by end of 2022. Study analysis was based on the policies and legislations, and sectorial development plans/strategies because biotechnology regulation in Kenya are based on policies and regulations and strategies which have been domesticated from global biotechnology-and-related regimes (Kingiri & Hall, n.d.).

Moreover, national development plans/strategies is a globally practiced approach to SynBio development and regulation. For example, in the USA, the development and application of SynBio to different sectors is driven by the National Bioeconomy Strategy of 2012, while in the UK it is the Synthetic Biology Strategic Plan of 2016 which replaced the Synthetic Biology Roadmap of 2012. This necessitates the need to establish whether the Kenyan development planning landscape has been driven by ST&I and whether that creates a ground to justify adoption of SynBio technologies as a driver to the several national visions stated in 2030 and other national development plans. Since SynBio is still a grey area and alien concept to common Kenyans, the discussions above also reveal the academic necessity of exploring experts' perspectives on SynBio and its adoption and implementation in Kenya to generate evidence from biotechnology (and SynBio experts) which can inform policy makers and regulators on the existing gaps in current approaches applied to GMO R&D.

The literature on public surveys on SynBio, which informs my study objective four, reveals perspectives on the SynBio and its perceived impacts on health, environment, social fabric and other spheres, all of which are important regulatory concerns on SynBio and should inform SynBio policy making in the USA. For Kenya to adopt and implement SynBio technologies, stakeholders' perspectives, particularly the experts', need to inform SynBio debates by helping in the identification of current gaps in biotechnology governance, education, and research. This should inform a more pro-SynBio debate and formulation of a robust policy, legislation and a national development plan.

1.2.Statement of the Problem

High-value emerging forms of Science, Technology & Innovation are increasingly becoming a major determinant of national development, and subsequently a measure of relative power in international relations. The more the level of advancement of ST&I a country possess, the higher the country in terms of significance at the global scale because such country is able to manufacture drugs to detect and cure existential diseases such as the recent COVID-19. Moreover, food and nutrition security, and environmentally friendly manufacturing among others can be delivered by latest highly disruptive technologies. But beyond domestic utilities of ST&I is a key item to change the status of a country and give her more bargaining power at the international scene. Through production in surplus, such items can be exported for sale with high returns as opposed to the export of agricultural raw products – a common case in developing countries. This way, producers of high-value ST&I are able to keep non-producers/importers at a disadvantaged/dependent state and hence decide such countries fates through perpetual loans inflows among other strategies used by advanced countries to keep small countries at their mercy.

Though the latest of all current bio-innovations, SynBio is ranked among top 10 most significant technologies globally, at number 2 overall in 2012. Despite this, only the technologically advanced countries dominate its production, utility and export, due largely to the regulatory frameworks they have adopted/adapted from previous bio innovations such as GMOs or created. As a result, the significance of SynBio has gone beyond paper and laboratories where the manufacturing happens, to become one of the most critical technologies being utilized in advanced countries to turn around their bio economies, ensure stable, healthy and environmentally secure populations as well as pursue their technological power aspirations. Recent surveys of the bio-innovation global market buttress this global leverage dimension of SynBio by showing that the market increasingly becoming a target, though unfortunately remains dominated by developed countries, especially USA and the UK.

But SynBio is not just discussed in the literature as entirely good and risk-less technology. To be clear, the risks notions surrounding the technology go much beyond most of the other disruptive technologies. Such risks including contentions that hinge on the need to ensure governance frameworks cover potential biosecurity, advanced biosafety issues, social, cultural, ethical and economic issues, environmental impacts and biological diversity among a list of other grounds for

potential risks, means that adoption or continued development of SynBio cannot be viewed only rom the "promises" standpoint. The need to understand how these risks grounds will be mitigated in especially late comer countries become more and more paramount. A fact that is corroborated by the kind of discussions going on global (CBD and concerned platforms such as its protocols expert formations) and regional multilateral forums (such as the G20).

Kenya yearns to join the league of global SynBio competition and has gone ahead to commission a PPP research program whose aims are to come up with a biosensor for Cassava brown streak disease (CBSD), and diagnostic kit for cholera-causing organism– as the first phase to ushering SynBio. However, whether the current biotechnology [especially GMO] regulatory environment is sufficient to cover regulatory issues peculiar to SynBio remain both unclear and unexplored. Consequently, this study thus explored the sufficiency of the current biotechnology regulatory frameworks in light of synthetic biology regulation. As such, the study was a creative venture to explore how the promises of SynBio can be made real in Kenya through an elaborate regulatory framework learning from GMO and other former biotechnology encounters in the county.

The study findings are critical for Kenya domestically and in her international relations. Domestically: such evidence is needed to ensure a responsible research & innovation of SynBio for optimal enjoyment of its promises for national development: health, industrialization, agricultural, livestock; within governance framework that can mitigate on potential risks. From an international relations standpoint, such evidence will inform the installment of a robust regulatory environment that will see Kenya take a proactive role in the production of SynBio products for industrialization and export to the global market. Hence, reducing the country's dependence on importation-led science, technology and innovation approach and increase her bargaining power, regionally and internationally in her quest to attain synthetic biology powerhouse status.

1.3. Objectives of the Study

The general objective of this study is to establish the extent of robustness of biotechnology regulatory environment in Kenya for the regulation of Synthetic technologies as an avenue to unlock sustainable livelihoods and attain Kenya's quest for a regional technology powerhouse.

1.3.1. Specific Objectives

a) To explore Kenya's biotechnology-related policy frameworks for adoption and implementation of Synthetic biology technologies;

b) To explore Kenya's biotechnology-related legislations for adoption and implementation of synthetic biology technologies;
c) To explore the extent to which the embedding of the theme of Science, Technology and Innovation (ST&I) in selected national development plans may facilitate adoption and implementation of Synthetic biology technologies;
d) To explore synthetic biology key expert stakeholders' perceptions on SynBio and its adoption and implementation for attainment of Kenya's.

1.4. Main Research Question

The overall question: Does Kenya possess the requisite biotechnology regulatory environment for adoption and implementation of synthetic biology technologies within an efficient regulatory environment?

1.4.1. Specific Research Questions

a) Does Kenya possess the requisite policy frameworks for the adoption and implementation of synthetic biology technologies?
b) To what extent can Kenya's biotechnology-related legislations facilitate the adoption and implementation of synthetic biology technologies?
c) To what extent is the theme of ST&I embedded into selected Kenya's national development plans (NDPs) and can that create a platform to mainstream synthetic biology into national development planning?
d) What are the perspectives and expectations of expert stakeholders concerning current biotechnology regulatory environment in regards to synthetic biology adoption and implementation?

1.5. Significance of Study

This sub-section identifies the philosophical, academic, and policy/empirical justifications of the study. To begin with, the philosophical standpoint of this study sits within the domain of technology studies as theorized and studied in the field of International Relations (IR) (Acuto, 2015; Moore, 2011; Mayer & Acuto, 2014; Murphy & Yates, 2009; Herrera, 2003; 2006; Musembi, 2023). This standpoint argues that technology must be treated as a key analytical category in IR, and moved from the peripheral contours of the discipline, mainly because disruptive transnational technologies in their own rights, not as/necessarily as instruments of state

power, have fundamentally transformed global affairs. This philosophical standpoint is further reinforced by arguments from adaptive global governance that argues that disruptive technologies in international relations have provided international organizations the power to set the agenda for states, in attempts to govern the uncertain futures (Berten & Kranke, 2022). By studying Synthetic biology, and unravelling regulatory gaps in Kenya, the study generated data will inform discussions around preparedness of developing countries to regulate SynBio which is fundamentally a transnational technology – begging questions of benefit sharing, biosecurity, border governance and such like, issues that are governed at the global and transnational scales. The data also points to Kenya her opportunities and gaps to which she will have to bridge in order to join the leagues of UK and Singapore, and reap from the technology by enhancing for example the responsiveness of her health systems, food and nutrition security, environmentally safe manufacturing (Gronvall, 2015; Trump, 2017).

Simply stated, to field of International Relations (IR) this study make a key contribution. First, while both Realists and Liberals agree that the nature of power has shifted in International Relations, and that technology is currently a key source of it, systematic studies of the value of technology in enhancing the global leverage of states paradoxically escapes attention of IR students. Secondly, while high-value ST&I such as SynBio portends immense potentials for transformation in the developing countries - it has the opportunity for create in them independence through improved production and innovation along the sectors such as health, agriculture and so on - IR students from developing world continue to study traditional aspects revolving around trade/commerce and war-political issues, and fail to prioritize technology studies as a key determinant variable for states development: domestically and extra-territorially. This study thus attempted to remove technology from a peripheral status (as an issue domain worth studying in IR) to a key object of study in IR.

Most importantly, the insights from the study illuminated on the current national status of Kenya's biotechnology regulatory regime in light of the regulation of SynBio technologies, especially within the framework of ongoing global discussions at the CBD Technical Series on Synthetic Biology. This way, the insights from the study will inform Kenyan participation in international platforms such as the COPs, MOPs, AHTEG, etc., on what Kenya's position is with respect to its preparedness to regulate SynBio as well as areas where international support and collaboration

may still be needed. Beyond that, the study highlighted important gaps that need to be filled in policy, legislations, and NDPs in order for Kenya to adopt SynBio and gain from it optimally, that is, as a producer and an exporter, not a consumer/importer. Optimal production is possible through very skill-fully implemented innovative culture which is impossible without robust regulatory frameworks that will spell out who does what, when and how. To unlock her quest for regional technology powerhouse, argues this study, Kenya must ensure that she has an adaptive anticipatory governance framework that will mediate a balance of the risks and promises of SynBio.

Thirdly, the study further makes two contributions to the global debates on biotechnology and the justification for SynBio adoption and regulation. First, a large body of work discussing the need to adopt and regulate biotechnology and SynBio in particular is developed countries oriented, most of all because SynBio development is still dominated by developed economies (Marris & Calvert, 2018). This study generated important developing countries' perspectives on this debate hence was an attempt to bring technologically backward nations into this debate. Secondly, the study findings lay the basis for future research studies on regulating SynBio in Kenya. As the first of its kind, the insights generated in this study may serve as the baseline for future similar studies.

The policy/empirical significance can be stated as follows. Firstly, SynBio has become a lucrative market domain, growing at a rate of 34.4% between 2013-2018 (UNEP & CBD, 2017; Kolodziejczyk & Kagansky, 2017). By laying out evidence that can be used to generate a functional regulatory environment, this study will be contributing to Kenya's economic development. Moreover, SynBio is perceived as a key enabler of the knowledge-based bio-economy (WEF, 2016). The insights and debates generated from this study may initiate discussions that may lead Kenya to stand a better chance to enter into the league of synthetic biology products producers to not only boost and buffer its bioeconomy sectors such as health, blue economy, agriculture and the rest, but also to gain foreign income from the production SynBio products, hence assert its national power extraterritorially.

Still on the policy front, and more importantly, this study analyzed policies, legislations, and NDPs, as well as explored key stakeholders perspectives on the synthetic biology technology. These empirical insights will form the ground for further debates on the regulatory needs and approaches that the country may consider putting into place before the technology is adopted and implemented. As such, this study is the foundation for laying an adaptive and anticipatory

governance framework for SynBio in Kenya which will include the formulation of SynBio Policy, SynBio legislation and a Bioeconomy Strategy subject to further studies and decisions.

Lastly, on the normative front, the study insights will contribute to normative debates in global environmental governance scholarship, particularly the normative discourses spearheaded by the United Nations Convention of Biological Diversity platforms, including but not limited to: COP, SBSTTA, AHTEG, and SynBio Technical Series. These include, debates around asymmetrical gains in the global market share of SynBio between developed and developing countries (see, UK Parliament Office on Science and Technology, 2015), debates around technology transfer, benefits sharing, inclusion, environmental sustainability and so on (see, e.g., CBD, 1992; SCBD, 2021), and the fears for negative socio-economic impacts that may result from adoption and implementation of synthetic biology.

1.6. Scope and Limitations of the Study

Scope: Geographically, this study was conducted in four counties in Kenya, namely, Nairobi, Kisumu, Kakamega, and Kisii and on zoom meeting platforms. The actual population of the study from these sites were engaged physically through traditional interview-surveys or via online platforms. The study was restricted to documentary analysis of 6 selected policies, 7 legislations, and 4 NDPs related to biotechnology regulation and development in Kenya. The study primary data was based on survey, FGDs and KIs strictly from expert respondents in the biotechnology and related fields-drawn from academia, research, policy, regulatory & governance bodies, media and communications, industry, and medical sectors.

Limitations, biases and mitigation measures: a) potential actors in SynBio go beyond just like the experts whose responses this study was based. They include also the common Kenyan who has zero idea what SynBio technologies are. As an exploratory study, however, the study aimed to gather initial but critical information on stakeholders' perspectives on SynBio which is important to understand the current gaps and forge an adaptive anticipatory governance for SynBio. Such information may only be available with the experts not the general public. b) Secondly, the analyzed policies, legislations, and NDPs, may not be conclusive since SynBio has multiple contribution to nearly all sectors which may imply that all policies of the government of Kenya may need to be explored. For the purposes of this study, the documents analyzed are only those that may have a more direct contribution to the understanding of the current gaps in light of SynBio

governance in so far as they related to bioeconomy and biotechnology governance and development. Lastly, the study involved asking the sampled 'experts' to help identify the perceived gaps biotechnology-related policies, legislations, and NDPs in regards to the regulation of SynBio technologies. In certain instances, such level of expertise expected of the respondents encountered challenges since it would be difficult to comment on the exact content of a given regulatory document as people usually prefer to make general comments on a given policy. To mitigate this, the researcher conducted in-depth analysis of the selected documents before conducting interviews and surveys in order to isolate specific regulatory questions and put those questions in general terms to encourage and improve quality of responses.

1.7. The theoretical and Conceptual Frameworks

These assumptions, collection of data, analysis and the interpretation of study findings of this study, were conducted within limitations of the concept of national power as applied in the theory of Realism in IR and the theory of adaptive and anticipatory governance as applied in the governance of emerging technologies. The concept of national power helped the researcher situate the study within the discipline of IR based on the assumption that through adoption of SynBio in proper regulatory environment, Kenya will not only increase her national power in ST&I relative to her peers, but will also unlock sustainable livelihoods and human development. Secondly, to enable the researcher to collect, analyze and interpret data within a guided framework, the theory of adaptive and anticipatory governance (Trump, 2017) was applied. The theory provided a framework upon which research questions were formulated, and analysis and interpretations made. A conceptual framework was then formulated based on key concepts from the theory of adaptive governance.

1.7.1. The Concept of National Power

The concept of national power is the most important concept in the field of study of IR (Morgenthau, 1973; Treverton & Jones, 2005; Ahmad, 2012). The simplest understanding of power is given by Wikipedia as "power is a measurement of an entity's ability to control its environment, including the behavior of other entities." A definition applicable to international relations has been given by Rosen & Jones (1977) which emphasizes the international scene as the theatre for the entity exercising power. They assert that power is "the ability of an international actor to use its tangible and intangible resources and assets in such a way as to influence the outcomes of events in the international system in the direction of improving its own satisfaction

with the system." This concept implies the twin terms of power and influence, whereby influence is the very carrier of power (Ahmad, 2012). In international Relations, power has been characterized by Realists, commenters on Realism and non-Realists as relative, and subject to decline and growth (Griffiths, 2007).

National power, according to Sarkesian & Conner (2006) is "a mix of strategic, military, economic, political and psychological strengths and weaknesses of a country or a state." *The U.S. Dictionary of Military and Associated Terms* reinforces this conception thus: "National Power is the sum of all resources available to a nation in the pursuit of national objectives." Traditionally, power has been classified into two main broad categories: hard and soft power. Realists and non-Realists have all warned against the overemphasis of any one of these categories as the only components of national power. The chief Realist, the celebrated father of human nature Realism (see Grifiths, 2007), Professor Hans J. Morgenthau himself characterized such an approach to understanding the dynamics of national power as the "fallacy of the single factor." (Joblonsky, 1997, p. 35).

To understand the contemporary dynamics of national power, scholars have assessed evolution of the concept in practice and theory and have come up with three important analytical dimensions, also called the "power shifts" (Ahmad, 2012): violence, wealth, and knowledge (Toffler, 1990, p. 15-16). Violence has traditionally been the *sin qua nom* of international relations up to roughly the period of industrial revolution. According to Toffler (1990) there was a shift in the nature of power from violence undertaken by the "nobility" to wealth exercised by the "industrialists and financiers" during the industrial revolution. According to Ahmad (2012): "Today, a third wave of shifting power is taking place with wealth being overtaken by knowledge" (p. 85). In deed even long before the post-industrial period, the celebrated antiquity IR theorist, Kautilya, had recognized three dimensions of national power: knowledge, military might and valour (Coulombis & Wolfe, 1982, p.63). Nonetheless, in the 21st century the real owners of power, which empirically are also the richest in the earth are the owners of specialized knowledge most especially in information technology which is driving the information age. Elon Mask and Bill Gates are such individuals whose wealth combined measure much more than several the GDP of African countries. Not only do they have wealth but also have enormous power, and influence across all countries and global institutions, most of which they are leading individual donors to.

Knowledge in the studies of national power is described as the "highest quality power" comparable to violence or military power which is described by Toffler as lowest quality power and wealth described as medium quality power (Ahmad, 2012, p.84). The most advanced forms of knowledge as national power is through the manifestation of what some scholars have described as the fifth industrial revolution; where high-end innovations and highly disruptive technologies are produced through the convergence of the knowledge from digital, biological and physical worlds. Such innovations include what has been synthetic biology, a term which refers both to the bio-innovations products and the multidisciplinary fields of study that include engineering, biology, informational technology, and more that are applied to produce such products.

Indeed, there is vast evidence that the technologies of synthetic biology are the new arenas for possible shifting of relative national power. According Gronvall (2015), for example, the USA should fear and make necessary adjustments in policy, planning and funding because unlike before, the UK has entered the field and will compete equally with the USA on the global SynBio market, as well as applying the technologies in security and national strategic areas. The United States of America, and the United Kingdom are at the forefront of developing these products not only for bolstering their bioeconomy but also as products for international trade. Each country is seeking to be the "science superpower" by investing enormous shares of the GDPs to the advancement of synthetic biology and associated technologies. For example, the UK government currently spends 1.7% of its GDP on R&D and aims to upscale to 2.4% by 2027 in a bid to achieve her "science superpower" vision possible only through an "innovation-led economy" (Long, 2021; European Union, 2017). The USA, the global leader in spending on R&D and funder of global R&D projects, has sustainably increased its annual spending on R&D and today spends 105 times compared to 1955. The country allocated about $627 billion on non-defense R&D and $672 on defense-related R&D in 2021 and aims to increase this each financial year (FY) (Congressional Research Service, 2021; American Association for the Advancement of Science, 2021).

In this study, synthetic biology is viewed in two important ways, first as source of national power to Kenya and secondly as an enabler for sustainable livelihoods. In this way, the study is premised on the fact that by adopting the technology within a requisite regulatory environment, Kenya will enhance her science capabilities, keep and/or increase her national power compared to other

African countries. According to Morgenthau (1973) the purposes for which countries engage in power politics are three: to keep power, increase power or demonstrate power. Kenya will keep her science power in Africa because currently, Kenya's capability in terms of bioinnovation, in the form of genetically modified organisms (GMOs) is only comparable to that of South Africa (Reagan et al., 2022). Kenya will increase her science capabilities because synthetic biology is a move advanced technology than GMOs. Secondly, this study perceives synthetic biology as an important source of national economic development; contributing to health, agriculture, climate change, and livelihood sectors of the economy, just as is the case in the USA and UK where investment has been taken very seriously.

1.7.2. Theory of Adaptive Anticipatory Governance

The theory of adaptive anticipatory governance widely used across many disciplines of the social sciences including anthropology (Samimian-Darash, 2013), history (Andersson and Rindzevičiūtė, 2015), human geography (Anderson2010; Evans, 2010), sociology (Adam and Groves2007; Beckert, 2013; Bell & Mau, 1971), and very commonly by researchers in science and technology studies (STS) (Aykut, Demortain & Benbouzid, 2019; Borup et al., 2006; Jasanoffa & Kim, 2009; Trump, 2017). In the field of International Relations, a systematic analysis of the theory's relevance to issue areas in IR has been largely pegged on the role of International Organizations (IOs) and the need to govern uncertain futures. The works of Berten & Kranke (2022), *Anticipatory Global Governance: International Organisationsand the Politics of the Future* is the first of its own kind in the field to integrate literature from mainly ST&I and to account for the dynamics of anticipatory governance in international relations by coining the concept of global anticipatory governance. According to Berten & Kranke (2022) governing uncertain issue areas in international especially climate change, terrorism and emerging and highlighy disruptive technologies of of which exhibit a transnational dimension, require that states put into place the needed adaptive strategies that will anticipate and mitigate future risks, hence enable states to govern the future. To these scholars, the ideas, the knowledge of what future uncertainities to be governed and the push for the agenda to govern the unkown is a role that has been played by the international IOs.

Therefore, adaptive anticipatory governance though new in IR, has been recently proposed as one critical world view of understanding the processes through actors organize, collaborate, and do the politics of governing the future of global inherently transnational issue areas of IR. Emerging

technologies such as SynBio fit squarely within Berten & Kranke (2022) characterization of issues targeted for anticipatory global governance in two major ways: firstly, the governance of SynBio has been pushed by the UN's CBD and her protocols and expert institutions such as SSBTTA with states only buying most of what such institutions have suggested and the mechanism for governing SynBio such as benefits sharing, and expert and imports and the needs for checks at border points, the need for a proper anticipatory mitigation mechanisms to counter potential risks such iosecurity among others. Secondly, SynBio is the latest bio-innovation whose regulation requires harmonization of approaches to governance. This is why the CBD and mertings suh as COPs have laced SynBio discussed at their core business, calling on countries to adopt mechanisms which will ensure proper governance and development of the technology.

This study thus chise this theory has it had the capacity to embed this study within IR as well as its inter-disciplinary engagements with especially the field of STI. The researcher employed the theory as an analytical framework especially within the purview along which the theory has been used in ST&I particularly by Trump (2017) while stdying Singapore, UK and USA's SynBio regulatory approaches. This is in tandem with the arguments made by Berten & Kranke (2022) who assert IR will borrow from ST&I frameworks, as it consolidates her constructs especially in STI and related studies. Most importantly, the researcher found either of the mainstream theories in IR properly equipped to analytically guide the operationalization of this study in terms of data collection and analysis. The manner in which the theory of AAG applies in ST&I studies and in this particular study is discussed below.

Adaptive Anticpatory Governance (AAG) has been proposed in the emerging technology governance literature, including the governance of SynBio (Greer & Figueras, 2016; Trump, 2017; Marris & Calvert, 2018). It has been applied to identify regulatory gaps in SynBio regulation in technologically advanced economies such as the UK and the USA and Singapore (Trump, 2017). Several studies (Joyce et al., 2013; Bar-Yam et al., 2012; Pei et al.,2012; Kuiken et al., 2014; Giese & von Gleich, 2015; Douglas & Stermerding, 2014; Epstein & Vermerie, 2016; Malloy & trump, 2016; Edwards, 2014; Buhk, 2014; Guston, 2014; Carter et al., 2017; Calvert, 2013; Greer & Figueras, 2016; Trump, Cummings, Kuzma & Linkov, 2017; Wiek et al. 2014; Cummings & Kuzma, 2017) have argued that "anticipatory", "proactive" "sustainable" "responsible" and "adaptive" governance should be put into place to govern emerging technologies.

Trump (2017) contends that the need for an adaptive anticipatory governance for SynBio has two dimensions. In one hand, the technology enables developers and researchers to substantively alter the "genotype of viruses, prokaryotes, and eukaryotes, who may go on to interact with the natural environment" (p. 1) with the resulting products able to solve a myriad of endemic human challenges (Harris, McKemey, Nimmo, Curtis, Black, Morgan et al., 2012). Hence the need for proper policies to promote the technology. On the other hand "the release of various organisms with substantial genetic modification may potentially cause consequential and irreversible impact upon humans, animals, and the environment. Hence the need to ensure that even amidst investments in and development of SynBio technologies and products, the environment and health are properly protected through laid out mitigation measures should risks occur.

Trump (2017) and other scholars writing on regulating emerging technologies (such as Greer & Figuera, 2016; Boven, 2007; Fatehi, 2015; Abbot, 2012; Kelle, 2013; Calvert, 2013; Giese & von Gleich, 2015; Chugh, Bhatia & Jain, 2015; Oye, Esvelt, Appleton, Catteruccia, Church & Kuiken et al., 2014; Douglas & Stemerding, 2014;) have argued that five elements are core to the concept of adaptive anticipatory governance namely: transparency, accountability, participation, integrity and capacity (TAPIC) (Trump, 2017).

Trump argues that, a risk culture with respect to SynBio regulation relates to political and institutional factors that may frame how a country goes about its risk-management landscape for SynBio. These factors include three integral issues "the availability of biotechnology or GMO-centered regulation to capture SynBio, the degree of centralization within the policy reform and implementation process, and (iii) the manner in which regulatory disputes are adjudicated" "legalism" (*Ibid,* p. 2).

In 2017, Trump has advanced the TAPIC framework through a gaps analysis of the synthetic biology regulation in the EU, USA and UK. His assertion is that, the TAPIC framework provides the regulatory/policy researcher, with the framework to examine current regulatory environment and identify the gaps therein that may hinder successful regulation of SynBio. The TAPIC framework it is important "can contribute to the development of flexible, adaptive, and anticipatory governance to keep pace with the emerging knowledge of SynBio health risks" (Trump, 2017, p. 4).

The transparency element should cover two key issues: first, that transparent governance should properly spell out the policies applicable to SynBio regulation, with clearly stated scopes. This should also be communicated to the public through formal, regular platforms. Secondly, the governance framework should spell out regulatory rules and roles of regulatory bodies, stating clearly which authority and rules will cover which stage of technology's development life cycle (Trump, 2017; Greer & Figuera, 2017).

With respect to accountability, Trump (2017) argues:

> "that governance regimes promote accountability when those government actors, and key stakeholders are required to justify their decisions, and be held to account for such decisions if deemed improper, unjustified, or illegal. Such accountability can be difficult to build within the context of emerging technology governance, due to the lack of explicit regulatory instruments or risk management protocols dedicated to a specific technology like with nanotechnology or SynBio, where instead such standards and practices must be borrowed from pre-existing hard and soft law" (p. 5).

On the concept of participation, emphasis is laid on the notion that the creation of constructive, flexible, and anticipatory soft law for SynBio requires the engagement with key stakeholders within and without the government (Douglas & Stemerding 2014; Fatehi & Hall, 2015) as well as "the involvement of non-state actors within regulatory decision making is an essential element of producing policy that adapts to risk challenges posed by emerging technologies with uncertain risk profiles and health concerns" (Abbot, 2012 quoted in Trump, 2017). Trump (2017) distinguishes between two approaches of participation, bottom-up, where the government emphasizes on non-state actors participation and where government regulators only play a minimal role as in EU or a top-down, which is a state-experts driven governance approach where government policy makers and regulators play a critical role in framing the direction of SynBio regulation and development.

Concerning integrity, Trump (2017) asserts that "integrity for SynBio governance is largely borrowed from tangential yet directly relevant regulatory structures, within a given government until regulation specific to SynBio is crafted and implement" (*Ibid*, p. 5). At the same time, two integrity issues are being discussed in the literature as regards to SynBio regulation:

> The need for clear performance standards as well as the need for clear organizational missions relative to SynBio regulation and governance. For the former, standards relative

> to biosafety and biosecurity remain in relative infancy and are still being debated by many governments and organizations. Further, concerns relative to intellectual property of stepwise innovations within the field remain contested in various judicial systems (Trump, 2017, p. 6)

Finally, capacity issues in the governance of SynBio are at their initial stages owing to the emergingness of SynBio as a bioinnovation. Trump (2017) recounts that in the EU, USA, Singapore, the cross-cutting approach is through targeted government funding of key institutions and through promotion of public private partnerships in research endeavors.

This study employed the theory to explore regulatory gaps that exist in Kenya's biotechnology regulatory frameworks. The study will apply the TAPIC model to conduct a gaps-analysis of the current biotechnology policies, legislations, and NDPs in Kenya. The following paragraph elaborates the manner in which the TAPIC framework was applied in this study.

The theoretical framework provided an important analytic frame to analyze the selected documents, and explore expert stakeholders' perspectives on SynBio. The researcher derived 13 questions from the TAPIC concepts which guided the documentary analysis and the primary data collection and interpretation, finally allowing TAPIC modelled recommendations. During interpretations, where necessary, the TAPIC questions will be denoted by letter Q, where for example Q1 will denote question 1. Therefore, the analysis of 6 biotechnology-related policies, 7 biotechnology-related legislations, 4 NDPs, and the exploration of expert stakeholders' perspectives and expectations along five thematic categories. The table below enumerates the questions derived from each of the TAPIC concepts based on the foregoing discussion on the theory.

Table 1: TAPIC Gaps Analytic Questions Framework

1. TRANSPARENCY
Q1 Are there existing SynBio policies with clearly stated scopes?
Q2 Are there existing regulatory bodies charged with SynBio regulation with rules governing their operations?
Q3 Are these rules clearly stating which phase of SynBio development cycle will be covered by which body (ies)?
2. ACCOUNTABILITY

Q4 Can current regulatory regimes hold government and other key stakeholders accountable for SynBio decisions & actions they might take?
Q5 Can existing law be borrowed to facilitate accountability?
3. PARTICIPATION
Q6 Is there an established stakeholders' engagement platform that brings together industry, academia, and government for specific discussions concerning SynBio/Biotechnology development issues?
Q7 Which participatory approach is more appropriate for early stages of SynBio R&D in Kenya? (bottom-up, top-down or mixed methods)
4. INTEGRITY
Q8 Are there clearly stated performance standards guiding institutions undertaking SynBio processes?
Q9 Are there clearly stated organizational missions relative to SynBio regulation and R&D?
5. CAPACITY
Q10 Are there positive gestures of government funding for SynBio Projects?
Q11 Are there good positive of public private partnerships of SynBio research?
Q12 Are there positive gestures of donor funded SynBio projects?
Q13 Are there positive gestures of available local human resource, and equipment (labs and other critical assets) capabilities to spur SynBio R&D?

Table 1: TAPIC Gaps Analysis Framework

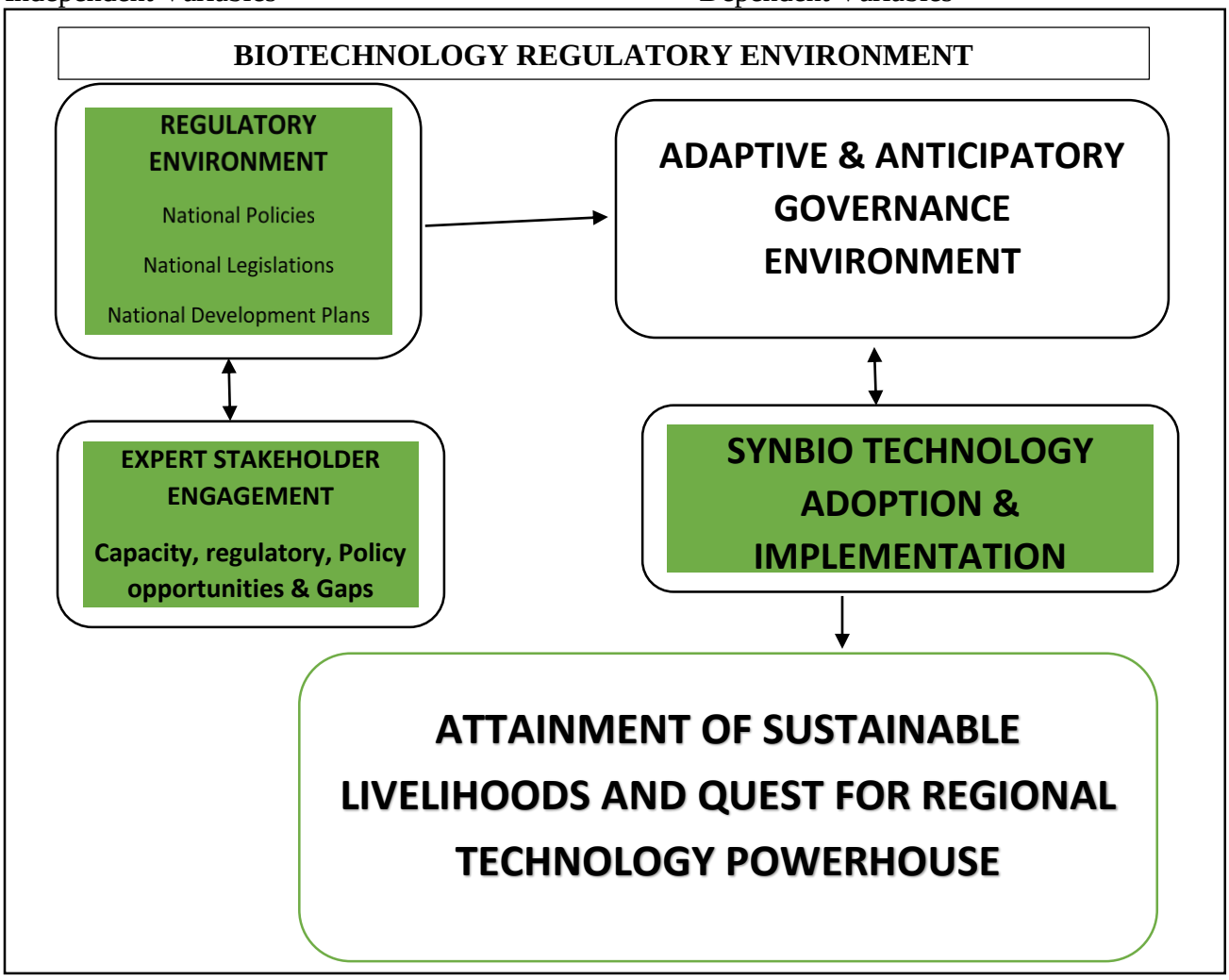
Source: Modified from Trump (2017).

1.7.3. The conceptual Framework

This study was guided by three key concepts; policy environment, stakeholder engagement and SynBio technology adoption and implementation drawn from the theory of adaptive governance to guide collection, analysis and interpretation of results. From the conceptual diagram below, a biotechnology regulatory environment entails two primary broad concepts: policy environment and stakeholders' engagement. Whether these are robust enough to cover SynBio development and regulatory issues will lead to or not, an adaptive anticipatory governance framework for SynBio technologies. With the adaptive anticipatory governance in place, SynBio adoption and implementation would happen seamlessly hence leading to attainment of national power and enhancement of Kenyan citizens' livelihoods. Figure 1.0 is the diagrammatical relationship

between the variables of the study. The relations is then discussed into detail in the following sub-sections.

Figure 1.0. The Conceptual Framework Diagram



Source: Researcher (2022).

1.7.3.1.Policy Environment

There are three important aspects of a policy environment in the public policy analysis literature: the policy document, or sometimes called Sessional Papers in countries like Kenya. This contains policy objectives, guiding principles, policy intensions and programs (Brewer & DeLeone, 1983; Birkland, 2005; Stone, 1997; Parton & Sawicki, 1993) and is the formal evidence that there is a policy in place. Page (2006) adds concept of "overarching ideology guiding the policy" document. In the context of this study, an ideology underlying policy processes can be either pro-Science, Technology & Innovation (ST&I), in which case adopting and implementing emerging disruptive technologies, like SynBio, could be justifiable and easier. Underlying ideology can also be anti-ST&I, in which case, emerging technologies may not only be difficult to adopt but may experience serious concerted opposition even from within and out of government and among scientists themselves as has happened with GMOs discourses (Pamela, 2006) or from the general publics (UK Parliamentary Office on Science and Technology, 2015).

Policy document can be national, regional or global in scale. Global and regional policy documents, usually called soft law or international regimes; including but not limited to declarations, recommendations and resolutions (Shelton, 2011). These may become part of national policies and law either automatically through incorporation/ or "direct applicability" (Shelton, 2011) in countries where international law enjoys hegemony over national law such as in Kenya (Opong, 2006; CoK, 2010, Article 1 para. 5 & 6). The study carefully selected[9] 16 biotechnology-related policies, which were analyzed with a view to identify current gaps in biotechnology policies, which will affect the smooth adoption and implementation of SynBio in Kenya. Because from an IR perspective (if not all), domestic policies are localized from the international regimes to which nation-states have subscribed, the study delved into analysis of the global regulatory frameworks concerned with SynBio in greater detail. However, because this was beyond study scope, the task was achieved within the literature review section. This informed the study on the current SynBio regulation gaps identified globally, hence the justification for this study.

[9] The selection process of the final documents analyzed was informed by the engagements with supervisors among which was a key person in Kenya on Synthetic biology issues. The key person leads SynBio debates in Kenya and is the country's as well as Africa's representative to the CBD where debates around SynBio emerged and are ongoing.

A second dimension of a policy environment is development planning (Page, 2006; Birkland, 2005; Anyebe, 2018). This comes in the form of national development blueprints/plans (NDPs) for institutions aimed at actualizing recommendations of certain policies, for example, most institutional NDPs in the post-2007/08 have integrated the visions of the Kenya Vision 2030, and those in the post-2018 have integrated the visions in the so-called Big Four Agenda. National development plans on other hand can be based on a pro-ST&I ideology or otherwise. The study analyzed 7 key NDPs to establish the extent of embedding of the ST&I theme with the assumption that if Kenya's development plans are driven by an innovation-led economy, adoption of SynBio could be easier or at least face only a few challenges to be mainstreamed in national development planning.

A third dimension of a public policy environment are the legislations and acts of parliaments (Anyebe, 2018; Birkland, 2005; Page, 2006) meant to legalize (or transform into law) the approaches adopted in a policy document, and meant to be actualized through the nation-wide and/or regional, sectorial or otherwise, institutions. They are meant to legalize the commitments the policy document bestows on the government, partners and stakeholders in the given area of public administration of interest to the policy in question. The study analyzed 7 biotechnology-related legislations with the view to identify current gaps in the biotechnology laws of Kenya within the TAPIC framework.

1.7.3.2. Stakeholder Engagement

Equally important component to the concept of a policy environment, particularly during this so-called the era of democratic triumph, is the concept of stakeholders' engagement. For this study, stakeholders' engagement derives from the assumption that an adaptive anticipatory governance of SynBio is unattainable without the involvement of key stakeholders. From current practices, it is actually reported that, a key enabler to the TAPIC concept of capacity in countries that have succeeded in bolstering their bioeconomy through SynBio, is the ability to establish stakeholders engagement platforms where industry, academia, policy makers and regulators and researchers meet and generate important evidence to guide SynBio R&D through written consensuses on ways forward for SynBio (Trump, 2017). Emerging from the private sector (Freeman, 1984), the concept has been used in the studies of public policy to denote the importance of a pluralist approach to consensus building, and solving public demands that are beyond the capacity of any autocratic

leader (Anyebe, 2018). Empirical literature (Trump, 2017; Keiper & Atanassova, 2018; SCBD, 2021) have particularly argued for the need for stakeholders engagement in public and private discourses concerned with SynBio.

Marris & Calvert (2018) have argued that new technologies such as SynBio, are riddled with numerous uncertainties and as such, engaging both governmental and non-governmental stakeholders provide an opportunity for nations to involve the varied visions, perspectives, knowledge, and attitudes of various population categories whose lives will be affected by the new technology. The study used the concept expert stakeholders' engagement to justify why the study had a fourth objective of this study. The study thus explored expert stakeholders' perspectives on SynBio and factor that would affect its adoption and implementation in Kenya. Expert sample were drawn from academia, relevant industries, policy, regulatory and governance bodies, media and communication and research sectors. The stratification enabled us to gather perspectives from a wide spectrum of experts. The study surveyed and interviewed selected experts based on the TAPIC framework, which lead to specific regulatory, policy, capacity, and environmental, ethical and social aspects of SynBio all of which were key to understanding the state of the current biotechnology regulatory environment.

By engaging experts, the study also hoped to generate important pro-SynBio perspectives, that may serve to inform SynBio debate that is more informed and which exhibits better understanding of the regulatory questions concerned with SynBio. This was hoped to demystify mythical opinions and anti-biotechnology notions which have stagnated biotechnology and GMOs development in the country (Mugo et al., 2011; Pauline, 2006; Regan et al., 2022). Important to note is that, the stakeholders engagement model was limited to purposively experts only because the study assumed that as a new technology in Kenya, the opinions that may matter now in regards to identification of current regulatory gaps are only from those experts who have in one way or another engaged in biotechnology regulation, research, policy making, or at whatever capacity. It these experts from whom the study was able assess the gaps and the opportunities the study identified from the documentary analysis further as well as establish capacity, and other emerging regulatory, policy issues based on their experiences with biotechnology and related development activities.

1.7.3.3.Technological Innovation and Adoption and Implementation

SynBio is the most promising of all current bio-innovations (Keiper & Attanassova, 2018). At the same time, literature emphasizes that its adoption must consider its double-edged sword nature (TWN, 2017; Trump, 2017). Designing an adaptive anticipatory governance for it is thus primarily seen as a way to eliminating or even mitigating its potential risks (SCBD, 2021; Trump, 2017; Reagan, 2022) while facilitating a robust environment for its development and utility for national development. This study exploited the concept technology adoption as a dependent variable. The assumption here is that with robust policy environment (policies, legislations, and NDPs), and broader engagement of the relevant expert stakeholders this will lead to adaptive anticipatory governance for SynBio leading to the SynBio technology adoption and implementation (as captured in figure 1 above).

Further the study's key argument that a robust policy environment and expert stakeholders' engagement leads to adaptive anticipatory governance that will mitigate the challenges which usually accompany emerging technologies in the Third World such as unfavorable (unclear and ambiguous) government policies, lack of technical infrastructure, inadequate human infrastructure and a culture that does not favor the adoption of technological innovations (anti-SynBio) (Ejiaku, 2014; Andada, 2006; Mugo et al. 2017; Abbot, 2012; Kuzna, 2013; Lynch, 2001).

Finally upon successful adoption of SynBio in an adaptive anticipatory governance framework Kenya will be able to enjoy the benefits that have accrued to developed countries such as USA and UK. The country will enhance her national science capabilities, hence increase her national power relative to her peers. She will also be able to improve the livelihoods of her citizens, sustainably owing to the green methods that SynBio comes with (Bojar, 2018; Reagan et al., 2022; Keiper & Atanassova, 2018).

CHAPTER TWO

LITERATURE REVIEW

2.1. Introduction

This section presents the theoretical and empirical literature review. The literature review served four main purposes in this study. Firstly, the literature helped in identifying gaps in current policies, legislations, and national development plans in used to regulate GMOs in the regulation of SynBio. Secondly, through the review, the researcher was able to isolate certain key concepts that are relevant for the field of science technology and innovation, as studied in International Relations, and in the literature on the regulation of SynBio. Thirdly, through the review, the researcher was able idenfy key global governance concerns about SynBio and hence fit a case study of Kenya within this broader debate. Lastly, it was through a very extensive literature review that the researcher was able to refine the study objectives, and define qualitative and quantitative questions for the study.

The review framework adopted a global-to-regional-to-local-objectives based approach (GRL-O approach). This is the analycal outline of the review. Section 2.2 outlines issues pertinent to revising current biotechnology regimes as highlighted from mainstream international regimes which constitute of the CBD and its protocols. Section 2.3 outlines literature on the perspectives of emergent global regulatory frameworks for SynBio, since SynBio regulation has been perceived to go beyond CBD and its protocols that have guided national domestication on GMO and related regulations; to involve for example, the Bacteriological Weapons Convention (BWC) due to the dual-use and biosecurity notions of the technology. Section 2.4 outlines literature on the empirical evidence about the SynBio regulatory experiences of technological advanced countries, using the cases of USA, Europe, UK and Singapore. This section borrows very heavily from Trump (2017) work, one of its kind that have ventured into a comparative study on how SynBio is regulated in these countries.

Section 2.5 sheds light on the state of biotechnology research in African sub-Sahara region by pointing at the regulatory issues that have riddled the process. Section 2.6 critically reviewed GMO regulation and development on Kenya based on empirical records of past studies on GMO projects as documented by researchers who were involved. Two materials were particularly found useful, namely Pamela (2006) and Mugo et al. (2017) other non-Kenya specific works butwhich were

critical a they encampoassed Kenya within the sub-Saharan African scope was were works by: Reagan et al. (2017) Otieno et al. (2017) and Olembo et al. (2017). Overall, works on biotechnllgy regulation in Kenya are very scarce, something that justifies this study. Moreover, this is the first study ever to examine the biotechnology regulatory framework with a view to establish its robustness to regulate issues concerned with SynBio – a more advanced technology.

Section 2.7 explored the literature pointing to the basis of national development planning as a critical step taken by advanced countries to reap the most form SynBio, through mainstreaming the technology in national and sectorial plans. It illuminates the approaches to mainstreaming SynBio into National Development Planning and the value of a SynBio roadmap and strategic plan for latecomers like Kenya. Section 2.8 presents empirical work that has been conducted in line of gathering public perspectives as a step toward bettering regulation of SynBio. The final section, 2.9 concludes by summarizing the gaps in the reviewed literature.

2.2. The Global Regulatory Frameworks and Perspectives on Synthetic Biology

2.2.1. Convention on Biological Diversity and its Protocols

Introduced for ratification at the Earth's Summit in Rio de Janeiro in 1992 (United Nations, 1992; Jenks, 1995), the Convention on Biological Diversity (CBD) has become the central discussion forum for SynBio since its substantive discussion began in 2012. The CBD objectives are set in Article 1 as follows: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies. CBD does not refer to SynBio but its conception of 'biotechnology' has been construed as covering SynBio (AHTEG, 2000; AHTEG, 2021). Three main provisions of the CBD lay groundwork for national regulatory frameworks of biotechnological innovations.

Article 3 states that; "States have following the Charter of the United Nations and the principles of international law the sovereign right to exploit their resources according to their environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction". This implies that States Parties to the CBD and its processes (including the COPs, protocols, AHTEG, SBSTTA) have the right to domesticate their international legal obligations within the limits of international law.

Article 14.1(a) of the Convention obligates each State Party to, as far as possible and as appropriate, "*introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity*. Article 14.1(b) requires each Party, as far as possible and as appropriate, to "*introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account*" (AHTEG, 2021, p. 75). Within the context of SynBio, this provision implies that Parties should put in place regulatory guidelines for environmental impact assessment, as stated in Article 14(a) that will help minimize the potential risks of SynBio. However, as already highlighted in the background section, the exact amount of SynBio risks are not yet quantifiable because most innovations are underdeveloped or near-market circumstances. Moreover, ''…the interpretation of "likely" and "significant" as used in Article 14 (a) may also have to take into account the case of low-probability, high-impact scenarios which some SynBio applications may pose'' (*Ibid*).

Articles 8(g) and 19 (4) lay down the biosafety guidelines for LMOs. According to Article 8(g) Parties should 'establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which is likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.' From Article 19 (4) 'Parties shall provide any available information about their use and safety regulations in handling any LMOs resulting from biotechnology that may harm the conservation and sustainable use of biological diversity, as well as any available information on the potential adverse impact of the specific organisms concerned to a Party into which those organisms are to be introduced'.

Biotechnology concept is defined in Article 2, thus, 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. The International Union for Conservation of Nature's (IUCN) *Guide to the Convention on Biological Diversity*, contends that the biotechnology definition above was 'designed to include both present and future technologies and processes' (Glowka et al., 1994, cited in SCBD, 2021). The difficult question has been whether CBD and Nagoya Protocol's definition of biotechnology is broad enough for SynBio regulation. The SCBD (2021) response is that '…the extent to which biosafety provisions of the Convention apply to SynBio depends on

the interpretation of [living modified organisms resulting from biotechnology] likely to have adverse environmental impacts' and 'potential adverse impacts', and use and release (p. 75). The Technical Series concludes that the one criterion for considering an organism resulting from SynBio techniques' as an LMO within the scope of the CBD might depend on which products of SynBio are considered as "living". It lists four such SynBio organisms beyond the CBD biosafety regulation: 'DNA- and RNA-based circuits, protein engineering, metabolic pathway engineering, genome-level engineering, protocell construction, xenobiology, and cell-free systems'. This reinforces the background literature that the LMO regulatory framework cannot cover the full range of SynBio methodologies and techniques, which largely involve SynBio DNA as a core tool. Moreover, biosensors and diagnostic kits which Kenya aims to adopt at the end of the NRF SynBio Project fall out of the scope of 'living' organisms, necessitating the need to establish such a pre-finding further through policy and legislation review as well as a review of current biotechnological practices.

2.2.1.1. Cartagena Protocol to the Convention on Biological Diversity

The Cartagena Protocol on Biosafety is a follow-up legal instrument that refines and puts into perspective the biosafety provisions of the Convention on Biological Diversity. It came into force in 2003 and has 173 members by March 2021. The scope of the protocol is stated as 'this Protocol shall apply to the tranboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health' (Article 4). Article 1 reiterates the *precautionary principle* embedded in Principle 15 of the Rio Declaration on Environment and Development.

Article 3(g) defines LMOs (which were not defined in the CBD), thus, "any living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology". Consequently, SynBio applications must fulfil three criteria to qualify as LMOs i) be a living organism, ii) possess a novel combination of genetic material, and; iii) result from the use of modern biotechnology (SCBD, 2021). Article 3(h) defines living organisms as any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids (*Ibid*, p. 4). Genetic material is not defined in the Protocol but is in the CBD's Article as: containing functional units of heredity. Based on these understandings of definitive

aspects, moreover, 'many areas of research in SynBio would be considered as producing living organisms, including microbes produced by genome-level engineering and cells altered by SynBio metabolic engineering' (*Ibid*, p. 84). To put it another way, some aspects of SynBio are not covered by the Cartagena Protocol. AHTEG's 2019 Report on SynBio took up the question of SynBio outcomes that fall out of the Cartagena protocol's LMOs. The AHTEG acknowledged that 'virus-like macromolecular assemblies and protocells were not LMOs as they do not constitute living organisms'. The report is unclear whether some transiently modified organisms would constitute living modified organism as defined in the Protocol. Mackenzie et al. (2003) contend in IUCN's *Explanatory Guide to the Cartagena Protocol on Biosafety* that what should form part of LMOs was hotly debated during the negotiation of the Cartagena Protocol. The negotiated definition of LMO products was laid in Article 39(c) Cartagena Protocol 'detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology'. Following this definition, Wellhausen & Mukunda (2009) argue that SYNBIO products that are made from LMO organisms can be regulated by the Cartagena Protocol.

While some commercial SYNBIO compounds fall within the protocol's conception of modified/processed LMOs, it is unclear to those SYNBIO products which are 'DNA and constituent parts' (Mackenzie et al., 2003). Moreover, Article 3(h) of the Cartagena Protocol was not meant to directly include 'plasmids or DNA' (*Ibid*). According to SCBD (2021) Cartagena Protocol provisions on risk assessment and the minimum required information to be included in notifications under some of the Protocol's procedures may apply to naked DNA and its constituent parts resulting from SynBio techniques if they contain 'detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology' (p. 85). This interpretation has not been nationalized since, 'in practice… many countries do not apply the Cartagena Protocol's provisions on risk assessment and the minimum required information to naked DNA and its constituent parts because they are considered to be components rather than products of LMOs' (*ibid*). This further reinforces the argument that national regulatory frameworks are as yet not robust enough to govern the full range of SynBio methods and techniques.

2.2.1.2. Nagoya– Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Supplementary Protocol) was adopted at the fifth meeting of Parties to the Cartagena Protocol on 15th October 2010 by the 27th Conference of Parties on the CBD. It has 48 Parties as of March 29th 2021 and entered into force on March 2018 (SCBD, 2021). The Supplementary Protocol takes further the discussions on the theme of liability and redress for damage that can result from trans-boundary movements of LMOs, a theme that emerged and was unresolved from Cartagena Biosafety Protocol negotiations (Article 27 of the Biosafety Protocol).

The objective of the Supplementary Protocol is defined in its Article 1 as: ‘’…to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to LMOs’’. Article 3 sets the objectives as: ‘…applies to damage resulting from living modified organisms which find their origin in a trans-boundary movement. The living modified organisms referred to are those: (a) intended for direct use as food or feed, or processing; (b) destined for contained use; (c) Intended for intentional introduction into the environment’.

It applies to damage accruing from three sources: any authorized use of the LMOs; resulting from unintentional trans-boundary movements as referred to in Article 17 of the Cartagena Protocol, as well as from illegal trans-boundary movements as referred to in Article 25 of the Cartagena Protocol Article 3). Article 2 (2b) defines ‘damage’ as: “an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that: (i) is measurable or otherwise observable taking into account, wherever available, scientifically-established baselines recognized by a competent authority that takes into account any other human-induced variation and natural variation, and (ii) is significant. How significant damage is, is elaborated in Article 2(3) as the long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period; the extent of the qualitative or quantitative changes that adversely affect the components of biological diversity; the reduction of the ability of components of biological diversity to provide goods and services; the extent of any adverse effects on human health in the context of the Protocol.

In case of damage, the Supplementary Protocol provides three avenues for responses: 'Parties shall require the appropriate operator or operators, in the event of damage, subject to any requirements of the competent authority, to, immediately inform the competent authority; evaluate the damage; and take appropriate response measures' (Article 5 (1)). Consequently, 'the competent authority is given three responsibilities: identify the operator who has caused the damage; evaluate the damage; and determine which response measures should be taken by the operator (Article 5(2).

The Supplementary Protocol defines the terms 'operator' and 'response measures'. An operator refers to a person in direct or indirect control of LMO, as may be determined by domestic law, including inter *alia*, the permit-holder, a person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier (Article 2(2c). Response measures refer to reasonable actions to prevent, minimize, contain, mitigate or otherwise avoid damage, as appropriate, or reasonable actions to restore biological diversity (Article 2(2d). Finally, Article 12 of the Supplementary Protocol establishes its implementation framework and relationship to civil liability for material or personal damage associated with the damage as defined within its scope. It states that 'to implement this obligation, Parties shall provide for response measures following this Supplementary Protocol and may, as appropriate: apply their existing domestic law, including, where applicable, general rules and procedures on civil liability; apply or develop civil liability rules and procedures specifically for this purpose, or apply or develop a combination of both.

From the discussions in 2.2.3. SynBio can, under certain definitions of LMOs, fall under the category of 'living modified organisms. At same the same time, as already discussed, SynBio applications potential risks can cause adverse effects on the conservation and sustainable use of biological diversity as conceived in the Convention of Biological Diversity. According to SCBD (2021), such adverse risks from SynBio can include, for example, 'unintentionally released organisms may transfer the inserted genetic material and thus change biodiversity at a genetic level, intentionally released organisms may become invasive due to engineered fitness advantages (p. 92). In this line of reasoning, SynBio innovations can be regulated by the Supplementary Protocol. However, and has been discussed across this paper, some, particularly more recent

SynBio applications (those of synthesized DNA) do not fall under the definition of LMOs thus the extent to which national regulatory frameworks based on the CBD and its protocols can regulate such is unclear. SCBD (2021) asserts that 'there appears to be significant controversy as to the scope and therefore "significance" of the potential damages. The applicability of the provisions of the Supplementary Protocol would have to be assessed for particular cases' (p. 92). The two cases of SYNBIO innovations: biosensors and rapid diagnostic kits which Kenya aims to adopt must be exposed to this analysis, hence this study.

2.2.1.3. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

The Nagoya Protocol was adopted on 29th October 2010 and came into force on 12th October 2014. As of March 2021, it has a total of 130 Parties. The protocol is a follow-up of Article 15 of the CBD which left a gap for further developments to facilitate achievement of its objective 3. Its scope is set in Article 3 as: 'shall apply to genetic resources within the scope of Article 15 of the Convention and the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge'. The Nagoya Protocol sets out core obligations for Parties in regards to access to genetic resources and traditional knowledge associated with genetic resources, benefit-sharing and compliance.

According to the SCBD (2021), three aspects of the Nagoya Protocol are particularly important to the regulation of SynBio (SCBD, 2021). The applicability of the phrase of 'utilization of genetic resources, 'benefit-sharing and the degree to which genetic resources can be modified under SynBio methods and techniques, and finally, the applicability of the concept 'derivatives' to the regulation of SynBio innovations.

Article 2 of the Nagoya Protocol deals with definitional issues and states that concepts defined in Article 2 of the Convention on Biological Diversity also applies to the protocol. The protocol defines 'utilization of genetic resources' as 'conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology and defined in the Convention' (Article 2). The concepts 'genetic material', and

'genetic resources' and 'biotechnology' are adopted from Article 2 of the CBD. SCBD (2021) avers 'SynBio may be a way of utilizing genetic resources as defined in the Nagoya Protocol and the definitions can also help to determine which activities related to SynBio would be within the scope of the Nagoya Protocol' (p.93). At the same time, TWN (2017) reports that most SynBio products and applications are at their advanced stages of development or already in the market for commercial use, particularly in the agricultural sector. Hence, the Nagoya Protocol as currently construed requires further interpretations on how SynBio fits within the scope of 'utilization of genetic resources' provision.

The second aspect of the Nagoya protocol and the SynBio regulation is on the issue of benefit sharing and the degree of modification of SynBio genetic materials. According to Wang et al. (2009), SynBio comes with a variety of techniques that can manipulate naturally existing materials for more customized purposes. Such methods include controlled/directed evolution like the multiplex genome engineering technology (MGIT/MAGE)[10] which can use SynBio DNA to produce 'billions of mutant genomes per day' (SCBD, 2021). The question which emerges from such SynBio techniques is: what is the threshold upon which manipulations of national genetic materials cease to become subject to benefit-sharing as state obligation? Technical Series on SynBio (2021) argues that ''national implementation and the negotiation of mutually agreed terms can assist Parties to an access and benefit-sharing agreement to clarify until which extent of the value chain the obligations to share benefits would continue to apply to components, organisms and products resulting from SynBio'' (p. 93). Therefore, Nagoya Protocol leaves space for national legislation and regulatory frameworks development that will help contextualize 'benefit-sharing obligations. This also speaks to the need for scientific assessment of existing policies and legislations to establish their robustness to cover such matters on SynBio.

Article 2 of the protocol defines a derivative as 'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of Heredity'. One of the questions which arise from the

[10] This technology replaces slow and expensive previous genome editing methods. Created by scholars at the Wyss Institute at Harvard University Multiplex Automated Genome Editing (MAGE), enables quick, cheap and efficient in vivo genome editing using a small machine (see, Wikipedia, 2021, https://en.wikipedia.org/wiki/Genome_editing).

application of this definition to SynBio is *whether or not biochemical compounds produced by synthesized organisms could be considered a 'derivative' as defined by the Protocol* (SCBD, 2021, p. 94; see also Erickson et al., 2011). The Technical Series on SynBio recommends that Parties still have a role to play by way of making this interpretation clear enough to solve ambiguities in the Nagoya Protocol's conception of 'derivatives'. It states, 'national implementation of the Nagoya Protocol can assist in further clarifying the definition of 'utilization' as well as the scope of access and benefit-sharing requirements about derivatives'' (*Ibid*, p. 94).

2.3. Emergent Global Regulatory Frameworks for Synthetic Biology

2.2.2.1. The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and Their Destruction (BWTC)

BWTC is an international legal instrument regulating the conduct of international warfare. The 1925 Geneva Protocol, the forerunner to the BWTC prohibited use of chemical and bacteriological weapons in war and the Regulations annexed to Hague Convention No. IV of 1907 already banned the use of poison or poisoned weapons as a means of conducting warfare (United Nations [UN], 1972). *The Convention was drafted during the Conference of the Committee on Disarmament and subsequently adopted by the United Nations General Assembly. It was opened for signature on 10 April 1972 in London, Moscow and Washington. The Convention entered into force on 26 March 1975 and is now binding on the vast majority of States* (International Committee on Red Cross [ICRC], 2014). The BWTC intends to set out its preamble to *exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons*. It prohibits the development, production, stockpiling, acquisition, retention and transfer of bacteriological weapons, and requiring their destruction.

The place where SynBio meets the BWTC is through the concept of dual-use which light has already been shed on. The fears that SynBio innovations may amount to double use, that is, that SynBio application may be used for unintended purposes by people who may acquire them for good intentions but turn them into biological weapons of mass destruction. The discussions already do in the context of the USA and Al-Qaeda is exactly what is implied here. BWTC, through the

national implementation, therefore may be seen as an extended regulation to cover such possible dual usages of SynBio applications. The extent to which the national BWTC regulation is robust to cover such issues is not clear making the policy instrument a candidate form evaluation in the studies.

2.2.2.2. UN Security Council Resolution 1540 (2004)

Security Council resolution (UNSCR) 1540 established a programme of action to prevent non-State actors, in particular terrorists, from proliferating nuclear, chemical and biological weapons (United Nations Office of Disarmament Affairs [UNODA], 2017). 'Governments all over the world are working hard to implement its requirements. The Security Council decided that all States shall refrain from providing any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, and requires all States to adopt and enforce appropriate effective laws to this effect. The resolution also requires all States to establish various types of domestic controls to prevent the proliferation of such weapons and their related materials. A Security Council Committee was established under resolution 1540 to report to the Council on the implementation of the resolution. Security Council resolution 1977 (2011) extended the mandate of the Committee until 25 April 2021' (UNODA, 2017).

The UNSCR is another regulatory ground whereby SynBio applications are perceived as capable of posing risks of dual-use. The particular target of non-state actors and prohibiting states from supporting such actors from developing, accessing or using WMDs of biological significance is important to SynBio since the applications are feared to have unintended use by unsuspected consumers who while they acquire such application within the prisms of the national laws, may use them in this regard. As Kenya is Party to this resolution as well as the said Committee, it is important to assess the national programmes that are geared toward the implementing of the resolution within the new context of the risks and opportunities of SynBio.

2.2.2.3. Nuclear Threat Initiative (NTI) and the World Economic Forum (WEF) Working Group's Report on SynBio DNA Regulation

The NTI and WEF working together with established an international expert *Working Group (*called the NTI-Forum Working Group*) on Preventing Illicit Gene Synthesis* 'to develop the basis for a durable, global norm to prevent the misuse of SynBio DNA and for a possible mechanism that could facilitate the implementation of such norms' (NTI & WEF, 2019). The two institutions recognized that SynBio was increasingly being accessible for large uses and its tools such as SynBio DNA were increasingly being produced and accessible globally as its cost was becoming cheaper with the increasing innovation of bench-top SynBio DNA machines, creating massive commercialization. The worry that underlines the working group's formation was the luck standardized global norms for regulating intentional or accidental misuses of Synthesised DNA, with existing practices only emanating from private actions of gene SynBio thesis companies, notably the International Gene Synthesis Consortium (IGSC) (p. 8) The 2019 report of the Working Group (generated by a multi-stakeholder engagement consisting of policy experts, leading industrial providers of gene synthesis and academic experts) advised for development of ''global standing multi-stakeholder, a technical consortium to develop a common DNA sequence screening mechanism that is accessible at low cost, secure and easy to use by all providers of DNA and providers of bench-top DNA synthesis machines'' by 2020 (NTI & WEF, 2019, p. 7). At the same time, the report advises that while 'the screening mechanism is developed, the Consortium should consider security precautions and built-in technical safeguards to prevent its misuse.

Consequently, as Kenya prepares to begin her journey in applying SynBio to solve health and food and nutrition problems as pioneer sectors of her bio-economy, it remains uncertain the extent to which the country's regulations are properly placed to regulate the use of SynBio DNA, at the center of SynBio tools. There is a need for assessing the country's regulatory framework in this regard for two main reasons. First, once SynBio is adopted in the country, commercialization will boom, making it possible for experiences of intentional and accidental misuse of acquired SynBio DNA. Secondly, as bench-top SynBio DNA machines enter the market on a large scale, access to SynBio DNA will be expected to boom, and sellers and buyers may skip privately-driven screening mechanisms. These and other reasons suffice for a study like this.

2.4. SynBio Regulation in Technologically Advanced Countries

2.4.1. Experiences from the UK

The UK is recognized as a world leader in SynBio (UK BioIndustry Association, 2014). The country undergoes SynBio research largely through public private partnerships (PPPs) and funding. The country has a SynBio Roadmap (2012-2016) and inaugurated her SynBio Strategic Plan in 2016. Through the SynBio Roadmap, it has established 6 multidisciplinary research centres, a SynBio research hub, and high profile technology translation infrastructure all of which have witnessed a dynamic R&D engagements between small and medium scale innovations companies with SynBio multinational companies (UK Parliamentary Office of Science and Technology, 2015). The country is cognizance of the fact that certain SynBio products and components are not GMOs and may challenge existing regulatory frameworks. This is why in the UK SynBio Roadmap of 2012 provisions for responsible research and innovation (RRI) were embedded to regulate publically-funded SynBio research in the areas of biosecurity, biosafety, and environmental and social responsibility (UK Synthetic Biology Roadmap Working Group, 2012; UK Parliamentary Office of Science and Technology, 2015).

In the UK, regulation of SynBio is based on similar approach adopted in the USA and Canada, where regulation focuses on the novelty of the traits of the product itself (trait-based, regulation) (*Ibid*, p. 2) as well as the approach adopted by the EU, where regulation is more on the process of genetic modification used to make a product and whether or not the GMOs are released to the environment (*Ibid*). This, however falls within the GMO regulatory frameworks for those products such as protocells, the country faces a regulatory gap because protocels fall under the category of chemical and biological safety regulations than to the GMOs category. Moreover, whether food substances created through SynBio should be labeled as GM foods has been another regulatory challenge because such techniques go beyond the EU's definition of GMOs "where the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" (Directive 2009/41/EC, 2009; Directive 2001/18/EC, 2001).

Considering the gaps in GMOs regulations, the UK has been applying two important EU legislations constituted of by two important Directives on GMOs.

> Risk assessment of synthetic biology research is covered by two EU GMO directives (other regulations cover marketing of products such as medicines, cosmetics and chemicals) The

Contained Use Directive (2009/41/EC) which covers contained activities, such as those carried out in a laboratory. These are regulated by the Health and Safety Executive in the UK, advised by the Scientific Advisory Committee for Genetic Modification. The Deliberate Release Directive (2001/18/EC) which covers the release of a GMO to the environment. Defra is the lead UK department. Decisions on releases solely for research purposes are made at a national level following guidance from the Advisory Committee for Releases to the Environment. Applications to market an organism or for GM food or feed, are decided at EU level (UK Parliamentary Office of Science and Technology, 2015, p. 3).

The UK Government therefore applies the precautionary approach as laid in the EU risk assessment framework. The approach lays out three important concepts

i) Case-by-case approach. All activities that involve GMOs are considered on a case-by-case basis depending on the scale of the activities, the nature of the manipulation and the specifics of the environment.

ii) Step-by-step principle. This is applied where the ultimate application of an organism involves its release to the environment. It involves gradually reducing containment and increasing scale when evaluation of human and environmental health indicate it is safe to do so.

iii) Comparative analysis. For release to the environment, the novel organism is compared against a 'wild-type' (non-GM) comparator in order to determine if there is a possibility of increased risk. For contained use, the characteristics of the parent organism and any introduced traits are used to estimate a risk level for the novel organism and select an appropriate level of containment (UK Parliamentary Office of Science and Technology, 2015, p. 3).

UK's approach is sensitive the biosecurity issues of SynBio. The country conceives biosecurity as directly related to dual-use; when the same scientific work can be used to do well or be intentionally used unethically in civilian or military applications (*Ibid*). The country applies EU's regulation 388/2012 which controls the export of potential dual-use items to non-EU countries (*Ibid*). Additionally, as in the USA, the country applies the BWC which prohibits: the development, production and stockpiling of microbial or biological agents and toxins, whatever their origin or method of production, for any purpose that is not peaceful; their transfer to other

states; and helping other states to manufacture or acquire them (UN, 1972). The third approach to regulating biosecurity is the reference to the Harmonized Screening Protocol which sets provisions aimed at stopping the sales of DNA synthesis to individuals who may reuse them as biological weapons by ensuring that customers and persons making orders are properly screened and their details documented. This is, however, a voluntary protocol with some good level of success as 80% of world leading DNA Synthesis companies have signed to it (UK Parliamentary Office of Science and Technology, 2015, p. 3). These notwithstanding there is concern in the UK that as DNA Synthesis machines become more available many people may get to use them and this may complicate the use of such voluntary or international regimes to ensure biosecurity. It is suggested that there needs to be put into place counter-measures that will ensure biosecurity in the event these techniques are used for negative purposes.

Biosafety concerns in the UK is a regulatory gap is with other countries. The have been suggestions and counter-suggestions that to ensure biosafety, there is need to ensure "safety-by-design" approaches; where for example, xenobiology, might be used to incorporate safety features that ensure the organism dies if it escapes from the lab. Cou8nter suggestions to this has been that such a moratorium would damage advances in the field of synthetic biology (*Ibid*, p. 3). Biosafety concerns have also been expressed within the DITYB concerns. The Government has been divided in regards to whether to encourage or discourage DITYB because the benefits that emerge from it and the challenges that it comes with are more or less equal.

> One potential concern is that the technology may become more available to DITYB practitioners who have no awareness of their legislative responsibilities before they carry out any synthetic biology activity. Another is that practitioners may not be familiar with biological safety, risks and good laboratory practice. Codes of conduct have been established within the DITYB community by individuals who are aware that their behavior reflects upon the community as a whole. Online training courses and increased accessibility to risk assessment and management may be useful because they can be readily updated (*Ibid*).

Summarily, regulatory issues on SynBio in UK revolve around four issues, namely:

a) Initial SynBio products such as artemisinin, fragnances and vaccines in contained facilities fall under GMOs and are properly regulated by the existing GMOs frameworks such as

the Contained Use Directives. However, as SynBio advances, there appears to be glaring gaps in GMOs regulations.

b) Risk assessment of novel complex organisms becomes more difficult. This is because "assessment of current GMOs involves comparing them with an equivalent non-GMO organism, a relatively straightforward task where there are only one or two traits involved. But as the number of traits and their sources increases, it becomes less obvious what comparator organism to use. However, Complex novel organisms are developed step-by-step, with researchers seeking regulatory approval for each new combination of traits. This makes the process difficult (*Ibid*, 4).

c) There are concerns that synthetic biology may increase the burden on the current regulatory authorities. This may occur in two main ways: the expansion of the range of technologies available and the speed at which modifications can be made could increase the volume of applications being handled the increasing complexity of the risk assessment process is likely to be more time consuming for regulators (*Ibid*, 4).

d) As more advanced products are created, it is not clear which exact regulatory mechanisms are applicable. For some applications, it may not be clear if the synthetic biology product falls under the deliberate release or contained use regulations. For example, a biosensor being developed by the Arsenic Biosensor Collaboration uses GM bacteria contained within a secure casing, but is intended for use outside of the laboratory. Using GMOs in this way usually means getting approval through the deliberate release regulations (*Ibid*, 4).

2.4.2. USA's Experiences

Gronvall (2015) argues that for USA to remain in the global leadership in the SynBio, the country must: invest in developing human expertise who will provide the forefront leadership in the field; invest in regulation and governance of the technology by reevaluating the biotechnology regulation mechanisms and governance approaches and, have a targeted or strategic approach to the development of the technology to ensure maximum contribution to strategic fields like security and health and medicine. Jayanti (2020) highlights pertinent issues to SynBio USA, among them current governance and regulatory. He argues that 'currently, the regulation of SynBio is concentrated at the federal level, being governed under existing regulations for biotechnology

more generally. (p. 7). Trump (2017) confirms this argument from his analysis of SynBio regulation in EU, UK, and Singapore, where SynBio is regulated under the existing biotechnology frameworks. The overall governance framework is overseen by the Coordinated Framework for Regulation of Biotechnology (CFRB) under the office of Science and Technology Policy (OSTP). The CFRB outlines the functions of several agencies pertaining to regulation of synthetically engineered organisms. These include: the U.S. Department of Agriculture (USDA) through the Animal and Plant Health Inspection Service (APHIS), the Department of Health and Human Services (HSS) through the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), and the National Institutes of Health (NIH), and the Environmental Protection Agency (EPA) (p. 7). The federal framework on SynBio concentrates on issues related to: biosecurity, consumer safety, and environmental protection.

The specific regulations and authorities dealing particular issues related to the above three areas are:

> ‘’NIH Guidelines on Recombinant DNA: Establishes guidelines for NIH-funded research using recombinant or SynBio DNA in order to minimize risks to the user and the risk of accidental release. Applied to most federally-funded research; Toxic Substances Control Act (EPA): Allows the regulation of microbes with SynBio DNA in order to prevent the release of harmful microbes into the environment; Plant Protection Act (APHIS): Allows regulation by APHIS of plants altered with DNA derived from plant pests or using plant pests as a vector; Federal Food, Drug, and Cosmetics Act (FDA): Allows regulation of any modified organism that is used as or produces a human or animal drug, food, food additive, dietary supplement, or cosmetic. Allows regulation of any animal with SynBio DNA by classifying that DNA as a “new animal drug”; Public Health Security and Bioterrorism Preparedness Response Act (CDC/APHIS): Allows for the regulation of Select Agents, which are defined as organisms or toxins that pose a severe threat to public, animal, or plant health and safety. Regulations prevent the Synthesis of DNA sequences derived from Select Agents; Screening Framework Guidance for Providers of SynBio Double-Stranded DNA (HHS): This guidance prevents companies from Synthetizing long stretches of DNA from select agents without applying strict “know your customer” rules. Additionally, it restricts certain pathogens from being Synthesised, such as smallpox; the National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee that addresses

issues related to biosecurity and dual use research; the NSABB is comprised of members with a broad range of expertise including molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and other related fields' (p. 8-9).

At the same Jayanti (2020) like other scholars (Suppan, 2014; Trump, 2017) who have studied USA SynBio regulation, lament that biotechnology regulations as currently constituted cannot properly regulate SynBio. Jayanti identifies eight areas where current regulation is deficient but which should be considered by policymakers. These challenges include;

a) The first area is that combining SynBio with biotechnology generally reduces USA's national focus SynBio research and development. This also reduces focus on 'risk-focused regulation of SynBio R&D'.
b) Regulatory burden as R&D progresses and a number of companies are seeking for field trial permissions as well as increasing number of commercialized SMOs making risk-assessment a burden to the authorities whose work covers all forms of biotechnology including SMOs.
c) The current open approach to SynBio regulation in the USA does lacks a risk-management framework that can be used to deter the possibility of a dual-use scenario where DIY biologists can accidentally or intentionally weaponize SMOs (Pauwels, Stemerding & Vriend (2011).
d) There are, technically speaking, regulatory gaps with the current biotechnology regulations. Jayanti (2020) argues for example, that ''due to their unique characteristics, certain SynBio products, such as genetically modified plants that were not made with the use of a plant pest, are currently not regulated by a specific authority. Switchgrass engineered to be a more efficient feedstock for biopower, for example, is not regulated by the APHIS because it is not a plant pest, nor was it made using a plant pest. It is important for policymakers to consider how SynBio fits under current regulation frameworks, and where there may be room (and a defined necessity) for additional, targeted regulation'' (p. 10).

e) Issues like consumer knowledge about the technology are still very law. Assuming that SMOs are the same as GMOs lead to a lack of focus on strategic consumer education and awareness creation.
f) Public acceptance of SynBio, even in USA where the technology has been for some time, is still low (Hart Research Associates (2010; 2013). Jayanti (2020) advises that 'it is important for investors, developers, and policymakers alike to consider what would encourage the acceptance of SynBio technology by the broader public' (p. 11).
g) Jayanti (2020) argues that current biotechnology regulation does not take particular consideration of the security and safety issues, asserting that 'SynBio products create new avenues for the creation of bioweapons, including pathogens and toxins' (p. 11), creating a critical area for consideration by policymakers and regulators.
h) The uniqueness of SMOs from GMOs imply that they have a different potential impact on biologically. Assessing USA's biotechnology approach, Jayanti (2020) argues 'while increasing biodiversity is not thought to be a negative impact of SynBio, it poses questions about how decisions to reintroduce a species of change the makeup of a community should be made. There is also a concern that SynBio developed organisms could outcompete their natural competitors or disrupt ecosystems' (p. 11).
i) Finally, and related to the issues of biosafety and biosecurity, biotechnology regulation in the USA as in other countries (Trump, 2017) has relied largely on containment approaches- 'the extent to which SynBio products will be able to be prevented from replicating or propagating SynBio genetic elements within naturally occurring organisms' (Jayanti, 2020, p. 11). According to Jayanti, 'though there are approaches that are being developed and testing, it is important to consider how regulation and oversight plays a role in the effect governance of SynBio created organisms, especially as it pertains to their release and containment' (p. 11).

Trump (2017) on other hand contends that to understand gaps in SynBio governance, one has to begin by understanding the biotechnology risk culture of that given country, that is, the political and institutional factors that frame the risk management environment. Accordingly, he argues that a risk culture constitutes three factors, namely, '(i) the availability of biotechnology or GMO-centered regulation to capture SynBio, (ii) the degree of centralization within the policy reform

and implementation process, and (iii) the manner in which regulatory disputes are adjudicated (described in literature as 'legalism') (p. 3).

Describing the risk culture of USA, Trump (2017) argues that USA applies chemical regulations to oversee the SynBio development life cycle and has several 'veto points', at throughout the Executive, Legislative, and Judicial arms of USA Government. On the second aspect of the risk culture, that is, degree of centralization of policy reform, he argues that USA exhibits 'an adversarial style of legalism'. From his assessment, he concludes that "with respect to regulatory policy, the limited availability of biotechnological and GMO-centered regulation, may challenge the efficacy and validity of legislative instruments, such as the Toxic Substances Control act to inform proper governance of SynBio enabling technologies" (p. 3). He adds that 'the presence of multiple and decentralized veto-holders in the policy generation, implementation, and reform process makes the development and reform of hard law a complex and politically intensive effort that can take years to decades to achieve. Lastly, a reliance upon courts to resolve regulatory disputes may complicate or dis-incentivize efforts to develop a multi-stakeholder approach to inform SynBio governance' (p.3).

Assessing closely what regulations capture what governance considerations for SynBio, Trump (2017) reports that the US, like in the EU and Singapore, regulate SynBio at least eight risk areas: gene transfer, mutation and proliferation, ecosystem health and biodiversity, commercial consumption, laboratory/worker safety, accidental release of premarket material, pharmaceutical development, and finally, import, export and shipment. Risk issues related to laboratory and workplace health are regulated by National Institute of Health Guidelines for Recombinant DNA Molecules (NIH), and the Occupational Safety and Health Administration (OSHA) which are explicit GMO governance mechanisms. Other than process-based regulations as the NIH, Trump (2017) argues that other product-based regulations are also applicable to ensuring safety of producers and developers. In his own words: 'such regulations are designed to promote the safe development throughout the life cycle of specific products by mitigating, managing, or eliminating potential risks to humans, animals, or the environment. For example, all pharmaceuticals in the United States (SynBio-driven or otherwise) are governed by the Federal Food, Drug, and Cosmetic Act (FDCA)". He adds that specifically, Chapter 5 of the FDCA outlines regulatory approval and testing of pharmaceuticals, including specifications on safe handling of such pharmaceuticals,

labeling, instructions on safe use of such pharmaceuticals, and requirements for clinical trials (p. 3). The challenge with applying such GMO-centered regulatory instruments is that 'such requirements may not be specific to SynBio, and may instead be centered around general risk concerns about pharmaceutical dose response, safe use, unintentional exposure, and general toxicology, among several other risk concerns' (p. 3). Overall, Trump (2017) argues that SynBio biosafety frameworks in USA and other countries alike, are structured around three issues, namely, '(i) the unintentional exposure of novel genetic information to humans and the environment, (ii) the proliferation of such novel genetic material in the environment beyond the scope of its approved use, and (iii) the potential for horizontal gene transfer to occur where artificial genetic material may alter or impact the genetic information of humans, animals, or the environment' (p. 3).

In the same breadth, Trump (2017) agree with others (Keiper & Atanassova, 2018; Jayanti, 2020, Calvert, 2013) that biosecurity issues revolve around two issues: access and plausibility. Access to SynBio products mainly concerns 'how nefarious agents could gain expertise and materials to misuse SynBio research for harmful purposes' while plausibility questions relates to "how likely are biosecurity events' access directly implies the dual-use fears which include the potential for SynBio research to have 'dual-use' implications, where a nefarious agent could use technological capabilities to develop harmful substances like a genetically modified virus. According to Trump, the debate around dual-use 'has developed to focus more specifically on how biosecurity threats may be mitigated in specific regulatory areas, including export control, screening of SynBio research prior to public dissemination, and regulatory approval of proposed experiments for dual-use implications and harms' (Trump, 2017, p. 3).

Trump (2017) also applied Greer & Figueras (2016) TAPIC framework to analyze SynBio governance gaps in USA, EU and Singapore. Citing Greer & Figueras (2016) he argues that adaptive multisectoral governance is possible first and foremost:

> When the scope and operation of policy decisions are clearly articulated to the general public. For SynBio hard law, this includes a clear account of which regulatory instruments and authorities, are responsible for capturing various elements of the process of technology development. Such an environment promotes expectations of behavior in policymaking

and regulatory decision making, which in essence sets the rules that gatekeepers and decision makers operate within relative to technology governance.

The scholar asserts that in the USA, this transparency is ensured through the law and bureaucratic redundancy to an extent it is cultural. This, however, contradicts Supan (2014) who asserts that there are three interrelated avenues that make current USA SMO regulation inadequate; a) the Confidential Business Information (CBI) principle, the product not process approach, and the lack of SMO-specific regulations. The CBI implies that for products at the verge of commercialization only government expert reviewers conducts their associated risk assessment. Every public expert review processes are thus blocked. This contradicts transparent adaptive SynBio governance as conceived by Trump (2017). The greatest benefits of transparent governance is that it enables the designing of a regulatory regime that "promotes clear rules for developers to follow alongside predictable punishments for violators that expose the population to various categories of health risk" (Trump, 2017, p. 4). At the same time, transparency has its inadequacies.

Both Kelemen (2011) Kagan (1991) assert that this 'a drawback of improved transparency in regulatory policy contexts may include the potential for increased adversarial legalism' (Kelemen (2011) and Kagan (1991), cited in Trump, 2017), 5). Adversarial legalism notes Kelemen & Sibbitt (2004) is a situation where 'a push for increased transparency, can raise the opportunities and costs associated with legal challenges to policy proposals, hence, potentially reducing the opportunities for reform for fear of inducing lawsuits and costly legal challenges for the case of the United States' (Trump, 2017, p. 5). What Trump proposes for USA as well as EU and Singapore is that, a degree of transparency can help signal best practices and remove confusion relative to the active players for SynBio governance (Carter et al., 2017, cited in Trump, 2017) yet a constant need to publish and discuss the intricacies of all policy decisions, may foster an environment that actually resists adaptive policy reform and increase the potential for regulatory lag and pacing problems" (Ibid, p. 4). For SynBio transparent adaptive governance thus, Trump (2017) proposes transparency to some extent to avoid adversarial legalism tendencies. This notion could be the driving force behind the CBI approach in the USA (see Supan, 2014). The limitations imposed on transparency, he argues can be realized through accountability, another important aspect of the

adaptive multispectral governance approach. On grounds of accountability, Trump (2017) cites Wales (2012) who contend that:

> Governance regimes promote accountability when those government actors and key stakeholders, are required to justify their decisions and be held to account for such decisions if deemed improper, unjustified, or illegal. Such accountability can be difficult to build within the context of emerging technology governance, due to the lack of explicit regulatory instruments or risk management protocols dedicated to a specific technology like with nanotechnology or SynBio, where instead such standards and practices must be borrowed from pre-existing hard and soft law (p. 4).

The USA, like the EU and Singapore, places a lot of emphasis on the accountability of government actors and researchers. This is derived by an adherence to bureaucratic redundancy and explicit rules stating the limits on power that a given regulatory body may have. Depending on the intended research item and potential product, such rules are derived from the Toxic Substances Control Act, Plant Pest Act, and the Food, Drug, and Cosmetic Act, although potential regulatory gaps relative to the process of SynBio development. In this vein, independent government and non-governmental watchdogs such as with the Government Accountability Office (GAO) or the Genetic Working Group independently, review action by government policymakers and regulators related to technology development, and can seek a Freedom of Information Act (FOIA) request to obtain transcripts and other knowledge relevant to regulator decisions and actions (p. 4).

It is argued that, a strong accountability for an emerging technology like SynBio may be economically and time convenient compared to investing in building public acceptance and support. The challenge, however, is overstressing accountability from the parts of stakeholders; governmental, academia, industry and non-governmental for an emerging technology with potential risks uncertainties of the magnitude of SynBio (Keiper & Atanassova, 2018). Trump (2017) captures this concern relative to the problem of overregulation identified by Jayanti (2020), he argues that "specific concerns center on the still nascent and emerging nature of the technology's research alongside fears of harsh or excessive hard law limiting the technology's exploration. Further, the politically charged nature of genetic engineering and past public resistance to genetically modified organisms (GMO) may draw public pressure to resist early stage

research and encourage harsh, face-saving measures by bureaucrats to encourage such resistance". In the face of these realities as has been witnessed in Africa and Europe concerning GMOs, Trump (2017) councils that "accountability must be developed alongside other elements of the TAPIC framework, yet for certain cases may be a central focus of technology governance within environments of low transparency and high accountability like with Singapore" (p. 4).

Participation is the third element of adaptive and anticipatory technology governance. A number of scholars argue that the creation of constructive, flexible, and anticipatory soft law for SynBio requires the engagement of key stakeholders outside of government bodies (Douglas & Stemerding, 2014; Fatehi & Hall (2015), cited in Trump, 2017, p. 5). Abbot (2012) reinforces this perception when he argues that "the involvement of non-state actors within regulatory decision making, is an essential element of producing policy that adapts to risk challenges posed by emerging technologies with uncertain risk profiles and health concerns (Abbot, 2012, cited in Trump, 2017). The involvement of non-state actors in the governance of an emerging yet disruptive technology like SynBio can play three critical functions by way of providing critical feedback to policymakers and regulators; (i) realistic risk and benefit outcomes posed by emerging sciences, (ii) societal perception and response to such sciences, and (iii) aligning incentives and research goals for developers moving forward with respect to various areas of hazard, exposure, and consequence measurement for health risk (p. 5).

Trump report that in the USA, participation is realized through public private partnership (PPPs) frameworks, for example through the Nano-Safety Consortium which provided a platform for interaction and feedback between government, academia and industry as well as the public on issues related to nanotechnology. The feedback from such a platform is utilized by EPA to make decisions related to carbon Nanotechnology and learning of best practices. Other participatory platforms include the National Academy of Sciences (NAS), which serves as a non-profit organization that frequently hosts various parties in government, industry, and academy with the pursuit of reviewing research goals and best practices for various endeavors as with emerging technology development. Joyce et al. (2013) reports that the NAS platform, through its NAS Workshops on SynBio, has been very critical for SynBio agenda setting and generation of risk awareness documentation which has served key tools for SynBio governance.

Trump (2017) asserts that such multi-stakeholder participatory platforms are critical for adaptive anticipatory governance of SynBio, because they can "directly facilitate information-sharing and best practices to mitigate risk…and help foster soft law guidance that aligns government goals with industry capacities and needs relative to technology development" (p. 5). Important for making the best out of SynBio participation are considerations for the type of participation to be adopted. Trump identifies two; the bottom-up and the top-down. The former implies an emphasis on the role of non-governmental experts such industry, academia and NGOs. The challenge here is to have a coordinating authority, for example, in the form of NAS, for USA, or European Scientific Committees (ESC) for the EU to structure such participation "in a direction useful to local governance". The benefits of a bottom-up include engaging multiple stakeholders which can reduce administration redundancy leading in inefficient governance. The bottom-up is particularly important owing to the fact that, SynBio is a highly uncertain field which makes it very possible to oppose by the NGOs, academia, and industries which may not be involved in its development or may fear that SynBio enabling technologies can interfere with their traditional ways of production even rendering them jobless.

The top-down approach lays emphasis on the role of government experts in deciding the direction of SynBio governance. Trump reports that this approach usually manifest in soft-authoritarian states like the Singapore. This approach has its good and bad sides because "can help ensure that stated government priorities are addressed and discussed by experts, yet can limit exploration in other areas of regulation, governance, and risk" (p. 5) possible only through the involvement of experts and non-experts from the NGO, academia, and industry worlds.

Integrity as part of the TAPIC framework for adaptive anticipatory governance of SynBio relates to two main issues: 'the need for clear performance standards as well as the need for clear organizational missions relative to SynBio regulation and governance' (Trump, p. 6). The scholar argues that these integrity issues are difficult to consider, mainly because SynBio regulations are not as yet specific to the technology but are borrowed from such regulations as chemical regulations (in the case of USA) and biotechnology regulations as in the case of EU and Singapore. For this reason, governance domains for SynBio, including biosecurity, biosafety, intellectual

property rights, have not achieved a fashioned "performance standards and best practices" and are still being debated nationally and regionally- the extent to which depend, argues Trump (2017) on the nature of the risk culture defining technology governance in a given territory. Comparing USA, EU and Singapore with respect to the first integrity issues, Trump argues that:

> Where the governmental structure, existing legislative and regulatory instruments, and propensity towards adversarial legalism may prevent future developments of SynBio governance in the form of *sui generis* hard law in the United States and European Union. Singapore may have a somewhat easier time instituting such standards and best practices due to fewer veto points within its regulatory decision making alongside a more cooperational approach to legalism, yet such reform may be impeded due to the high market share of SynBio research taking place in the United States and European Union (p. 6)

Regarding the second aspect of integrity, the need for clear organizational missions relative to SynBio regulation and governance, Carter et al. (2017), Bar-Yam et al. (2012) argue that USA exhibits a strong reliance on already existing regulations and authorities where the missions statements of such institutions was not originally conceived to regulate SynBio, hence, for example, they that both the EPA and FDAC share SynBio regulation. Jayanti (2020, p. 10-11) confirm this line of argument by identifying a myriad of institutions and regulations formerly coined for GMOs and biotechnology by applied SynBio. The inefficiencies of the reliance on such authorities and regulatory tools, the USA is trying to adopt a participatory and facilitative role by providing funding to a myriad of groups. Trump (2017) reports this situation, thus: "the United States does provide funding for various research groups, organizations, and academic institutions related to SynBio state of science and social science concerns" (p. 6). Kuiken (2015), however, points out that funding as at the time of his writing was limited.

The final issue in the TAPIC framework in capacity to regulate SynBio. This capacity is impeded by the relative newness of the technology but also due to the fact that, "limited guidance is available to foster evidence-based decisions for SynBio regulation and governance, and many relevant stakeholders may have a professional or scholarly background outside of the technology and its applications" (p. 6). This challenge has been taken up by governments across the globe, particularly those that are in the forefront of SynBio development such as USA, Singapore and

EU. Approaches to remedy the capacity gap include "through funding and support for academic, industrial, and non-governmental groups that conduct research relevant to the field and foster networks by which government decision makers may draw expert advice" (p. 6). Such effort in the USA include those R&D programmes going on in institutions such as the Wilson Centre, NAS SynBio workshops, the Alfred Sloan Foundation, the National Institute for Health, just to mention a few.

2.4.3. Experiences from the European Union

Features of the Risk culture in the EU's practice of SynBio regulation resemble closely that of the USA. "It has a larger body of biotechnology governance, a more decentralized approach to developing and implementing such governance, and a more cooperation approach to legalism relative to the United States (Trump, 2017, p. 2)". Biotechnology governance in the EU include "a series of Directives specific to GMOs and emerging biotechnologies ranging from labeling, proper containment, transshipment, and safe use in research environments" (*Ibid*, p. 2). The risk culture is also characterized by "a decentralized group of states who are able to implement Directives into respective national legislation in a manner that works with each individual member state" (Ibid, p. 2). Such decentralized approaches include the UK SynBio Roadmap 2016 (SBLC, 2016) which serves as the policy framework for SynBio R&D in the UK. On the last element of the risk culture, legalism approaches, the EU European Union governance has exhibited a cooperation nature with a greater willingness of governments, industry, and non-governmental organizations to develop shared best practices" (*Ibid*, p. 2) trending towards a more adversarial legalism notwithstanding as notes Kelemen (2011).

This kind of risk culture therefore has a level of implication of the extent to which the five elements of a TAPIC multi-sectorial adaptive and anticipatory technology governance play out as promoters or de-promoters of technology governance. Before we look at the TAPIC framework it is important to understand the governance considerations of SynBio in the EU. Trump (2017) argues that the same seven governance areas of SynBio considered in the USA, also characterize SynBio governance in the EU. These include: gene transfer, mutation and proliferation, ecosystem health and biodiversity, commercial consumption, laboratory/worker safety, accidental release of premarket material, pharmaceutical development, and finally, import, export and shipment. These

governance areas are not exhaustive in themselves but are indicative of the 'key areas of potential risk to human and environmental health that may accrue within the development of SynBio', especially biosafety elements of potential SynBio risks (Trump, 2017, 2). These risk areas of SynBio have been extensively covered by two directives, namely, Directive 2009/41/EC and Directive 2000/54/EC.

Considering transparency and accountability elements of the TAPIC framework in the EU, Trump (2017) argues that the EU has a more or less similar trend to the USA's SynBio governance transparency system. Thus, it is characterized by 'bureaucratic redundancy and power sharing through the relationship between the European Commission and its individual Member States, respectively' (p. 2). Bovens (2007) adds that the European Court of auditors plays an important role in the ensuring of transparency by reviewing budgetary processes, and identifying cases of maladministration. Direct checks and balances on the actions of policymakers and regulators is further ensured by power-sharing arrangements between EU and its Member States. This mainly contributes top transparency through ensuring that there is confidence with relevant laws and through upholding of expected standards of actions and practices (Trump, 2017). For the case of SynBio, asserts Trump (2017):

> This includes a use of Directives that allow Member States to achieve regulatory goals via their own institutions and laws, yet retain oversight over the process to ensure that such goals are actually met. Non-compliance results in punishment levied by the Commission through the Court of Justice of the European Union upon the given Member State, although such rulings may take years to hear and execute. Overall, a separation of powers within differing branches within the European Union and between the Union and its Member States helps to collectively promote transparency and accountability simultaneously (p. 4).

To ensure participatory adaptive anticipatory SynBio governance, EU takes a more similar approach to USA. This includes institutionalizing PPPs that then brings together academia, NGOs, government and other groupings of the public to discuss and chart a course for SynBio development and regulation (*Ibid*). Kelemen & Sibbitt (2004), however, argues that unlike USA, EU takes a more informal approach to PPPs platforms as opposed to formal meetings and agreements. One possible cause for this informal approach to PPPs could be due to the fact that

EU at the very beginning of the GMOs movement was seriously opposed to the technology, hence to involve EU citizens and experts could be a strategy to go around such opposition, which of cause still exists to date as Marris & Calvert (2018) recounts. The EU there adopts a more bottom-up approach, with only top-down to some limited extent. Trump (2017) records that:

> One such stakeholder often included here is the European Scientific Committees, which is a non-governmental organization consisting of six sub-groups that seek to facilitate cooperation and excellence in scientific endeavors and understanding amongst academia, government, and industry. The Committees levied three documents related to SynBio governance, including (i) general definitional support, (ii) risk assessment and safety, and (iii) environmental health, biodiversity, and research priorities for SynBio moving forward. Such efforts seek to align knowledge and incentives across various European stakeholders, engaging with SynBio research by encouraging participation by such stakeholders in joint governance-building exercises (p. 5).

Integrity issues in EU's SynBio governance relate to, like in the USA, whether regulations and authorities have a clear mission statement to cover SynBio. It is reported that EU applies existing biotechnology governance capabilities to SynBio regulation (Trump, 2017). The European Scientific Committees play additional role in ensuring that these existing regulations are properly adapted to SynBio regulation. It does this through tasking NGOs and respective governmental research organizations 'to directly consider SynBio risks to human and environmental health within their countries' (p. 6). Such approaches to integrity assurance remain at their early stages but could require reinvigoration since a lot of the SMOs are now in the market produced even through bench-top SynBio enabling technologies (see Jayanti, 2020). Capacity of the SynBio governance in the EU is driven by institutions whose work have been aligned to SynBio research. These include, the Scientific Committees, ERASynBio, and SynBioberc among others whose work continues to inform regulators, policy makers and other SynBio discourses in the EU.

2.4.4. Experiences from Singapore

Compared to USA and EU state entities, Singapore is by far smaller in population, geography, and economic prowess. What is striking in the SynBio literature is that, the country is poised as one where the technology has taken root with tremendous support from both the government and

private organizations, academia and industry (Trump, 2017; Ning, Aggarwal, Poh, et al. (2018). This is visible through the country's investment of millions of dollars in SynBio R&D and the numerous number of international SynBio conferences it has hosted (see National University of Singapore, 2015). A regards to its SynBio governance risk culture, the country has GMO and biotechnology-oriented regulatory frameworks (Genetically Modified Advisory Committee, 2015). It has a 'soft-authoritarian form of governance' (Trump, 2017, 2) characterized by a centralized parliamentary structure exhibiting few veto points, unlike the USA's and EU's which makes contentions on policy adaption likely unlikely. Trump (2017) reinforces this assertion, thus: 'Singapore's soft authoritarian nature generally ensures a cooperation style of legalism, where industry and academic stakeholders work with the government to inform the state of SynBio science' (p. 3). Governance considerations are like those considered in the EU and USA and include: gene transfer, mutation and proliferation, ecosystem health and biodiversity, commercial consumption, laboratory/worker safety, accidental release of premarket material, pharmaceutical development, and finally, import, export and shipment, including biosecurity and biosafety.

The centralized decision making model in Singapore, however, does not impact on the mode of transparency the country has adopted in its SynBio governance. Trump (2017) asserts that it has "Singapore's soft-authoritarian nature and drive to participate within international scientific development has pushed it to adopt risk management and policy priorities developed in the United States and Europe – effectively borrowing such transparency by keeping pace with available best practices for risk management' (p. 4). Singapore's accountability for SynBio governance is reportedly higher, despite its low transparency. Such accountability derives from clear limitations on power sharing via established legislative instruments noted in alongside a governmental drive to eliminate corruption in all sectors of government – making Singapore one of the most corruption-free countries worldwide (Lingle, 1996, cited in Trump, 2017, p. 5). The soft authoritarian regime establishes a government structure with limited transparency but simultaneously ensures consistent accountability and predictable behavior to media; internal government watchdogs and strong predictable adherence to the constitution and legislative standards established through hard law relevant to emerging technologies like SynBio. For SynBio, this specifically includes the presence of multiple governmental bodies within the governance of early stage research, such as with the Ministry of Manpower (MOM) and The

Workplace Safety and Health (WSH) Council for matters dealing with occupational health and safety for technology research and development (Trump, 2017, p. 4-5).

On the element of participation, Trump (2017) reports that "Singapore's attempts at fostering participation in the SynBio governance processes are still, though a more recent work, Ning, Aggarwal, Poh, et al. (2018) points to tremendous steps in fostering a conducive participatory environment. The participatory approach emphasizes government-funded programs to research institutions including mainly; National University of Singapore, Nanyang Technological University, and the Agency for Science Technology and Research (A*STAR) (Trump, 2017). This approach is more top-down than it is bottom-up and brings members of academia, industry and government policymakers and regulators to interact and frame SynBio directions. The authoritarian politics model facilitates such a system of SynBio governance through strengthening regulatory institutions by promoting a robust scientific community and ensuring that regulatory rules are not only clear, but they are also applicable to the governance aspect of SynBio (Roy, 1994; Turner, 2015). The merit and demerits of the authoritarian top-down participatory approach is captured by Trump (2017), thus: such approaches ensure that governmental priorities are addressed relative to the governance of SynBio, yet may limit opportunities to explore other areas that may not yet be governmental concerns (p. 5). As regards to integrity element, Singaporean Genetic Advisory Committee tasks NGO research institutions and other research establishments, including government to ensure adherence to SynBio risks to human, environment and socio-cultural aspects (Trump, 2017; Turner, 2015).

Finally, as regards, capacity of the governance framework, Trump (2017) reports that the Singapore Government has targeted key institutions and built their capacity to undertake research in SynBio, including through promoting and hosting international SynBio programs. In his own wording:

> Singapore has sought to bolster its technical skills and network capacity by directly funding Nanyang Technological University, the National University of Singapore, and A*STAR to provide both experimental insight into the risks and benefits posed by SynBio's enabling technologies as well as policy guidance related to its governance. Collectively, international meetings such as with the Biobricks conference series and the International

> Genetically Engineered Machine (iGEM) competition serve as networks across and within governments and other key stakeholders to review emerging concerns in the field and identify common standards and best practices to abide by in the process of the technology's development (p. 6).

2.5. Biotechnology Discourses in Africa

Within the African Sub-Saharan (ASS) context, SynBio research remains meagre (African Center on Biological Diversity [ACB], ETC Group, TWN, 2018) with emphasis laid toward agricultural biotechnology particularly in traditional techniques of biotechnology (Kivuva et al. 2015). This trend in the literature can be accounted for by two main factors: a) Africa depends on agriculture for its survival with more than 60% of the African Sub-Saharan (ASS) population being smallholder farmers and 23% of ASS GDP accounted for by agriculture (Goedde, Ooko-Ombaka & Pias, 2019). Secondly, biotechnological innovations that are largely implemented in ASS is exploiting GMOs techniques with few exceptions of SynBio enabling technologies in South Africa and Ghana (Kivuva et al., 2015). Otherwise, SynBio innovations are not yet available for use in Africa and as such, perhaps, studies are yet to analyze its varied aspects and what exactly are the regulatory gaps (Reagan et al., 2022). Reagan et al. (2022) have emphatically argued that for successful adoption and implementation of SynBio technologies in Africa, regulatory gaps in the current biotechnology regimes: policies, legislations, development plans and guidelines, should be reviewed and gaps used to formulate adapted frameworks. This study is a pioneer study in this direction, and highlighted regulatory gaps in current biotechnology frameworks in Kenya. Study insights will inform policy makers and regulators on what opportunities and gaps there are for smooth adoption and implementation of SynBio technologies.

ACB, ETC Group, & TWN (2018) posed a fundamental question to Africa: *what does SynBio mean for Africa?* The scholars report that the increased production of SynBio (which they call 'GMO 2.0') products and materials in the Third World mean that Africa will be one the target market for such production. They also assert categorically that GMOs 2.0 are raising real environmental, health and socio-economic concerns, and their potential impact on the African continent requires a thorough review of existing regulations to address such concerns (p. 1). Moreover, the study points out that re-looking at the existing policy frameworks should be seen as *an opportunity for the shaping of the biosafety discourse to suit the technologies' developers, and others that stand to benefit from the use of the technology* (p.1). The study challenges African

governments that without any proper regulatory frameworks in place to regulate SynBio research and products, African countries are likely to remain importers (asymmetrical technology transfers) of SynBio products and scientists instead of being researchers, producers, and exporters of SynBio technologies like their developed countries counterparts which have not only adapted their regulatory frameworks for SynBio but have also gone ahead to ensure there are national development plans to facilitate smooth SynBio R&D. By exploring underlying gaps in current biotechnology governance frameworks, this study identified the gaps that may help Kenya to initiate processes leading to formulation of a regulatory regime that will lead to adoption of SynBio within an adaptive anticipatory governance environment.

In their *Agricultural biotechnology policy review in Africa*, Kivuva, Yegon & Ndue (2017*)* put the claim that 'many African countries have developed Agricultural policies which address the research, development, production and regulation of genetically engineered crops and animals. Through these policies, many new crops have been developed tested and approved, addressing important traits of particular significance for smallholder farmers in Africa' (p. 47). However, the scholars assert that many provisions of the regulatory guidelines (particularly in Kenya) are yet to be implemented. These arguments are supported by Ochieng & Ananga (n.d.) in their review of *Biotechnology in Agricultural Policies of Sub-Saharan Africa* who assert that;

> While many biotech products such as tissue culture banana, hybrid maize, and others are now frequent at farm level, the adoption of some of the technologies remains relatively low, partly due to political and regulatory bottlenecks that have hampered farm deployment and entry into market systems of genetically engineered crops and products (p. 1).

While many changes may have happened across Africa and Kenya in regards biotechnology development since Kivuva et al.'s and Ochieng & Ananga (n.d.) analyses, a recent analysis of the biotechnology regulatory gaps in Africa in light of SynBio technologies adoption (Reagan et al., 2022), has argued that countries like Kenya and South Africa which already have biotechnology policies, legislations and issue-specific guidelines should not have a great challenge adopting SynBio technologies, because the biotechnology governance applied to GMOs should be adapted to SynBio. Such an argument is supported by the scholars who propose an adaptive anticipatory governance model to the regulation of SynBio (Trump, 2017; Keiper & Atanassova, 2018). Reagan et al. (2022) further argued that to adapt these legislations, policies, and guidelines to the regulation of SynBio research and products, Kenya and South Africa (which are the leading in terms of GMO

research in Africa) should review the pieces of biotechnology regulations; policies, legislations and guidelines to identify possible regulatory gaps that may hinder successful adoption and implementation of SynBio technologies and fill those gaps accordingly. This is the bedrock upon which current study is based.

2.6. Kenya's Experience with Biotechnology Regulation

Mugo, Gichuki & Mwimali et al. (2017) outlines Kenya's journey with the regulation of *Bacillus thuringiensis* Maize (Bt Maize); the first ever GMO plant to be authorized in Kenya, followed by Bt Cotton and recently Bt Cassava (Kenya Agricultural and Livestock Research Organization, 2021). The scholars argue that Kenya's GMO activities are regulated by the Biosafety Act, the Biotechnology Development Policy and a "biotechnology awareness strategy" to enable research and development of GM crops' (Mugo, Gichuki & Mwimali et al., 2017, p. 4682). Moreover, there is a 'National Biosafety Authority (NBA) that regulates plant biosafety through technical institutions including the Kenya Plant Health Inspectorate Services (KEPHIS)' (p. 4682). Because synthetic biology technologies go beyond traditional biotechnology approaches used in the GMOs era, it remains unclear whether the biotechnology regulatory system in Kenya is applicable to synthetic biology technologies. This warrants a study such as this, while intent is to assess the extent of applicability of the policies and legislations used for GMOs to synthetic biology technologies and products.

Olembo, M'mboyi, Nyende, Oyugi, & Ambani (2017) conducted a cross-country analysis of the state of crop biotechnology is sub-Saharan Africa. The scholars report that most of the biotechnology activities in sub-Saharan Africa is aimed at increasing agricultural crop production. There are three categories of countries in sub-Saharan Africa in terms of biotechnology development:

> those that are generating and commercializing biotechnology products and services using third generation techniques of genetic engineering; (b) those that are engaged in third generation biotechnology R&D but have not developed products and/or processes yet; and (c) those that are engaged in second-generation biotechnology (mainly tissue culture). In the first category are Egypt, Zimbabwe and South Africa, while Kenya, Uganda and Ghana are examples of the second. Tanzania and Zambia are in the third category (p. 2).

The authors contend that, crop biotechnology portend a lot of promises to improved agricultural production and food security. They argue for example that Kenya produces about 7 tons of sweet potatoes compared to 18 tons in China, and 33 tons in USA partly due to the impact of Sweet Potatoes feathery mottle virus which affects the East and Central Africa regions. By exploiting crop biotechnology innovations through synthetic biology technologies, the country stands a chance not only to increase productivity but also incomes of the majority smallholder poor farmers who are the most affected. Under the NRF SynBio Project, two pioneer products are expected to result, including PBSD biosensor, a disease which affects production of potatoes in Kenya among commercial and smallholder farmers alike. To ensure such processes are properly guided, with proper adaptive anticipatory governance frameworks to ensure any biosafety, biosecurity, bioethical, socio and economic issues pertaining to SynBio are covered, and that local capacity is properly utilized to poise Kenya as key producer both for local and international production, a review of current gaps in the biotechnology regulatory regime is warranted.

The traditional regulatory system for GMOs may therefore be inadequate to capture this new generation of biotechnology. Indeed, some studies have already pointed out to the inadequacies of the GMOs regulatory system (Pamela, 2006). Therefore, to understand the current possibilities and impossibilities of the Kenya's GMO regulatory system in regards their applicability to synthetic biology technologies, this study conducted an analysis of policy documents and legislations, and NPDs complimented with biotechnology exterts' perspectives.

Pamela (2006) analyses the legislative framework for GMO regulation in South Africa and Kenya, 'the two leading producers and exporters of GMOs in Africa' (p. 1361). Citing UNCTAD (2000) Pamela argues that while modern biotechnology advances are riddled with challenges opportunities, the analysis of cutting-age innovations 'is almost always focused on the challenges rather the opportunities'. She discusses contend that the challenges facing biotechnology regulations should be perceived as opportunities and limits for its regulation and therefore, the need to strike a balance between the promises of biotechnology advances and the issues that lead to their rejection or 'pessimism' from quarters including the media and even biotechnology scholarship itself.

Pamela (2006) reports that 'prevailing situation of pessimism and antagonism may, arguably, be attributed to the fact that the laws and regulations that govern such advances have not been effectively developed (p. 1361). She argues that there are two broad problems that lead to inadequate laws and regulations on biotechnology. The first is that 'the legislative processes leading to the enactment of laws and regulations are often splintered'. For example, in her analysis of the Bt Maize Project in Kenya funded by the Rockefeller Foundation and implemented by the Insect Resistant Maize for Africa Project, there was a mismatch between Kenyan (through her regulator, the Kenya Plant Health Inspectorate) biosafety needs and the understandings of the funder. While the government was laying emphasis on biosafety details, current and future impacts of the Bt Maize on farmers' incomes, health and environmental issues, the funder insisted that the techniques and the product had been tested elsewhere and that there was no need for 'unnecessary regulations'.

The other problem facing biotechnology regulation is 'decentralised organisational framework with governmental and intergovernmental organisations having overlapping jurisdictions'. This implies that, several organizations must take part in the regulation of biotechnology even if there exists an overall regulator, for example in the form of National Biosafety Authority (NBA) in the case of Kenya. For example, the Kenya Biosafety Act of 2009 establishes the NBA and lists membership for all the eight regulatory bodies including Ministry of Health, Department of veterinary services, Kenya Bureau of Standards, Kenya Plant Health, Inspectorate Services, Kenya Industrial Property Office, Kenya wildlife Services, Pest Control Products Board and the National Environmental Management Authority (NEMA).

Pamela contends that such decentralization related challenges lead three regulatory problems: complexity of biotechnology-for example, biotechnology topics may be too complex for the understanding of certain societal sectors such as media, and the general public who may want regulations to have too much that is unachievable in reality. At the same time, escaping biotechnology democratization may lead to oppositions of the technology hence affecting the effectiveness of regulations and regulating authorities. Another related challenge to decentralization is 'fiscal challenge'. Pamela argues that 'though regulations have the advantages

of laying down standards directly, avoiding complexity and having an apparent fairness, law-making "is a lengthy and costly procedure". Such regulatory costs may have spillover effects on the consumers and tax payers. Regulations can equally "be expensive to monitor and enforce. They quickly become outdated and require frequent and expensive revisions' (p. 1362). Finally, globalization also impacts effectiveness of biotechnology regulations. In Pamela's (2006) own words:

> The main challenges of globalization are Lack of frameworks for coordinated action in the regulation of biotechnology; institutional overload and inability to agree and set priorities. This is evident from the manner in which various regions and nations have resorted to using diverse regulatory standards that take into consideration their unique concerns because, in some cases, they may not find the recommended international standards suitable for such concerns (p. 1362).

These revelations from Kenya's experiences with GMOs can serve as the starting point for regulating SynBio. For a better understanding of the regulatory frameworks, there limits and opportunities and coin a functional framework for SynBio, this study analyzed policies and legislations as well as policymakers' perspectives on these documents and GMOs programmes.

Finally, Kivuva, Yegon and Ndue (2017) reviewed Kenya's biotechnology policy against the backdrop of the realities that have unfolded in the GMOs regulation. The scholars outline the content the Kenya National Biotechnology Policy 2006 and assesses how the policy provisions have been implemented in two cases: the case of *Bt* Cotton and *Bt* Maize. On the case of cotton, the scholars argued that the due procedure was followed and the bullworm resistant cotton was produced. The challenge was released at the commercialization stage where it argues that 'if these seeds were handed to the farmers, this would have a very significant impact on the Kenyan Cotton industry, and the country's economy by proxy' (p. 52), leading to non-commercialization. This according to the scholars and Pamela (2006) reviewed above, was due to inadequacies in the biotechnology development policy that failed to foresee the economic and social impact scenarios of certain GMO crops. On the case of maize, the scholars report that by end of 2014, the Government of Kenya through Kenya Agriculture and Research Organization (KALRO) in collaboration with Insect Resistant Maize for Africa (IRMA) project and International Maize and Wheat Improvement Centre (CIMMYT) succeeded in producing a maize variety resistant to 'three

main maize pests in Kenya, stem borers, maize weevils, and the larger grain borer (LGB)' (p. 52). Unfortunately, 'the uptake of these commercialized varieties was low since the Kenyan policy was not particularly clear on the matter at the time of release, therefore making it difficult to advertise or market the varieties (p. 53).

These challenges with GMOs development cycle and regulation, are good lessons for policymakers' as the country prepares to move to the next generation of biotechnology. The policy, legislative and the accompanying regulatory stakeholders' perspectives are key to the preempting such challenges and making them substantive in SynBio research, development and regulation. Overall, existing literature on Kenya's experiences with GMOs reveal the GMOs regulatory frameworks, GMOs case studies, and the deficiencies of the GMO policies and law through case projects. This study is the very first attempt to explore Kenya's biotechnology related policies and legislations to reveal their opportunities and limitations in regards to SMOs regulations.

2.7.Synthetic Biology in National Development Planning

SynBio is seen as a critical enabler of a sustainable bio-economy (EU, 2012; Bojar, 2018). This notion in reinforced by the International Advisory Council on Global Bio-economy (2020) asserts that by 2020, several countries including South Africa have at least tried to incorporate policy statements regarding emerging and new technologies in the bio-economy strategies. Ranked among the top ten most significant technologies by World Economic Forum [WEF], (2016) and number six most significant technology for a sustainable future by European Union's [EU] Bio-economy Report, 2012, SynBio is increasingly becoming a critical developmental factor for most states around the world. The Organization for Economic Development [OECD], (2006) has also credited the technology a priority and has called upon member countries to develop bio-economy policies and strategies that accord the technology special attention in terms of research and development. The net result has been a trend toward attempts at mainstreaming SynBio into regional and NDPs and policies. The following paragraphs highlight a few of such cases. The aim is to justify why there is a need for such attempts in Kenya which should be based on scientific evidence, which this study aims to generate.

United Kingdom is a world leader in the research and development (R&D) of SynBio (Scrutton & Le Feuvre, 2018) and has been a benchmark country to upcoming countries and regions in this area (Ning, Aggarwal & Poh, et al., 2020). The country has placed SynBio at the center of its bio-economy and has listed the technology as part of the 'Great Eight Technologies' of the UK in her SynBio Roadmap of 2012. The SynBio Roadmap 2012 set out a clearly stated vision for the UK's SynBio journey, that is, to make it economically vibrant, with a clear public benefit, and to be developed as a cutting technology. The Roadmap makes several recommendations including the establishment of SynBio educational centers, a leadership council, international cooperation, and establishment of SynBio special interest groups to develop a thriving nationwide community of academics, industrialists and other stakeholders and continuing responsible research and innovation through regulation.

By the account of the UK's Bio-economy Factsheet 2018, the SynBio Leadership Council (SBLC) is established already *provides a steering structure and a governance body to assess progress, update recommendations, and shape priorities for future implementation of SynBio roadmaps* (SBLC, 2016). To underscore the importance of SynBio in the UK, the SBLC has produced landmark publications including the SynBio Strategic Plan, 2016 (SBLC, 2016). Taking from the achievements of the 2012 SynBio Roadmap, such as the establishment of six SynBio Educational Centers, the UK SynBio strategic Plan was drawn from a broad expert dialogue and engagement spanning business and research communities. The document focuses the UK on five related areas of strategic import, namely accelerating industrialization and commercialization; maximizing the capability of the innovation pipeline; building an expert workforce; developing a supportive business environment, and building value from national and international partnerships (SBLC, 2016, p. 1). These strategic areas are supposed to be catalysts to the Plan's aim; to deliver the original target of a £10bn SynBio-based platform technology2 in the UK by 2030.

Above all, the UK SynBio roadmap primarily aims at mainstreaming SynBio into bio-economy sectors including food, agriculture, health, advanced materials, security and environmental protection (p. 4-6). This is to be realized through the hand-in-hand working of the SBLC with the other two national Working Groups on Bio-economy namely, Industrial Biotechnology Leadership Forum (IBLF) and the Agri-Tech Leadership Council (ATLC), to ensure alignment between the role and potential value of SynBio and this broader vision for the UK bio-economy (p. 4). The

result has been the integration of SynBio into food and nutrition security programmes and strategies, environmental programmes and strategies (UK National Energy and Climate Plan 2021), health programmes and strategies, industrialization programmes and strategies (The Industrial Strategy 2030), energy programmes and strategies (The UK Renewable Energy Roadmap 2020) among other fields to which SynBio has direct or indirect impact in enhancing the efficiency of production by lowering costs while increasing large scale production of environmentally friendly systems, and products within a very short time (SBLC, 2021).

The lessons from UK's approaches to SynBio can constitute key important success insights for learning and chatting a way forward for a latecomer like Kenya. In this regard, there is a need for an assessment of NDPs and selected NDPs for primary institutions in the bio-economy to establish current practices and advice on how SynBio can be synchronized into national development discourses in the country.

A common approach to national development planning for emerging technologies development and integration into national development around the world today, is the 'technology road mapping' (Marris & Calvert, 2018). Originating in the 1980s in the private sector, technology roadmaps have become integral tools for enhancing competitiveness of public industries since 2000s (*Ibid*). This notion of technology roadmaps is aptly captured by Nuffield Council on Bioethics (2012) commentary on the role of technology roadmaps in emerging biotechnologies:

> "Having a technology roadmap conveys the impression of purpose and inevitability in the way that a new technology is expected to unfold, and perhaps also seeks to associate the new technology with people's experience of rapid change in computer technology" (p. 102).

As a means to governing the future of emerging technologies, technology roadmaps aim not only to inform decision-making but also to "weave a picture of the future that attempts to galvanize actions in the present" (McDowall, 2012, p. 531). Drawing from their experience with the UK SynBio roadmap, Marris & Calvert take this assertion further to argue that technology roadmaps 'conflate' three critical aspects of the future:

> 'Expectations (what is likely to happen?), desires (what is hoped will happen?), and promises (what will be made to happen?) Another important feature of roadmaps is that who is involved

has a large influence on the path sketched out for the future and also on the legitimacy of the roadmap' (Marris & Calvert, 2018, p. 4).

A national SynBio roadmap, like other roadmaps for emerging technologies like nanotechnology and artificial intelligence, should outline societal expectations-including benefits and risks of the technology. Steven Suppan of the Institute for Agricultural and Trade Policy has expresses the fear that SynBio roadmapping as has been encountered in the USA has neglected the purpose vision by adopting a SynBio deregulation approach (Suppan, 2014). This has been achieved, he argues, in three ways: by considering Synthetic biology products as genetically modified organisms (GMOs) hence failing to consider those SMOs that are not derivatives of GMO compounds (SCBD, 2021; Jayanti, 2020; Suppan, 2014).

Secondly, the USA's approach is based on the so-called Confidential Business Information (CBI) which bars public peer-review of "synthetically modified organisms" (SMO) processes and products which are to be commercialized (Suppan, 2014, p. 4). Thirdly and related to the second, the USA SynBio development roadmap is based on a 'proactionary' principle which aims to regulate SMO products but not the processes through which they are produced (Suppan, 2014; Jayanti, 2020).

Marris & Calvert (2018) express similar concerns with regard to UK SynBio road mapping where the process leading the roadmap is highly technical, driven largely with the Business sector and technologists, and does not involve the participation of the other experts and the publics, as well as a systematic contribution of social scientists who can provide the necessary regulatory perspectives.

Another approach to development planning for emerging technologies is the formulation of National or Regional Bioeconomy Blueprints or Strategies. This is the case for the USA and EU countries. The US National Bioeconomy Blueprint 2012 for example, takes cognizance of benefits of SynBio to its strategic sectors such as national security, health and medicine and industries and aims to keep USA as the world's most competitive country in SynBio; by not only developing and supporting the technology but also laying frameworks for massive commercialization of SynBio

products domestically and in the global markets. The EU, OECD countries, Singapore and China have adopted a similar approach and have, in the words of one author, placed SynBio in the driver's seat of bioeconomy development (Ning, Poh & Aggarwal, 2020; Finish Ministry of Employment and the Economy, n.d.; EU, 2017; EU, 2012; *McCormick, Kes; Kautto & Niina, 2013; EU, 2017b; Environmental Development, 2015'* Wesseler*, Spielman & Demont, 2011; Staffas, Louise; Gustavsson, Mathias; McCormick & Kes, 2013; fao.org., 2021).*

For latecomer countries like Kenya, learning from these lessons are important at least for three reasons. National development planning of bioeconomy through development and integration of SynBio is one most important way to ensure decision-and- policymakers are guided by the real issues pertaining to the technology. This should, among other things, help them learn important lessons about the structure of SynBio governance, the focal institutions and interagency cooperation that can adopted or customized according to Kenyan situations. Secondly, this process has not been easier even in the developed world where it has happened. Criticisms from experts in the case studies for example in the UK and USA, should be taken seriously while charting a course for a national planning that constitute an environment for adoption, implementation and further development of SynBio. Lastly, evidence must be drawn from current national planning to identify the extent to which science, technology and innovation (ST&I), and maybe emerging technologies have been accorded a space in national development planning as enablers of national development priorities.

2.8.Perceptions on Synthetic Biology Technologies Regulation

There is generally a dearth of scientific studies which have explored perspectives key stakeholders regarding SynBio. The few existing studies exhibit two characteristics: a) they are based on exploration of the perspectives of the general public (Hart Research Associates, 2010; 2013; iGEM, 2020; iGEM, n.d.) and b) secondly they focus on SynBio products which fall under GMOs (iGEM, 2020; iGEM, n.d.).

The Hart Research Associate, working under the SynBio Project in the Woodrow Wilson International Centre for Scholars, has been researching and analyzing public awareness and impressions on new and emerging technologies from 2008. In 2010, the institution undertook a nationwide survey among 1000 adult's *attitudes toward the entities involved in the oversight of new scientific and technological advances, awareness of nanotechnology, and awareness of and*

attitudes toward SynBio and two potential applications of the science (Hart Research Associate, 2010, p. 1). The 2010 study was the third time attitudes, awareness and knowledge research was being conducted in the USA on SynBio. The report of the findings of the study indicated that Americans awareness of SynBio has been increasing and their attitudes have been progressively becoming positive. In 2008, only 9% reported being aware of SynBio, in 2009 it was 22% and in 2010 it was at 26%. Those who reported being aware supported forging ahead (80%) despite uncertainties of SynBio than those who have heard nothing (52%). The study reveals that when adults are asked about SynBio risk-benefit trade-off and presented with options such as risks equal benefits, more benefits and more risks, a good percentage still think risks will equal benefits (33%); with 19% taking more benefits and 16% taking more risks.

The study also sorts to ask the adults whether they think SynBio development should continue as its effects on humans and the environment are being explored, or it should be banned until the real risks to humans and environments are known and a mechanism for their management dealt with. The study established 2:1 ratio of those who support the technology should be developed as risks are being explored and managed (63%) against those who think the technology should be banned (33%). When the respondents are disintegrated into African Americans, Hispanics and Pure Americans, a higher number of African Americas support the technology ban (52%), Hispanics (43%), evangelicals at 43%, women at 40% but those over 50 years old want more ban (46%) than women below 50 years. When respondents were presented with two paragraphs of a description of what the technology is about; more support for the technology was reported, for example, those who had selected benefits outweigh risks selected forging ahead at 90% and 64% of those who think risks outweigh benefits supported a ban.

The study also sorts to ask the perspectives of the adults on regulatory institutions. Options given were whether they thought federal government authorities were better placed to govern SynBio or voluntary guidelines developed through government-industry cooperation. The majority of Americans (52%) want federal government agencies to regulate the technology and only 36% prefer voluntary guidelines. Confidence of the public in the regulatory agencies and one research agency was sort. The results were highest for the United States Department of Agriculture (USDA) (60%) followed by the Food and Drug Authority (FDA) (57%), Department of Energy (DOE)

(52%) and lastly Environmental Protection Agency (EPA). The study also revealed that while most Americans want SynBio research and development to continue, they still express fears that the technology could be used to create harmful systems such as biological weapons, they also expressed ethical questions about the possibility that could be an avenue for 'playing God' by creating artificial life, that it had a potential risk for human life and environmental risks.

These findings on attitudes and knowledge/awareness on SynBio, have been used in the USA as part of national planning for the field of SynBio (Hart Research Associates, 2013). The findings have been used to undertake targeted public education and awareness creation, plan resources allocation and build institutional capacities and confidence in the regulation of SynBio (*Ibid*). This study, utilized Hart Research Associates (2010) approach to establish public awareness and impressions in Kenya as a prism with which to compare findings in the USA and Kenya. However, the study adopted an experts' perspectives survey framework, to purposively target sample populations from six sectors, which the study assumes should play the pioneering role in the adoption and implementation of SynBio. While Hart Research Associate (2010) exploited purely quantitative research, this study will employ a mixed-mode approach to find respondents explanations of their choices in a quantitative survey which was used to establish their knowledge, practices and attitudes. Lastly, this study only targeted experts who in one way or another have worked in biotechnology projects. This was a deliberate effort and was meant to enable the researcher get needed information to answer research questions, based on an exploratory design since SynBio is still an alien concept to the general publics in Kenya.

2.9.Chapter Conclusions

The foregoing section reviewed empirical literature from three main types of sources: international regimes under the CBD regulating biotechnology (more particularly GMOs) and emerging international regimes applicable to the regulation of SynBio, such as the protocols laid under the International Genetically Engineered Machine (iGEM) and the provisions of the Bacteriological Weapons Convention (BWC). The second type of literature reviewed in this section assessed the SynBio regulatory approaches adopted by pioneer countries in the field and practice of SynBio: USA, UK, European Union and Singapore were used as case studies. Additionally, literature on biotechnology and GMOs research in African sub-Sahara, and biotechnology regulation, research and development in Kenya was reviewed. Lastly, empirical evidence on national development

planning and public perspectives, as key approaches to bolstering SynBio development and promotive regulation were presented. Jointly, the empirical review contributed to this thesis study in two major ways: laying the study conceptual groundwork, and identifying gaps based on the study objectives.

Regarding objectives one and two of the study; which aimed to explore policy and legislation/legal gaps in Kenya's biotechnology frameworks, the empirical review revealed three intricately inter-related major gaps which this study aimed to fill. Firstly, that there is a consistent trend to question the sufficiency of the biotechnology and GMOs regulations as to their effective regulation of SynBio. Secondly, that the gaps in the policies and legislations regulating GMOs makes it difficult for the institutions charged with the GMOs mandates to cover SynBio regulation in an environment of accountability, transparency, integrity, participation, capable (TAPIC) institutions and actors.

Lastly, there is therefore the need to explore the robustness of biotechnology-related pieces of legislations: policies, legislations, and institutions to generate the evidence that will give policy makers and regulators the directions for creating functional regulations or adapting existing ones accordingly. This study, thus aimed to build on existing literature to fill the said gaps with respect to Kenya through documentary analysis of selected biotechnology-related policies and legislations.

Concerning objective three of this study: to explore Kenya's relevant national development plans for adoption and implementation of Synthetic biology, the literature revealed that in the countries where the technology of SynBio is already revolutionizing the bioeconomy, SynBio has been placed at the center of national development planning. For example, from the literature I realized that the UK, the second country after USA (SBLC, 2016) in terms of advancement of SynBio; national development blueprints do not just integrate SynBio, they have placed SynBio in the driver's seat of their bioeconomy. This is exemplified for example by the UK's bioeconomy strategy, which is called "Biodesign for the Bioeconomy: Synthetic Biology Strategic Plan." In the USA, the "USA Bioeconomy Strategy 2012" treats SynBio as technology contributing not just to the bioeconomy but also to the security and defense sectors of the country. Against this backdrop, this study attempted to fill this gap in the Kenyan context through an exploration of 7

purposefully selected national development plans in order to establish the extent to which ST&I is embedded in them and how that can favor the mainstreaming SynBio in NDPs.

Finally, the review revealed that there are a few attempts at gathering public perceptions on the regulatory and development issues of SynBio; be they those that are advanced from GMO compounds or pure SynBio products (iGEM, 2020). This study, being an exploratory study will build on these but with a special focus on experts in biotechnology in order to answer research questions of the study. The next chapter will present the methods and the justification o their choices in this study, before presentation of findings.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1. Introduction

This chapter presents the methods used in the study and their justifications. Kothari (2004) makes a useful distinction between research methodology and research methods. Research methods relate to the various methods used, for example, to collect data, define samples, analyze or interpret data. Research methodology, on the other hand, go beyond methods to justify underlying assumptions that informed the selection of the methods, and why certain techniques were utilized in a given manner and not others. The methodical dimensions thus answer *what* and *how* (including *who* and *where*) questions while the methodological dimensions answer *why* questions. Together, it can be deduced, *what*, *how* and *why* questions are the interest of the research methodology section of academic research (Kothari, 2004; Bhattacherjee, 2012; Babbie, 2008; Crano & Brewer, 2002). Below is a discussion of the methods and justifications that underpinned their utility in this study. Figure 2 below is a summary of the research process – discussed in section 3.2.

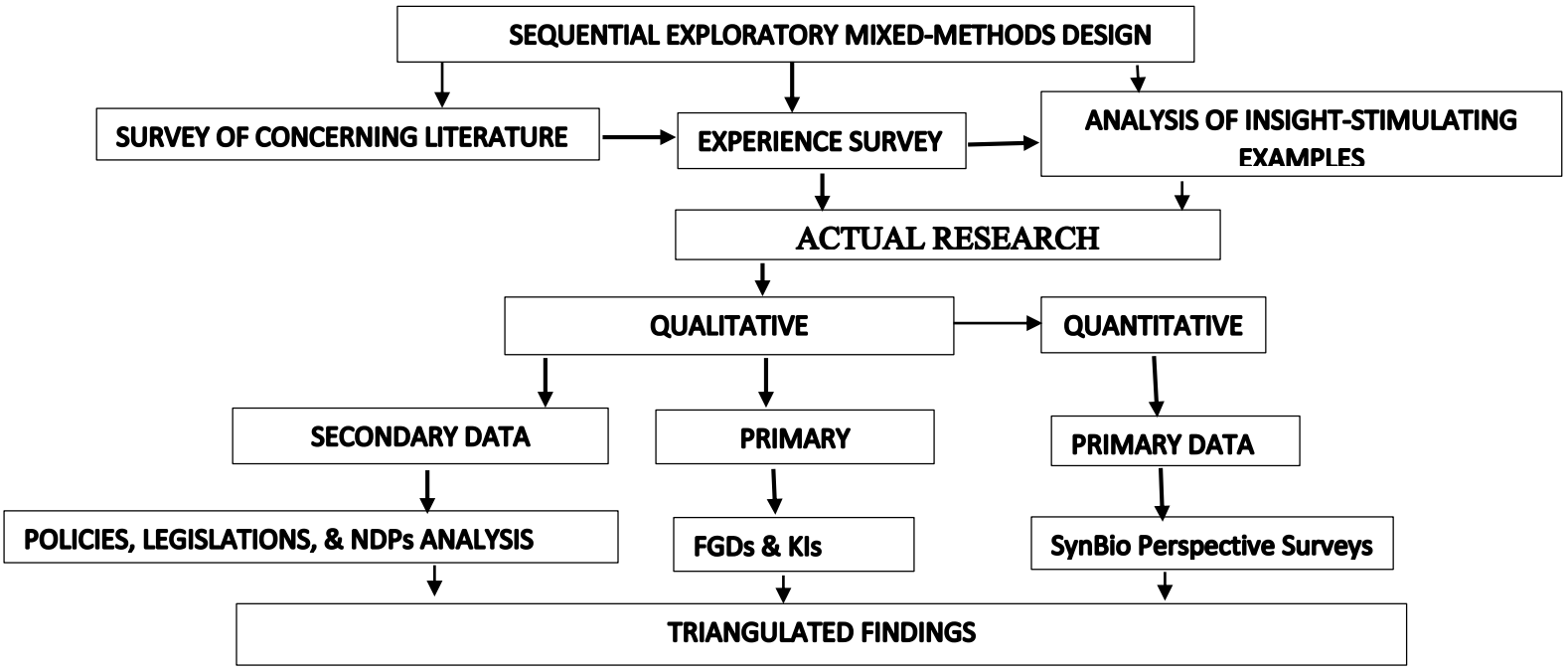


Figure 2: The Flow Chart Diagram of the Methodological Process
Source: Researcher (2022).

3.2. Research Design

A research design is defined as a comprehensive plan for data collection in empirical research (Bhattercherjee, 2012, p. 35). The overall plan for data collection in this study was guided by the sequential exploratory mixed-methods design' (*ibid;* FoodRisc Resource Centre, 2021). There are four types of mixed method research designs: sequential explanatory, sequential exploratory, concurrent triangulation and concurrent nested (FoodRisc Resource Centre, 2021). The utility of the sequential exploratory design was adopted due its relevance to the study. In sequential exploratory designs, qualitative data is collected and analyzed first before the collection and analysis of quantitative data. The analysis and interpretation integrate findings from both methods (*Ibid*).

The method thus, provided the advantage of enabling the formulation of research questionnaires, with higher construct validity as emerging issues from qualitative data pointed to new issues not previously known to the researcher, but were important to make the questionnaire tool more context-specific and precise. The method also enables corroboration or simultaneous interpretation of qualitative and quantitative data, hence filling in gaps that accompany the disintegrated analysis of qualitative and quantitative data. On the other hand, Mixed-mode design was preferred for this study because as succinctly put by Bhattacherjee (2012):

> sometimes, joint use of qualitative and quantitative data may help generate unique insights into a complex social phenomenon, that is not available from either type of data alone, and hence, mixed-mode designs that combine qualitative and quantitative data are often highly desirable (p. 35).

According to Kothari (2004), an exploratory design should involve three important stages at the pre-data stage: analysis of concerned literature, experience survey, and analysis of insight-stimulating examples. The findings from these processes are expected to inform actual research by making clear the issues with which the investigation is concerned. The development of this proposal involved a preliminary survey of literature about SynBio regulation, it also involved informal but objective conversations with experienced biotechnologists and policy experts from

NACOSTI, ISAAA AfriCentre, food and nutrition specialist from MMUST, Laboratory Medicine specialist from Maseno University, Biotechnologist from Maseno University, 2 Plant Genetic Engineers from Masinde Muliro University of Science and Technology (MMUST) and a medical pathologist from Kisii Level 5 Hospital. Insights stimulating examples from the United Kingdom, USA, and Singapore were used to establish some basic regulatory issues and later were used as literature review for more in-depth analysis to inform study objectives.

During actual research, the study followed a sequential mode as follows. Firstly, the study gathered qualitative secondary data through analysis of policies, legislations, and national development plans (NDPs). This was followed by qualitative primary data collection from 4 stakeholders' roundtables/FGDs and 22 in-depth Key Informant Interviews (KIs). The main significance of the sequential mode was that the findings from these two sets of qualitative data informed the revision of the survey questions. Interpretation was done simultaneously where qualitative data from each of the first three objectives which were collected from secondary data, that is, analysis of policies, legislations, and NDPs, and primary data, that is stakeholders' meetings and KIIs, was triangulated and presented in both statistical and textual formats. Because, SynBio is not only a grey research area in Kenya but also a technical field, the mixed mode design of collecting both quantitative and qualitative data and triangulating the findings through corroboration aided in generating more valid and reliable findings than when the researcher depended only on one type of data, and data collection techniques.

Additionally, gathering stakeholders' perspectives through surveys among stratified population, enabled the researcher to find divergences and convergences which can help shape a broader vision for the new technology, SynBio. This was important in generating an understanding of stakeholders' perspectives toward SynBio, which came in handy in making recommendations about how stakeholders' engagement can be enhanced to maximize results of SynBio technology adoption and implementation.

3.3. **Geographical Study Area**

This study was not limited by geography but by the subject matter. The choice of study participants depended on the expertise on the subject of biotechnology and SynBio regulation, research and

related issues and not where they stay. Nonetheless, this study was conducted in Kenya. The country is a bonafide member of the global community and has had a keen interest in global discourses related to biological diversity, exemplified by her hosting of the COP V in her headquarters in Nairobi. On the biotechnology front, the country's involvement dates from the late 1990s (Personal Communication with an Ex-Plant Engineer) and has since successfully produced three genetically modified foodstuffs (GM) namely GM cotton, GM Casava and GM Maize. The country has also played a key role in Synthetic Biology debates. For example, the Kenya's SynBio focal person domiciled at NACOSTI has been a key representative of not just Kenya alone but also Africa at various global discussions on SynBio within and beyond the scope of the CBD.

The data collection was largely concentrated in Nairobi County Headquarters where a large part of the respondents were based namely Government ministries, departments, and agencies (MDAs), biotechnologists from academia and industry fields, SynBio think-tanks. These included University of Nairobi (UoN), Kenyatta University of Agriculture and Technology (JKUAT) and Kenyatta University. ISAAA, KALRO, KEPHIS, KIRDI, Revital Health, NEMA, KEMRI, Pwani University. Other regions/counties covered were Kisumu (Maseno University (MSU) where two experts were drawn from the departments of Public Health and Community Development; Kakamega (MMUST) where two professors in biotechnology were drawn from Masinde Muliro University of Science and Technology (MMUST) from the Department of Biochemistry and Biotechnology; and Kisii County (Centre for Resilient Agriculture in Africa [CRAA]).

3.4. Study Population

The target population of this study were the biotechnology experts in Kenya, whose work has involved modern biotechnology or preferably aspects of synthetic biology. The unit of analysis were key experts drawn from across six stakeholder groups namely: academia, industry, medical, media & communication, policy, governance & regulatory bodies, and research. The quantitative data was based on a sample size of 83 people purposively selected from six categories which comprised the unit of analysis. The qualitative research was based on 22 key informant interviews and 4 FGDs/stakeholders roundtables. The selection of experts for recruitment into study survey and interviews experts was based on the following criteria; a) on a stakeholder's net-mapping exercise that was conducted by the NRF SynBio Project in June 2021 and which the researcher participated; b) informed by the visibility of the selected scholars/researchers in terms of

publication work accessible on Google scholar; c) known contribution to the biotechnology research, media reporting, regulation and otherwise as was recommended by experts within the project through snowball during the study.

The distributions were as follows: 5 interviews with biotechnologists from academia (2 from Maseno University, 1 from MMUST; 1 from UoN and 1 from KU); 1 from CRAA; 2 interviews with an expert of Kenya Institute of Primate Research (IPR) and the institution's focal person for SynBio research. 1 interview with Monitoring and Evaluation (M&E) expert from Program for Biosafety Services (PBS). 1 interview with a key expert, Kenya National Biosafety Authority (NBA). 3 interviews with senior scientists from Kenya Agriculture and Livestock Organization (KALRO). 2 interview with a senior scientist at KEMRI. Finally 8 interviews with senior scientists from NACOSTI (3), KIRDI (3), ISAAA AfriCentre (1), and KEPHIS (1).

3.5. Sampling Procedures and Sample Size

To get the type of population described in the above section, this study employed a stratified, purposive non-random sampling, and snowballing techniques. Based on a biotechnology stakeholder's survey and net mapping hosted by ISAAA AfriCentre in June 2021, there are six important categories of biotechnology stakeholders who may influence the adoption of SynBio technologies: academia; research; policy, governance & regulation; media & communication; medical and industry sectors. The survey also revealed that around 29% of these are in the academia, 25% in research, 23% in policy, governance and regulatory spheres; about 4% in media and communication, 13% in medical and 5% in biotechnology industries. Based on engagements with project PIs and supervisors, the researcher settled on 83 as the sample size. Following from the stakeholders net mapping, a total of 24 experts participated in the study from academia (that is, 25/83*100), 21 from research, 19 from policy, governance and regulation, 4 from media and communication, 11 from medical and 4 from industry, following the same criterion. However, to increase the chances of achieving the sample size, 93 experts were reached out of whom 89 returned the questionnaires and 83 of the returned were usable. Snow-ball technique was very critical as it allowed the researcher to accept referrals made during the FGDs and KIIs especially of the academia, and policy and regulators cohort from the government and the universities. This allowed the researcher to reach to the target audience and answer the research questions. In practice for example, the snowball enabled the researcher to navigate the challenges such as transfer of key informants from one Government MDA to another. Wherever such cases (which were common

during the study) occurred, the current office-holder was reached who then referred the researcher to his former colleague whom he thought could answer better the research questions. This was important in two respects: a) the referee was able to open up and say they were unable to answer research questions as appropriate as possible. This increased reliability of the study results; b) the referee then gave the researcher his/her colleague's phone number which increased the ease of reaching to them, and subsequently ensuring the sample size was reached according to the original design, or with very little modification where need arose.

3.6. Data Collection Techniques

Data for the study was collected per objective guided by the overall study design, and the analytical framework derived from the theory of adaptive and anticipatory governance. Objectives one, two and three data was based largely on secondary data through mainly document analysis. This was also triangulated with the results from FGDs and KIIs, which means qualitative data composed of both secondary and primary, albeit the weight being heavier toward secondary qualitative for the first three objectives. Secondary qualitative data was obtained through document analysis of 6 national biotechnology-related policies (objective 1), 8 national biotechnology-related legislations (objective 2), and 4 national development plans (objective 3). The first three chapters were also based on limited quantitative primary data derived the surveys on stakeholders' perspectives and their assessment of specific policies, legislations, and NDPs in regards to SynBio regulation in terms of their robustness to regulate SynBio issues that transcend current concerns with GMOs, and pre-GMO technologies.

The final objective (4) constituted of largely primary quantitative data collected through structured questionnaires, and partially based on Likert scale technique. Qualitative primary data collected through FGDs and KIs narratives were used to contextualize the survey results, hence utility of triangulation technique for comprehensive analysis. The methods are described in detail as below.

3.6.1. Document Analysis

Babbie (2008) defines document analysis as a technique, within qualitative research that involves "the study of recorded human communications, such as books, websites, paintings and laws" (p.530). Thus, document analysis is a technique of data collection which involves a systematic scrutiny of the content from written materials in order to make certain deductions based on the

study parameters/objectives. Babbie (2008) adds that sometimes, the technique can be employed in purely qualitative studies as a method of data analysis in its own right.

According to KENPRO (2012)[11] while citing the works of Marshall & Rossman (1995) asserts that, while undertaking document analysis, the researcher must bring out the document type (eg., report, records etc), the kind of document it is (government or institution document), its dates, where written, author and title, the aim of the document, the factual information contained, why the document is a valuable source of information, how the document can be used, what the document does not answer and could be answered by the author should all be brought out. This is done in order to validate the documents.

This was based in part on secondary data. This involved the policies selected, legislations, and national development plans all of which were relevant to the biotechnology governance in Kenya. As argued by KENPRO, the research in analyzing these documents, the researcher made clear what types they were, the dates they were first and became effective, the intensions and objectives of the documents, and the gaps they portend in terms of regulating SynBio technologies upon adoption in Kenya. A total of 18 government documents were analyzed to understand the policy, legislation, and national development planning states of biotechnology governance. Such information were corroborated with survey results as well as results from FGDs and KIIs. The documents were selected through a rigorous process as mentioned below. This was to meet the necessity highlighted by KENPRO above, that is, why the documents being analyzed are important and not others, for the given study.

3.6.1. Selection of Policies, Legislations and National Development Plans for Analysis

As already highlighted, this study was based on secondary and primary data. The secondary data analyzed included 6 biotechnology-related policies, 8 biotechnology-related legislations, and 4 NDPs. These documents were selected by design. The selection involved rigorous discussion with principal science analyst and an expert in biotechnology sciences regulatory at the NACOSTI. Following the discussions with this particular expert, who is also the Kenyan focal person for SynBio and the country's and Africa's representative to global SynBio forums; the selected documents helped the study explore research questions 1-3. The criteria used were as follows: a)

[11] Retrieved on 15th February 2023 on http://www.kenpro.org/document-analysis-method-of-data-collection/.

policies and legislations which are currently related to biotechnology research, regulation and otherwise; b) policies and legislations which are currently related to biotechnology research, regulation and otherwise and have a global origin, that is, have been domesticated in Kenya as a result of Kenya's international obligations to biotechnology, GMOs or bioeconomy-related development; c) development plans that meet the second criteria.

The rationale behind taking a bioeconomy view in the selection of the documents can be stated as follows: i) by analyzing and identifying gaps from key policy documents of the country's bioeconomy, the study would be contributing to the angle of the debate that policy makers and scientists have adopted[12]. Secondly, by so doing, the study would be informed by global practice. For example both in the USA and UK SynBio is directly linked to the bioeconomy. This is evidenced by the type of policies adopted as guides to SynBio R&D, such as the *Bioeconomy Strategy* in USA and the "*Biodesign for Bioeconomy: UK Strategic Plan for Synthetic Biology*" in the UK.

3.6.2. In-depth Key Informant Interviews

The researcher utilized this method on 22 experts spread as follows. In-depth Key Informant Interviews facilitate the generation of in-depth information from opinion leaders in an area of research (Silverman, 2004). The respondent can refer to the documentation at his disposal prior to the interview and be as informed and precise as he/she may want. The researcher' interest is not test the level of memorization, but he/she is in a quest for finer and finer details regarding the issue (s) he is investigating.

This study employed in-depth interviews at the second stage of data collection, after systematic documentary analysis. This was done through specific techniques such as phone calls (10 interviews), face-to-face interviews (5 interviews), and Zoom/Google-meet interviews (7 interviews); depending on which technique was convenient for a given expert respondent. Hence the techniques selected under this method enabled flexibility and hence encouraged participation of the respondents. The interview discussions lasted at least one hour thirty minutes with others

[12] During the March 29th 2021 Meeting of Stakeholders (policy makers and scientists) local and international held in Nairobi [this was the meeting that rationalized the need for the NRF SynBio Project], it was resolved that SynBio is globally viewed as been the spring boat for all bioeconomy innovations hence should be seen as a goldmine to bolster Kenya's bioeconomy.

even going for two hours. Such in-depth discussions enabled the researcher to answer study questions extensively.

The findings that emerged from such engagements with experts across the study population enabled the researcher to not only answer his research questions reliably, but also to be able to refine the survey tool for the next stage of data collection. The discussions met the intended objectives to a greater extent because the researcher; a) called the participants at least one week before the interview, to ask for their participation and after which emailed them consent/information forms and the interview guide. Emailing the interview guide prior to interview date enabled the respondents to be well equipped with the questions. b) The interview tool allowed for further probing since the researcher was able to explore new but hitherto uncaptured issues which emerged during the interview discussions. c) For accuracy of documentation, the responses were recorded using the same phones or on Google interview recorder platforms which were used to make the calls. d) The audio records were then transferred in to a secured (through password) folder in the researchers' laptop and transcribed in to text in preparation for thematic content analysis.

3.6.3. Focus Group Discussions

FGDs have become a familiar approach to qualitative research since the 1990s and engage a small number of people (4-6 (Bryman, 2012); 6-10 (Bhattacherjee, 2012, p. 78) or 12-15 (Babbie, 2008, p. 78) in a more or less informal discussion of a 'focused subject' using a series of questions or the 'FGD schedule'. The discussions are recorded and data transcribed for later analysis often through the use of content analysis (Silverman, 2004). Silverman (2004) adds that, FGDs should be conducted among a homogenous group so as to ensure power relations factors do not affect the responses through influencing the interactions during discussions. The technique was selected because it can generate information on collective views and the meanings that lie behind those views and helps to reinforce gaps that may emerge from surveys, and personalized interviews like KIs (Kothari, 2004). Silverman (2004) adds that it encourages group think hence generating lengthy and broader conversations than other forms of interview.

This study conducted 4 stakeholders' roundtable meetings (herein called FGDs) consisting of 8, 6, 11, and 14, participants per each interview. 4 were conducted on zoom and 2 were conducted physically. Attempts were made to ensure at least the composition was representative in terms of

the population stratification of the study. The method enabled interactions and consensus-building between policy, governance, and regulatory, research, medical personnel from government with their private sector actors enabling the researcher to retrieve vital in-depth information. It also enabled the collection of data within a short time from a large number of people who are too busy and difficult to find for personal interviews. To ensure accurate documentation, FGD responses were taken by way of note taking and through audio recordings. Voice records were later transcribed verbatim in to text for analysis. The researcher anonymized the participants by coding the FGDs in terms of the number of FGDs (1st. 2nd, 3rd and 4th).

Table 2: Composition of FGDs

Composition of FGDs

No. of FGD	No. of Participants	Representation by Population Strata	Mode of Meeting/Discussion
1ST	8,	Research-2; media & comm.-1; PRG[13]-2; academia-2; Industry-1	Physical (Nairobi-Safari Park Hotel)
2ND	6	Academia-3; PRG-3	Zoom
3RD	11	Academia-3; media & comm.-2; PRG-1; Medical-1; research-3; industry-1;	Physical (MovenPick Hotel-Nairobi)
4TH	14	Academia-4; research-6; PRG-4	Zoom

Table 2: Composition of FGDs

Source: Researcher (2022).

3.6.3. Flexible Surveys Techniques

This study exploited a mixture of survey techniques to allow for flexibility and to encourage questionnaire return rates. In the same vein, Babbie (2008) and Kothari (2004) argues that computer enabled techniques have made research very interesting since researcher no longer need

[13] Policy, regulatory and governance bodies

to strain with too much manual work in collecting and analyzing data and associated costs. The flexible approach included: SurveyMonkey, Zoom interview surveys, physical interview surveys and Email Surveys. The processes involved in each technique is described below.

3.6.3.1. SurveyMonkey

19 questionnaires of this study were filled on the SurveyMonkey platform. The researcher learnt about the terms and conditions of the platform, formulated research questions and copied them one-by-one on the platform. The survey link was generated and was shared with potential respondents via email. To increase return rate, the researcher called potential respondents at least two weeks before the emailing to confirm if they would be comfortable with the technique and then the link was shared after informing the participants on the date upon which the survey would automatically expire, or become inactive. The reasons for the success with the technique was that the researcher informed the respondents on the manner in which the technique operates, including active days of the link, and then after emailing the questionnaire did regular follow-up reminders which kept the respondents on toes, and could have then have not forgotten to have the tool filled. All the filled questionnaires were then transferred in the standard hard copy questionnaire and stored safely awaiting analysis.

3.6.3.2. Zoom Interview Surveys

The researcher had 12 questionnaires filled through zoom interviews. The technique involved three major steps. The first step involved requesting respondents to participate. The second was to email the study information and consent forms, and the survey tool. The third was to agree on an appropriate date once the potential respondent reads up the tool and raises any questions before the interview. The last stage, stage four, involved the actual zoom meeting. During this phase the researcher sent a zoom link and informed the respondent. During the meeting, the researcher shared his screen with the respondent with a display on the survey questions. The respondent then selected applicable responses of /his/her best choices. During the zoom interview, the researcher filled a separate hard copy questionnaire with the respondents name and phone number as the Questionnaire's unique ID.

3.6.3.3. Physical/Self-administered Interview Surveys

37 questionnaires were filled physically during a one-on-one interview between the researcher and the respondents. Like the other techniques, and with the aim of increasing the validity of the responses given and increasing the questionnaire return rate and to reduce amount of time per interview, the researcher emailed the questionnaire, the study information and consent forms two weeks before the physical meeting. Although not all the respondents had the chance to look at the questionnaires before the physical meeting, 30 respondents reported to have at least skimmed through the tool before the researcher actually met them for interview survey. The greatest advanagate of this technique was that, by the researcher himself reading out the questions and the responses, he was able to structure the respondents thinking within the scope of what was expected per question hence solving problems of misunderstanding a question by the respondents if he/she was filling it alone through other techniques.

3.6.3.4. Email Surveys

This technique is called email surveys because the entire data collection process was executed on email. The researcher requested the potential respondent for his/her participation. The respondent then agreed and the researcher email the study information and consent forms, and the survey tool. The researcher then asked the respondents to fill in the soft copy and email as soon as they can. The respondents filled the questionnaires by either putting a tick or any other sign on the spaces for making a choice. A total of 15 questionnaires were returned through this method.

3.7. Reliability and Validity

The researcher worked closely with his supervisors, who are qualified researchers, in the formulation of research instruments, to see into it that the questions asked have the ability to yield intended results and answer research questions. Secondly, based on the adopted design of sequential exploratory study, by first analyzing secondary data and conducting interviews and KIs before administering the surveys, the researcher was able to formulate relevant quantitative questions that increased the chances of getting relevant answers to meet study objectives. Thirdly, the researcher conducted a pre-test on the survey questionnaire during a stakeholders meeting held in July 2021 hosted by ISAAA AfriCentre. This enabled informed revisions of the quantitative questions for increased validity and reliability. Lastly, concerning “ecological validity” which according to Bryman (2012) relates to the ability and possibility of the researcher social contexts

of the study and to get his intended respondents, the researcher worked very closely with ISAAA AfriCentre and his supervisor from NACOSTI to recruit the targeted experts and ensure they were reach for participation.

3.8. Data Analysis and Presentation

The collected data was in the format of qualitative and quantitative data and thus had to be analyzed using both qualitative and quantitative methods and techniques. Qualitative data was gathered from secondary materials; primarily policies, legislations, and NDPs, and primary qualitative data collected from FGDs and in-depth key informant interviews.

3.8.1. Analysis of Qualitative Data

Qualitative data were analyzed through thematic content analysis. Qualitative data collected through documentary analysis, FGDs and KIs were sorted then cleaned, coded, memoired and concept mapped as argues Babbie (2008). The data emerging from this processing was then presented in a flowing interpreted manner, following the themes and sub-themes explored and those that emerged. To support the cases made during the interpretations, qualitative primary data in certain instances presented verbatim and data from documentary analysis presented in paragraph or line excerpts. Tables were also used to summarize qualitative data in certain instances. The discussions of findings were informed by the theoretical framework adopted in the study as is supported by (Kothari, 2004). Qualitative data was triangulated with survey findings and theoretical interpretations were made.

3.8.2. Analysis of Quantitative Data

Primary quantitative data was analyzed by the use of Statistical Package for Social Sciences (SPSS v. 26) to generate simple descriptive statistics. Data was presented by way of frequency tables, bar graphs, and pie charts, histograms and cross-tabulation and corroborated with qualitative findings from documentary analysis and FGDs and KIs findings (interviews). Quantitative analysis was mainly for objective four which was based on the survey findings on the expert stakeholders' perspectives and expectations on SynBio and its adoption and implementation in Kenya. For chapter four, whose data was collected by fully closed Likert Scale, a standard response mode and scoring guide were adopted throughout the chapter as follows;

3.8.2.1. Response Mode and Scoring Guide

A five point response scale was used to describe expert stakeholders' perceptions and expectations on the synthetic biology on issues pertaining to SynBio adoption and implementation as shown in table 3. In the presentations and discussions, scales 5 (strongly agree) and 4(agree) were merged as "had favorable opinion" and 2 (disagree) and 1(strongly disagree) as "at least disagree"/"had unfavorable opinion", while 3(neutral) was assigned "fair"/ "had fair opinion" as the scoring guide.

Numerical Rating	Verbal Description	Scoring Guide
5	Strongly Agree	"At least agree"/"had favorable opinion"
4	Agree	
3	Neutral	Fair
2	Disagree	"At least disagree"/" unfavorable opinion"
1	Strongly Disagree	

Table 3: Response Mode and Scoring Guide

Source: Researcher (2022).

Interpretation of findings from all methods and techniques used was done jointly. This enabled the triangulation of findings from different methods, techniques, and population categories enabling the researcher to fill in gaps that may have emerged from a given method, technique, or population category.

Findings from objective one were presented in chapter four, objective two in chapter five, objective three in chapter six and objective four in chapter seven. The format of data presentation was based on the alternative 2 provided by Maseno University School of Arts and Social Sciences Thesis Wring Format which school of SDSS also uses as a standard writing format (SASS, 2016) Chapter nine contained the summaries, recommendations and conclusions of the study.

3.9. Ethical Considerations

This study aimed to explore Kenya's biotechnology regulatory environment to generate evidence that may inform policy makers to adapt the environment to the regulation of SynBio technologies. To meet this task, I have set four objectives (stated in section 1.3.1) which were pursued by asking questions through FGDs and KIs, as well as administering questionnaires among an expert respondent population sample. The study adhered to the ethical codes which govern social science

studies as documented in European Union's *Ethics in Social Science and Humanities (EU, 2018)* and any other documents on social sciences research ethics. The study was guided by the following ethical considerations in this study.

Data collection was only initiated upon receipt of authorizations, that is from Maseno University's School of Graduate Studies (SGS) and a research permit from NACOSTI. Secondly, the researcher sought consent and voluntary participation of target respondents via the use of a consent form (Appendix 1) emailed to prospective participants before the interviews, surveys and FGDs. The form explained the intent of the study into detail. Thirdly, the study understood that some experts work within very strict institutional guidelines and which may make them fear diverging important information to the researcher. Such confidential issues were mitigated by ensuring that these experts were recruited at individual capacities rather than as representatives of the institutions they hail from. The researcher made all possible attempts to ensure that the information given was kept anonymous making it difficult for such information to be traced back to them through coding FGDs into 1st, 2nd, 3rd and 4th and by not including participant names in verbatim quotations. Fourthly, no vulnerable participants targeted by the study and no minor were engaged. The study was thus affected by ethical issues involving engaging vulnerable groups like children, PWDs, or women facing violence.

Fifthly, the data collected through notes, audio tapes and any other means was entirely kept by the researcher and only analyzed and interpreted information has been shared through one journal publication which has no reference to any individual names. Sixthly, the findings of this study will be made public for public consumption and will be published and shared through free access journal articles and through Government ministries, especially, NACOSTI which is a collaborator in this study and the Kenyan government's focal institution SynBio.

Lastly, the benefits of participating in this study did not involve payment as reward of whatever kind, or any short-term material rewards. Respondents entirely participated based on their voluntary decision to, without any enticements or unethical persuasions by the researcher. If any reimbursements were made, then it was by the project funder and due entirely to facilitate the respondent's movements. There were no foreseen risks and no risks were encountered and documented during the study.

CHAPTER FOUR

AN EXPLORATION OF THE SUFFICIENCY OF KENYA'S BIOTECHNOLOGY-RELATED POLICIES FOR ADOPTION AND IMPLEMENTATION OF SYNTHETIC BIOLOGY

4.1. Chapter Overview

In this chapter the study attempted to explore the question: does Kenya possess the needed policy frameworks for the adoption and implementation of SynBio? The chapter was based on the analysis of 6 policy documents regulating biotechnology and/or bioeconomy in Kenya. The framework of analysis was guided by the TAPIC framework and informed by the five key regulatory issues concerning SynBio: biosafety, biosecurity, economic and social impacts, biological diversity, and bioethical and religious issues. The documentary analysis was triangulated with survey and interview findings. The primary data served to put the documentary analysis findings in their current context. As presented in chapter 3, the structure of this thesis is such that chapters four, five, six, and seven constitute the findings from objectives one, two, three, and four respectively. Before the findings, this chapter is presented in this section, preliminary analysis tests and analysis of the demographic variables will be presented.

4.2. Response Rate

Hair *et al*. (2010) underscore the value of response rate when he asserts that, in quantitative surveys the response rate ensures that the targeted population are reached and the N value is achieved. This is because it ensures the questionnaires collected are valid for data analysis. In this study, a total number of 93 questionnaires were distributed to 25 people in academia; 29 people in biotechnology and related government and private research institutes, 20 people in government policy, regulatory, and governance bodies, 4 people from media and communication fields, 11 to people in medical research and practice institutions and finally, 4 to people in the biotechnology-related industries (table 1.0). Out of 93 questionnaires distributed, 89 were returned. The response rate was thus 95.70%. Because 6 questionnaires were incomplete, ineligible, or several multiple selection of

scaled data, only 83 questionnaires were used, and the six excluded from analysis due to the problems of outliers (*Ibid*).

Table 4: Response Rate

No	Response	Frequency	Per cent (%)
1.	No. of distributed questionnaires	93	100
2.	Questionnaires retrieved	89	95.70
3.	Unusable questionnaires	6	6.74
4.	Returned and usable questionnaires	83	93.26

Table 4: Response Rate

Source: Researcher (2022).

4.3 Preliminary Analyses Tests

4.3.1. Data Screening and Coding

The returned questionnaires were screened for incompleteness, ineligibility, missing data or multiple selection of scaled responses (Tabachnick & Fidell, 2013). The value for data screening creates the basis for the achievement of valid research results. According to Hair et al. (2010), quality of output of quantitative analysis is dependent upon the rigor and quality of preliminary data screening. The screening thus set aside 6 of the returned questionnaires as unusable. Coding of the collected screened and valid data from the 83 questionnaires followed after the screening exercise. This was done through creating a codebook containing variables and variable values and the data entry before analysis.

4.3.2. Missing Values Analysis

The phenomenon of missing values is common in social science research (Hayes, 2012). Dong & Peng (2013) identify two main reasons why missing data analysis are key before analytic procedures are undertaken on any data sets. First, some statistical packages will not work even with a single data missing. Secondly, even if a statistical data package does allow the analyst to

generate results with missing data, missing data will lead to the loss of vital information, which subsequently minimizes the statistical power and increases standard errors. Hair et al. (2010) adds that when two or more questions are not answered by one or more respondents, the data likely becomes inappropriate for subsequent analysis. For example, the data may be inappropriate for advanced statistical tests such as chi-square, regression analysis, and etc.

Three steps were taken to deal with or rather to reduce cases of missing data during this study. The researcher sent the questionnaire tool to the respondents at least one week before the actual day of data collection. This was accompanied by attachment of study information and explanation of underlying, but technical terminologies which were used in the questionnaire and study. This was meant to ensure that respondents understood not just the study but also the survey tool. Secondly, through pre-survey phone calls, the researcher explained the sections of the questionnaire and the intension of each thematic section under which questions were categorized. Lastly, the researcher did follow-ups on emailed questionnaires which had limited number of missing responses and which could be filled by the respondents and considered for analysis instead of discarding them as invalid. Based on Tabachnick & Fidell (2013) proposition, variables with missing values less than 5% were retained for analysis.

4.4. Respondents Socio-demographic Variables

A number of surveys on biotechnology (International Genetically Engineered Machine [iGEM], 2016; iGEM, 2020; International GMOs Survey, n.d.; Hart Research Associates, 2013) have shown that there is a tremendous significance in understanding the type of respondents through their socio-demographic variables before actual questions are asked to them. This study asked respondents 4 questions related to their socio-demographic information, namely gender, level of education, age, and institution of affiliation. The socio-demographic information are described below.

4.4.1. Respondents Distribution by Gender

This study targeted experts from both genders in the fields related to biotechnology and synthetic biology. The researcher tried as much as possible to find both men and women for surveys and interviews from all the population cohorts/groups of the study. The females and males reached were the highest qualified and available for the study within study time and resource limitations. Attempts were made to recruit equal number of male and female per population category. The

results show in the figure below does not emerge from any intentional discrimination at female respondents during the study whatsoever.

Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	61	73.5	73.5	73.5
	Female	22	26.5	26.5	100.0
	Total	83	100.0	100.0	

Table 5: Respondents Distribution by Gender

Source: Researcher (2022).

As shown in figure above, the study population was constituted by 22 (26.5%) females and 61 (73.5%) males. The imbalance in the number of males to females' was unintentional. By making sure that I reach an almost equal number of people of each gender, I hoped to be sure that the responses are not skewed by gender. Taking such a precaution ensured more reliable results and analysis. Moreover, for this particular study what was key was the knowledge and expertise on the subject of biotechnology and synthetic biology thus taking precautions of gender unequal participation were largely to avoid would-be cases of confounding variables. Despite attempts made by the researcher to balance between the genders may point to the lack of what can be called a critical mass of women in the field of biotechnology (and thus synthetic biology) compared to their male counterparts These findings have been corroborated by iGEM Africa's (2020) survey which found that there are a few females than male in the field of biotechnology be it in rearch, academia, or even industry. The excerpt from the FGD below reinforces this assertion.

> The government has been promising to support research and development in biotechnology. In fact, capacity building is a critical component of the Biotechnology Development Policy, 2006. One thing which has been lacking is that the government has not been asking a gender question: how many men and women should be in the field and

how can we support the few gender, which is obviously females in the R&D synthetic biology? (1st FGD, Response from a University-based academic, March, 2022 - MMUST).

4.4.2. Respondents Education Level

This study targeted mainly the experts in biotechnology and synthetic biology. As a result attempts were made to reach out to the experts across the six (6) population categories. Because in certain instances people with critical information to the study did not possess post-graduate education, these were reached and surveyed and/or interviewed. The aim was to arrive at perspectives given by the informed persons.

Figure 2: Respondents Distribution by Level of Education

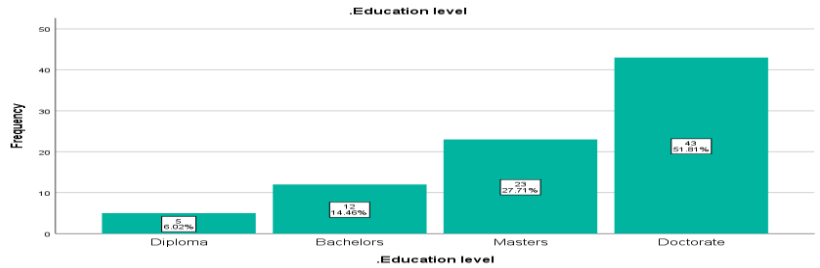


Figure 3: Respondents Distribution by Level of Education

Source: Researcher (2022).

As shown in the figure 3, education levels of respondents were as follows: doctorate or PhDs 43(51.81%), masters holders were 23 (27.71%), first degree holders were 12(14.46%) and finally the last category were diploma holders who were 5(6.02%). This implies most of the respondents who participated in the study were PhD holders who had either engaged in biotechnology research, regulation, policy making or teaching for a good number of years. Thence their perspectives on the technology could be taken as informative of the initial steps that the government of Kenya should take in order to adopt, and implement synthetic biology in the country.

4.4.3. Age of Respondents

Further, the analysis revealed that a majority 45/83(54%) of the survey respondents were aged 45 years and above. The other age categories were 18-45 (47%) and 70-100 (1%). This further reinforces the assertion already made that the selected participants for the study were those who had the needed expertise in terms of both education and years of practice[14], either as lecturers or

[14] Age was used to connote years of experience hence ability to answer to the research questions.

researchers from the government or private establishments. As this is the first study of its kind in Kenya, it was imperative that the perspectives of the respondents chosen from the six population strata be informative to give a clearer picture of the state of biotechnology regulatory environment in order to inform necessary adaptations for the regulation of SynBio.

Figure 3: Respondents Distribution by Age

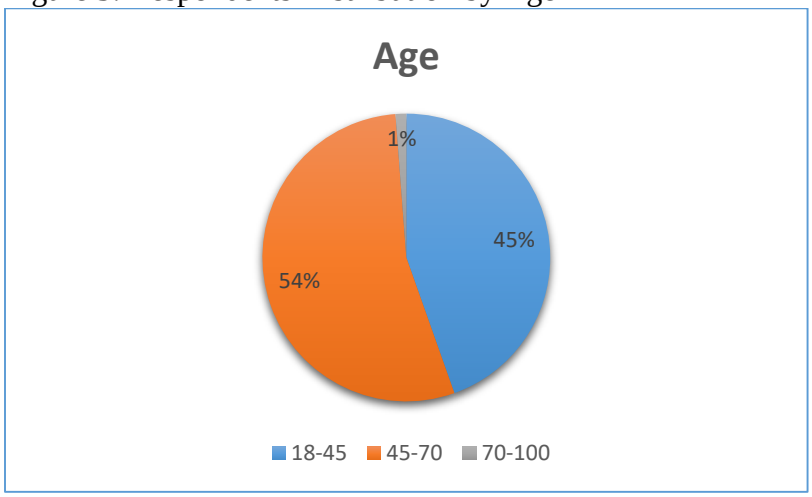


Figure 4: Respondents Distribution by Age

Source: Researcher (2022).

4.4.4. Respondents Distribution by Institutions of Affiliation

To ensure that the perspectives received during the survey and interviews were balanced and reflective of several quarters of the Kenyan experts, the study was based on responses from six categories of population. These were experts from academia which were largely senior lecturers in biotechnology and related fields which constituted 24 (2.92%); experts from both government and private research institutes who were 21(25.30%); experts from government policy, governance and regulatory bodies consisting of a total of 19(22.89%); 11 (13.25%) and 4(4.82%) were drawn from media and communications and biotechnology related industrial establishments. The media and communications persons chosen were those that have been either engaged in a preliminary unpublished survey conducted by ISAAA during the 29th of March 2021, or had reported previous synthetic biology meetings in Kenya and so they had some level of understanding on the subject at hand. Because technology communication is a critical aspect of new technology and innovations

adoption (See iGEM, 2020) involving communications, people in the study was by design since such a step has been praised as a booster to the process of not only SynBio adoption and implementation but also SynBio acceptance and uptake (*Ibid*).

Figure 4: Respondents Distribution by Affiliated Institution

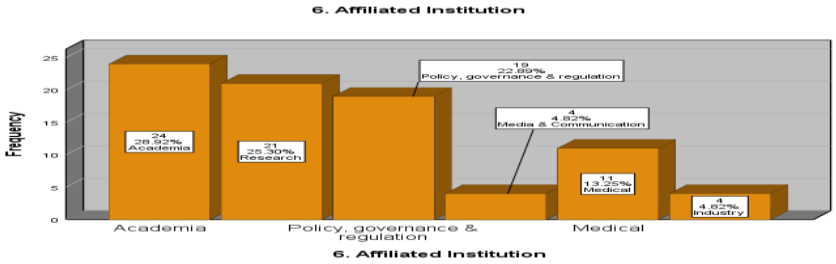


Figure 5: Respondents Distribution by Affiliated Institution

Source: Researcher (2022).

4.5. The Biotechnology Development Policy, 2006

Kenya is a State Party to the CBD, and its Cartagena, Nagoya and Kuala Lumpur Protocols. Therefore, to regulate GMOs and in the spirit of respecting her international obligations under the CBD and its protocols, the country has domesticated GMOs and biotechnology development regulating policy. The Biotechnology Development Policy (2006) is the country's main policy framework regulating biotechnology. The document was drawn with the regulation of GMOs as the primary objective. 'The immediate challenge' the policy recognizes, 'is how to boost the infrastructure, scientific and biotechnological capacity, promote entrepreneurship and facilitate effective technology transfer and product development (The Government of the Republic of Kenya, [GoK], 2006, p. 9). Long term aims were to a) 'become a key stakeholder in the international biotechnology enterprise within a decade' ; b) develop new technologies to facilitate the development of affordable drugs and vaccines and cheap, easy-to-use, low-cost diagnostics for rural clinics and hospitals to support detection and management of these diseases' (p. 8); c) to protect her over 35, 000 animal and plant species from biological diversity threat from environmental degradation (p. 8) d) 'the domestic regulations governing the importation and use of pharmaceuticals, biologicals, food and feeds, may not be adequate' hence the need to align the

policy ‘to the regulations and policies governing the importation and use of these products’ (GoK, 2006, p.10). The scope of the policy is to ‘address: traditional and modern biotechnology; genetically modified organisms that are human food and animal feeds, and pharmaceuticals. The policy covers all biotechnology applications including tissue culture and micropropagation, biopesticides and biofertilizers, bioremediation, Livestock technology, DNA Marker technology, and genetic engineering’ (*Ibid*, p. 10).

The policy document has six priority areas. First is agricultural biotechnology: where the government commits to develop ‘new plant varieties resistant to both pests and diseases, animal reproductive biotechnologies such as artificial insemination, embryo transfer, genetic improvement of local breeds, and somatic cell nuclear transfer (cloning) techniques, with special attention to the development of livestock that is resistant to diseases, have improved meat, milk or wool quality, can increase proteins in their milk or meat and new plant and animal diagnostic products, improved animal vaccines, biological pesticides, herbicides and fertilizers (p. 12). Education is the second issue area covered in the policy. The government undertakes to promote biotechnology education through curriculum mainstreaming at various levels to mainstream biotechnology education; strengthen the teaching of biosciences at the university level; develop the needed infrastructure; venture into informal public education and awareness creation, among others.

Thirdly is bio-resources where the government recognizes the critical role that biotechnology can play in biological diversity preservation and conservation. The country has over 35, 000 species which are perceived to be at threat if the current trend of environmental use and degradation are unchecked. To achieve this, the government undertakes to develop a central managed database on species in different ecosystems and the traditional knowledge associated with the species; undertake molecular characterization and prospect for novel products for the development and industrial production; accelerate the establishment of viable *in-situ* and *ex-situ* (Gene banks) conservation centres; focused exploitation of fauna, flora and microbes in marine and extreme habitats for novel genes for development of osmo-tolerant crops, enzymes, biopolymers, and marine pollution biosensors (p. 13-14).

The environmental biotechnology priorities deal with risks perspectives of biotechnology from the traditional standpoint. The policy is grounded on the precautionary approach as stated in Principle 15 of the Rio Janeiro declaration. The policy aims to prevent risks in the areas of safe transfer, handling and use of GMOs. The government also aims to tap the promises of biotechnology in the conservation of the environment and biodiversity by developing biotechnologies necessary for applications such as monitoring environmental pollution, eco-restoration, remediation of wastes, and control of biological invasions, among others. Three ways for containing biotechnology risks are highlighted in the policy, namely, risk assessment and management (RAM) wherein the government aims to mitigate potential risks associated with human health and the environment emerging from GMOs. Such RAM should be conducted in the RAM cycle which begins at the level of research to field trials to release and commercialization. RAM is based on Article 15 of the Cartagena Protocol which only considers scientifically proven potential risks as the only risks viable for RAM. The second aspect of risks is monitoring and evaluation where the government commits to put into place an inter-sectorial collaboration between M&E departments and authorities to avoid roles overlap in regards to regulating the introduction, development and use of biotechnology and its products. The M&E cycle for biotechnology is established, to begin with, monitoring and evaluating approvals, to trials & releases; to inspections; to LMO disposal; and finally to labelling in supermarkets and other outlets. The entire process is under the leadership of the National Biosafety Authority (NBA) established under the policy.

Medical Biotechnology is the fifth issue area. The aim is to harness the benefits of biotechnology in the field of health. The policy is ambitious that the revolutions in genomics such as DNA reading, writing and sequencing which have enabled the rapid development of vaccines for deadly diseases can be tapped through biotechnology. To this end, the government aims to develop medical biotechnologies to develop affordable and easily accessible tools for disease prevention, drugs and vaccines, and diagnostic tools, especially for rural clinics and hospitals to support the detection and management of these diseases. Ways to ensure this include; development of molecular diagnostics, recombinant vaccines etc.; promote basic and applied research in bioinformatics, genomics, molecular and cellular biology etc.; developing traditional medicine into more advanced industrial therapeutic products. The policy also authorizes the use of GMOs

which are health and nutrition-related, listed as vaccines, vitamins, hormones, diagnostic kits, and naked DNA (p. 18).

Under Industry and Trade - sixth and last priority area - the government aims to actualize the visions of the National Development Plan 2002-2008 regarding industry and trade. The plan aims to acquire and disseminate appropriate technology and to value addition to primary commodities (p. 18). Four action plans are listed in the policy: a) invest in initiatives that attract investment in biotechnology; promote industrial skills and development; provide a conducive investment environment for small and medium scale biotechnology enterprises; enhance quality, standardization and competitiveness of biotechnology products internationally. The proposed Biosafety Act is tasked to lay out the industrial applications of biotechnology.

To realize these action plans under each priority area, the policy makes seven recommendations with steps to take. These are, firstly, capacity building and resource mobilization through human resource development; establishment of the National Biotechnology Enterprise Programme (NBEP) to act as linkages and networking platform among public Research Institutes and Universities for optimum access and utilization of available resources. Secondly, through financial and business support where the government commits to create incentives to encourage partnerships between public research institutes and universities, and the private sector to attract private-sector investment in biotechnology-based start-up firms and direct public budgetary allocation to biotechnology research and development (p. 22). The fourth policy statement is on public protection and support where the government commits to take seriously the need to protect and support the public in an economy driven by biotechnology through observance of existing policies and regulations on intellectual proper rights (IPR), establish a Government fund to support the filing of patents from public research institutions, develop capacity for effective management of intellectual property. To protect the public from possible risks from GMOs the policy commits that any *products containing engineered genes or derived from genetically engineered organisms that are locally developed or imported must meet the requirements of the laws of Kenya governing Biosafety, Environment, Phytosanitary, Sanitary, Food and Pharmaceutical standards* (p. 23).

The policy statement are also pronounced on public access to information. The policy recommends that before any generation or development of a product of modern biotechnology there will be adequate information on the extent of modification, effect on the environment and consumer safety. Other issues the policy addresses itself include regional and global cooperation and promises that biotechnology will be developed and commercialized within the acceptable ethical practices and expectations of Kenyan societies.

Finally, the policy lays out the institutional and legal framework for the implementation of the policy. It calls for coordination among institutions concerned with food safety, phytosanitary and sanitary issues. These institutions include Science and Technology Act Cap 250; Environmental Management and Coordination Act Cap Standards Act Cap 496; Food, drugs and chemical substances Act Cap 254; Public Health Act Cap 242; Plant Protection under KEPHIS legal Notice No. 350 of 1996; Animal Diseases Act Cap 364, Public Health and Environment Management and Coordination Acts No. 8 of 1999 (National Council on Law Reporting, 2012d). Additionally, the policy establishes the NBA to act as the overall central institution for coordination and implementation as well as ensuring adherence to laws and regulations working with other relevant bodies. The functions of the NBA will include: guiding biosafety and related legal matters on biotechnology, establish linkages with institutions and Institutional Biosafety Committees (IBCs) according to the guiding principles of this policy, creating links with appropriate standards bodies, facilitating biosafety planning and articulation of policy, ensure coordination of the various sectors and harmonization of sectorial policies, and to provide technical advice to government departments and agencies (Ibid, p. 27). To spearhead the implementation of the action plans identified in the policy, the government commits to establish the National Biotechnology Council (NBC) to solve problems associated with inter-sectorial approach such as power diffusion and lack of mechanisms for coordination. The NBA was also established to serve as the biosafety reference institution and to work closely with NBC and other institutions such as the NBEP.

Gaps in the Biotechnology Development Policy, 2006

The study explored the gaps in the policy through a survey question which aimed to understand the sufficiency of the policy quantitatively. The results are summarized in the figure 5 below. 81.93% agreed that the policy need amendments to regulate SynBio, 9.64% said it cannot regulate

at all and only 8.43% thought the policy is well equipped. This confirms the findings from the analysis, and interviews. The policy thus needs to be revised along the gaps identified from the analysis and qualitative research.

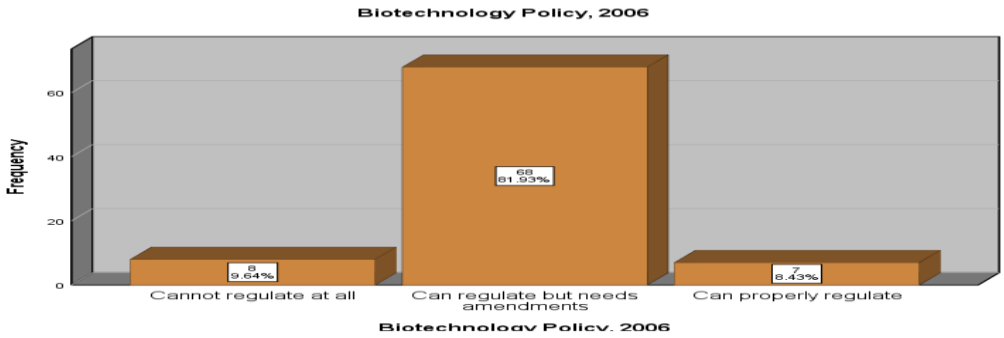


Figure 6: Sufficiency of Biotechnology Development Policy, 2009
Source: Researcher (2022).

The Biotechnology development policy is one of the greatest steps taken by Kenyan Government to bolster biotechnology and tap its benefits for national development. According to most of the experts interviewed during the study, they reiterated the findings from the documentary analysis and the survey results shown above that the policy as was drafted appears too robust, covering both aspects of traditional and modern biotechnology, and both plant, agricultural and medical biotechnology. However, in regards to Synthetic biology, the policy as it is cannot be applied to the development and regulation of synthetic biology. A TAPIC Framework reveals the following specific gaps in the policy. The analysis points to the areas where amendments will be needed.

Applying each of the TAPIC questions to the Biotechnology Development Policy 2006 reveals the state of the policy regarding the development and regulation of SynBio as follows. Concerning Transparency, the policy has not recognized anywhere the concept synthetic biology and makes no customized provisions regarding its development and regulation (Q1). It therefore charges no specific organizations, regulatory, research or otherwise with the specific tasks concerning the development and regulation of SynBio. The NBA which it establishes is constrained within the regulation of biotechnology elements covered in the policy and may only cover those aspects of SynBio which involves the modification of GMO product. The institution may only cover SynBio, especially in its advanced aspects if its mandates are expanded accordingly (Q2). Accordingly, no such rules exist in the policy as to guide the technology development phases (Q3). As appertains

to accountability, the accountability frameworks laid in the policy such as the RAM may provide a starting point for holding developers and regulators accountable, but is still deficient as this is with reference to traditional and modern biotechnology covered in the policy. Yet, certain SynBio innovations are purely synthetic products and not modifications from GMOs hence requiring their unique protocol for RAM (see SCBD, 2021) (Q4). Existing provisions can therefore only be borrowed to facilitate accountability only to the extent that SynBio products in question are made of GMO compounds. Pure/advanced products and components of SynBio may not be regulated properly under existing provisions in the policy (Q5).

The following gaps exists in regards to the TAPIC principle of participation. First, the biotechnology development and regulatory system is yet to adopt stakeholders' forum which has a regular meeting, and is an autonomous or semi-autonomous advisory forum to the government on matters of biotechnology. Such forums will bring together stakeholders from academia, industry and business, government, private sectors, and representatives from the general public such as critical religious voices. According to Trump (2017), it is such forums that have advised and propelled government R&D endeavors in Singapore, USA, and UK where SynBio development and regulation is enviable (Q6). Based on narratives of experts such participatory forum should, at least during the initial stages of adoption and implementation of SynBio in Kenya take a top-down approach where experts from academia, government, and industry play a lead role in generating the needed evidence for the development of an adaptive anticipatory governance framework. Experts also expressed that the NBC and the NBEP established under the policy are important platforms for consolidating a participatory forum for SynBio since such platforms are operational in Nigeria, and in advanced economies such as European Union and USA and have led to the successes achieved in terms of SynBio R&D and regulations thus far (Q7).

On integrity, it has no explicitly stated performance standards to guide institutions, neither does it recommend formulation of regulations which are relevant to SynBio processes regulation (Q8). Consequently, the institutions it establishes do not have as their organizational missions, stated missions concerning SynBio development and regulation (Q9). While the policy statement along the six issue domains are an important stating point to realize the principle of integrity, the policy must be amended to cover SynBio issues through setting of performance standards to specific

organizations and other actors charged with the development and regulation of SynBio. Such performance standards should enumerate expectations from such stakeholders along the regulatory issues concerned with SynBio, namely: biosafety, biosecurity, bioethical and religious concerns, biological diversity, and socio-economic concerns (10).

Finally, concerning capacity element of the TAPIC framework, the policy has had impacts. Through the policy statements committed to by the government of Kenya in the policy document, the government has funded the NRF SynBio Project (Q11). The said project has involved a partnership between government and private research institution, namely the ISAAA which is a gesture for PPP (Q12). Moreover, through the policy, study experts revealed, the government has been engaging with international funders and donors which have been responsible for the funding of past biotechnology study projects such as the Bt Maize, and Bt Cassava (KI Interview with Biotechnology Research NGO Director based in Nairobi, 2022) (Q13). The final question is explored in-depth under chapter 7 in the first thematic category. A research scientist summed the gaps in BDP as follows:

> The biotechnology development policy is one of the greatest achievement of Kenya in terms of promoting biotechnology as a component of ST&I. However, as I am informed, and based on what I know aboiut synthetic biology techniques, it is paramount to relook at this policy and put into it the different issues concerning synthetic biology such as biosecurity, ethical, social and economic fears such as fear of job loses, and the need for mainstreaming organizational mandates to ensure that loopholes will not be exploited to use the technology in bad light (KII with an Animal Genetic Engineer, Nov 2021, Kisii University).

4.6.National Food and Nutrition Security Policy

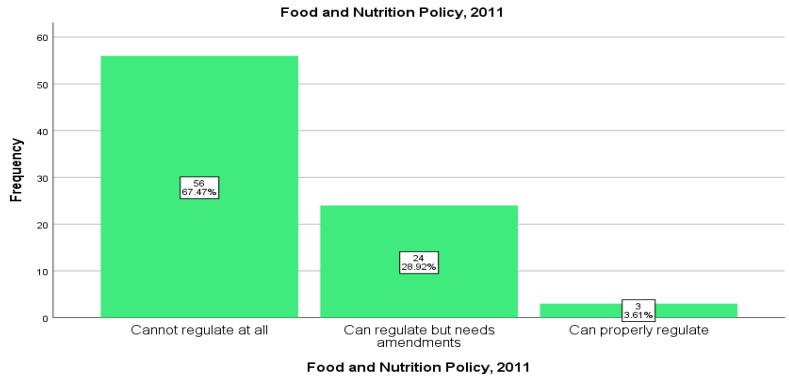
Kenya is a State Party to the Rome Declaration on Nutrition and its Framework for Action, and is bound by the WHO and FAO implementation framework of the declaration 2016-2025. The implementation framework include among other things formulation of a nutrition and food policy. The National Food and Nutrition Security Policy is one of the steps taken by Kenya to oblige to its international food and nutrition (and other related) commitments. This policy identifies food and nutrition security issues and lays out the intended measures the Government of Kenya needs

to take to ensure food and security. The policy sets up the National Food Safety Agency. It incorporates food traceability elements and international Sanitary or Phytosanitary (SPS) standards. It commits the GoK to update existing food safety regulations and Acts of Parliaments to international standards such as Hazard Analysis Critical Control Point (HACCP). The policy also establishes the Food Security and Safety Act which is envisaged to serve as the key regulating framework of national food safety issues. The Food Security and Safety Act which implements this policy was designed to be an all-encompassing Act covering the aspects previously divided across 20 Acts of Parliament and 12 regulatory bodies (Agricultural Sector Coordination Unit [ASCU], 2011, p. 24).

Gaps in the National Food and Nutrition Security Policy

Before a presentation of the gaps based on the TAPIC framework, the figure below shows the survey results from whence the study sought to understand the sufficiency of the Food and Nutrition Policy, to the development and regulation of food and nutrition application of SynBio in Kenya. As is evident in the graph below, a whole 67.47% were very pessimistic about the policy and said that it cannot facilitate the development and regulation of food and nutrition apscts of SynBio at all. About 28.92% had a more modest position when they said the policy can regulate SynBio upon amendments; only 3.61% supported the statement "can properly regulate". This survey finding reflects the general approach which has been taken by the Government of Kenya by its food and nutrition sector whereby the role biotechnology in food and nutrition has been under appreciated. This survey results reinforces study analysis of the gaps as follows.

Figure 7: Sufficiency of Food and Nutrition Policy, 2011



Source: Researcher (2022).

Bioinnovation is expected to expand into several sector of the bioeconomy including sectors such "agriculture, and food, consumer products and services" (Iyer & Bezamat, 2021). For this reason, there is need for clear policies to facilitate development and regulation of food and nutrition aspects which will "enhance value chains while offering alternatives to petro-chemically derived alternatives" (*Ibid*) and contribute to the country's food and nutrition challenges (see chapter six for in-depth discussion). Moreover, the study found that SynBio toolkits such as diagnostic kits and biosensors being constructed under the NRF for SynBio Project, will not only make agriculture a viable economic investment for rural poor smallholder farmers, the benefits accruing from such will catapult inclusive economic development and will reflect in the national economic growth. The following gaps exist in the policy.

Based on a TAPIC framework, the policy is not sufficient for the development and regulation of SynBio in Kenya. Since the policy does not make a linkage between food and nutrition and biotechnology development, the principles of adaptive anticipatory governance (or the TAPIC framework are difficult to achieve unless this policy is revised and emended in line with national priorities bioeconomy priorities through SynBio as the heart of bioinnovation and manufacturing.

Without such a linkage possible through an amendment, the policy is unable to cover the regulatory concerns pertaining to SynBio. The policy document does not cover the breadth of biosafety issues currently being discussed on SynBio regulation. For example, the National Food and Nutrition Security Policy Implementation Framework (NFNSPF) 2017-2022 sets out the risk assessment framework aimed at determining risk management priorities from 2017 to 2022 but fails to consider any risks that dual-use of biotechnology food materials may pose the successful implementation of the NFNSP. As the country moves into the era of SynBio, the policy should be realigned to make provisions on other regulatory issues such loss of jobs for those in traditional food industries upon adoption of bio-manufacturing methods enabled through SynBio; the extent to which application of SynBio to food and nutrition may present vulnerabilities to biosecurity and the possible mitigation measures put into place; potential of enhancing biological diversity and

risks to the same, and potential impacts on religious and ethical issues pertaining to food and nutrition.

The participatory platform envisioned in the policy and its latest implementing framework (NFNSPF) is both limited in scope in light the P element in the TAPIC framework. For example, the NFNSPF reiterates the policy's provision that the Stakeholders' Technical Committees for Food and Nutrition (STC-FN) is the overall platform for collaboration, coordination and cooperation on all national food and nutrition security programs. There is no provision, however, on the component of STC-FN and particularly how it will work to ensure that the academia, industry and government are brought to together to chart the course for the development and regulation of SynBio within the food and nutrition sectors. During the FGDs, a food and nutrition expert made an assertion that captures these gaps as follows:

> The sector of food and nutrition has been viewed as existing separately from biotechnology and evem other made technologies, hence lack of utility ofr ST&I in attaining the country's ambitions on the sector of food and nutrition security. Though we give credit to KALRO for woring rounf thw clock to ensure viable foods are innovated, as we move to SynBio, this disconnection must be bridged. SynBio must be part and parcel of food and nutrition policies, and institutions concerned with food and nutrition must be brought in through a policy framework to lay a role in ensuring the technology is responsibly and maximmaly used to attain food and nutrition security (3rd FGD at Nairobi – Movenpic Hotel, June 2022 – Response by a Food and Nutrition and Dietetics Expert,).

4.7.The National Environment Policy, 2013

Kenya is a State Party to the United Nations Conference on Environment and Development (UNCED) concluded in Brazil 3-14th June 1992 as well as other conferences and conventions that have followed thereafter. The UNCED forms the bedrock of to the formulation of the environment policy which was aimed at bolstering the achievement of Kenya's international environmental obligations. Environmental Conversation and Management has been a key issue in Kenya most particularly since the late 1990s. The regulatory frameworks aimed at realizing sustainable utilization of Kenya's natural environment include National Environment Policy (2012),

Environment Management and Coordination Act-EMCA (1999); Forests Act (2005); National Land Commission Act (2012) and Wildlife Conservation and Management Act (2009) and national development plans such as the Kenya vision 2030. The Constitution of Kenya 2010 is also explicit about environmental management and conservation and gives access to a healthy, clean and safe environment the status of a human right (Articles 42, 57 and 260) for both present and future generations.

The National Environment Policy, 2012 distinct itself from these other regulatory mechanisms as an overall policy, covering different aspects of the environment –"the totality of the surrounding such as plants, animals microorganisms, socio-economic and cultural factors" (Ministry of Environment, Water and Natural Resources, 2013, p. 1) – and includes tourism, land reforms, energy, human settlements, fisheries, livestock and others. The policy mainstreams previously emergent issues in environmental management such as health, gender, community-based environmental management, HIV/AIDS, and climate change.

The guiding principles to attaining the policy objectives are identified as the human right approach, environment development as a right, integrated ecosystem approach, public participation, equity, polluter pays, precautionary principle, good governance, total economic value, sustainable use and polluter pays. The policy commits the government to implement recommendations on sustainable use, conservation and management in ten areas of the environment. These include; fisheries, minerals, livestock, biological diversity, wildlife, soil, land, arid and semi-arid land (ASAL), mountains, coastal and marine ecosystems, freshwater and wetland ecosystems and forests ecosystems. The policy commits the government to adhere to the principles of community participation as an approach to realize conservation and management of these sub-systems of the environment and natural resources.

Gaps in the National Environment Policy, 2013

While the Kenya's national environment is key sector which will obviously be affected by SynBio technologies, the Policy currently regulating the sector does not make any clear linkages between biotechnology (and SynBio) and environmental management and conservation processes. Before

a discussion of the gaps as evidenced from the documentary analysis and expert opinion, survey findings that sought to explore the sufficiency of the policy quantitatively is presented as below. .

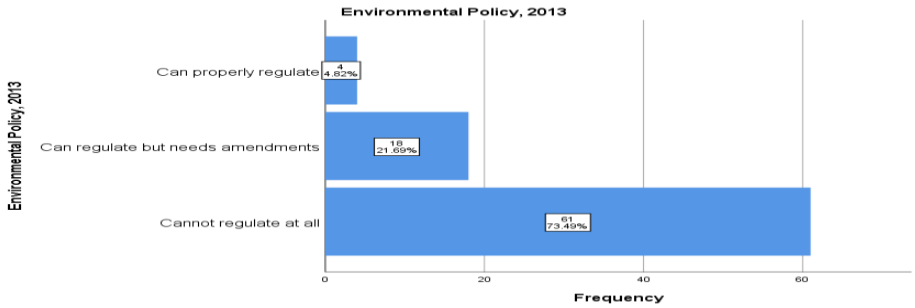


Figure 8: Sufficiency of the Agricultural Sector Extension Policy
Source: Researcher (2022).

As figure above shows, a majority, 61/83 (73.49%), rated the policy as "cannot regulate at all" 21.69% agreed it could regulate upon amendment while only 4.82% agreed that the policy can properly regulate SynBio. This points to the need for further exploration into the ways in which policy makers can make the case for SynBio technologies applications to the environmental development processes in Kenya. Experts' interviews and documentary analysis reiterated these gaps as follows.

The environment is the mother of the bioeconomy and such is a critical sector when it comes to SynBio development and regulation. This requires that environmental related policies are clear about SynBio technologies as they relate to environmental management and conservation. Along the TAPIC framework of gaps analysis, the policy has the following gaps.

The policy has no special mention of the role of biotechnology in the realization of a safe, healthy environment and as such does not set any development and regulatory scopes neither does it link and charge SynBio regulation to any particular organizations/bodies (Q1-Q4). The concept of technology is only mentioned 3 times in the entire policy document concerning; i) biodiversity concerning benefit-sharing of technology with communities where the genetic materials are obtained; ii) industrialization with reference general industrial technologies used to facilitate value addition; iii) environmental research, education and monitoring, where the value of technology and innovation in the management and conservation of the environment is appreciated. However, no policy statement commits the country to target and promote biotechnologies as a tool for

environmental management and conservation. An academic environmentalist expressed during a zoom FGD that the main challenge with the policy is its emphasis of enviromnetal protection within the older frameworks of the term when technology was not the primary driver. He asserts, thus:

> We have good policy frameworks, I must say. However, as the world advances, I mean as we move into the phase of human development when the physical, digital and biological are fused together in a single highly specialized devise and a biological socket, we must rethink how we make our policies. We must update older policies to reflect the new developments. The environment Policy should be reformulated to take cognizance of the role that SynBio can play in dealing with pollution at sea, on land and in the air. Technological aspects are missing in most of our frameworks. For environment, this gap means that actors with rights and duties cannot be held accountable for their actions. And institutions cannot take responsibility. These must be made clear (4th FGD on Zoom held in Nov 2021, Response by Environmentalists).

The table below highlights the TAPIC gaps. Capacity element is excluded because this a subject for chapter 7.

TAPIC Analysis of the Environment Policy	
Transparency	
Q1	Neither for SynBio specific guidelines nor envisages the use of SynBio or advanced biotechnology in the future of environmental management and conservation processes.
Q2	Charges no institutions with the mandates to ensure development, applications, regulation of environmental related applications of bioinnovation like SynBio.
Q3	States no rules go to abound specific actors as they attempt to develop SynBio products are they relate to the environment.
Accountability	
Q5	The country has very robust law to govern governing research processes and biotechnology development. These can be borrowed to hold actors accountable to their actions and decisions concerning SynBio technologies applications to the environment.

Q5	The policy provisions do not speculate on what should be done or not by biotechnology actors regarding environmental applications and impacts of SynBio technologies.
Participation	
Q6	The policy does not establish a stakeholder's forum that can be adapted to steer environmental issues within the possibilities of SynBio technologies.
Q7	Experts asserted that environmental scientists and political economists and other expert s should play a lead role in informing the government on possible ways of developing and regulating SynBio technologies as effective and efficient non petro-chemically approach to environmental conservation.
Integrity	
Q8	The policy thus does not set clear performance standards that should guide institutions charged with developing and regulating SynBio technologies as it relates to the natural environment
Q9	There are no clearly stated organizational missions that are aimed at achieving sustainable efficient environmental management and conservation through the use of SynBio technologies.

Table 6: TAPIC Analysis of the Environment Policy

Source: Researcher (2022).

4.8.National Policy Framework on Science, Technology and Innovation

The National Policy Framework on Science Technology and Innovation, 2012, aims to provide an impetus to the Kenya Vision 2030 by mainstreaming research and development (R&D) into the Vision. It recognizes that science technology and innovation (ST&I) in Kenya is underdeveloped and globally uncompetitive due to lack of a systematic approach to its development and utility as an enabler to national development (Ministry of Higher Education, Science and Technology, 2012).

The policy identifies 5 ST&I priority areas namely: biotechnology; space science; telecommunications, electronics and computers; and automobile and nuclear electricity (*Ibid*, p. vi). The policy aims to re-innovate the Kenya National Innovation System (KNIS) which should serve as the platform that ensures that the academia, industry and research sectors within

government and private are harnessed for the development of ST&I products that solve Kenya's problems. It established three institutions, the national commission on ST&I (NACOSTI) to set priorities and coordinate ST&I issues, the National Research Fund (NRF) to mobilize resources for the development of ST&I and the Kenya National Innovation Agency (KENIA) tasked to develop and manage the national innovation system. The policy also establishes the Centres of Excellence (COE) at the county, national, or international institutions. The COE are tasked to carry out research science technology and innovation work under the COE program (COEP) on areas of ST&I national priorities identified by the three core institutions.

The strategies and action plans envisaged in the ST&I policy are enumerated in Chapter Four of the policy document. The policy areas are listed in 5 categories including (p. 20-24):

> government through relevant institutions will leverage ST&I to transform the economy through identified national priority areas including telecommunications, electronics and computers technologies, software development technologies, automobile manufacturing technologies, satellite and space manufacturing technologies, renewable and green energy manufacturing technologies, food and nutritional security manufacturing technologies, nuclear energy technologies; the government will allocate 1% of GDP annually for the R&D sub-sector and motivate other stakeholders to participate in funding ST&I; government in collaboration with relevant stakeholders will identify, nurture, recognize and protect intellectual property rights of scientists, researchers and innovators; establish and promote ST&I knowledge sharing and awareness creation systems.

Gaps in the National Policy Framework on Science Technology and Innovation, 2012

Other than the Biotechnology Development Policy 2006, the ST&I policy 2012 is perhaps the next most important policy in regards to biotechnology, and thus SynBio development and regulation. In light of biotechnology, or SynBio more particularly, the following TAPIC gaps were identified from the documentary analysis and expert interviews conducted.

Firstly, the policy has no special focus on biotechnology and the value it adds to and ST&I driven economy. The concept of biotechnology is only mentioned twice in the entire policy document in the introduction section (p. vi) and not anywhere else. Moreover, of the 5 policies and 53 strategies

enumerated in the document, none makes direct reference to bio-innovations. Based on these, transparency questions are not clear from the ST&I policy because i) it outlines no scope for biotechnology (and SynBio) development and regulation; ii) it does charge any particular institutions with the task of biotechnology development and regulation by speculating policy statements that should inform formulation of legislations in that regard; iii) and finally, the policy does not spell out the rules to govern the development stages of biotechnology products.

Secondly, the fact that the policy only mentions biotechnology and makes no further pronouncements about it as an aspect of ST&I, including future expectations of advancements in biotechnology, consequently complicates the possibilities for realizing the principles of accountability, participation, and integrity. The policy therefore lacks in content are regards to the specific development and regulatory issues[15] that come to question when it comes to SynBio.

During the FGDs, an expert corobated these revelations on gaps of the ST&I policy by emphatically arguing that the task for Kenya is to ensure policking about ST&I is turned into action to ensure human security and ulock Kenya's potentials as a technology powerhouse. He contends, thus:

> ST&I is a key enabler of development. In developed countries it is seen as the fulcrum of all development in every sector. In developing it is the opposite. Politicians only mention it to woe the voters, especially the youths. We must move from word to action. We must begin to ask the question: SynBio will be soo here, how can Kenya tap on these potentials (while minimizing its risks) to promote related fields of academic specialization, and ensure that the technology is used at the industrial level to ensure food security, health security, cultural security and all forms of secruty. Only then can Kenya draw closer to her intensions for a technology leader within Africa and beyond (1ST FGD, Response from a Biotech Industry Expert).

[15] These ideally include biosafety, biosecurity, bioethical and religious issues, biological diversity, and socio-economic concerns. Since the policy does not pronounce itself on these matters, as the central ST&I policy, it may need to be modified to embed SynBio provisions.

4.9. The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009

This is another key policy document in regards to biotechnology (and now SynBio) development and regulation issues. Its formulation by the Government of Kenya is both a gesture to the international community as a country that respects her international commitments as well as an attempt at ensuring that genetic resources, traditional cultural expressions, and traditional knowledge are respected even as modern biotechnology advances in Kenya.

Kenya is a State Party to the CBD and its three key protocols. As a state party, Kenya is obliged under the CBD, Article 15, to put in place regulatory measures including legislation and policies to ensure access to genetic resources (GR) but also fair sharing of GR arising from their exploitation. Article 10(c) of the CBD particularly commits contracting states *to protect and encourage customary use of the traditional knowledge* on genetic resources. The relationship between the concept of traditional knowledge and associated GR is explicitly acknowledged in the CBD's Article 8(j) which calls on contracting states to

> "…subject to its national legislation, (to) respect, preserve and maintain knowledge, innovations and practices of …local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

The Nagoya Protocol to the CBD lays out the particulars for ensuring that benefits arising from the exploitation of GR are equitably shared, including with local communities. Cartagena Protocol delves into biosafety issues and spells the obligations for users, producers and other parties in the economics of living modified organisms (LMO) and related GR. The challenges necessitating the formulation of the policy are listed as;

> lack of recognition and mainstreaming of traditional knowledge, genetic resources and traditional cultural expressions into national policies and decision-making processes; lack of comprehensive traditional knowledge, genetic resources and traditional cultural expressions database; high cost of collation and documentation of traditional knowledge,

genetic resources and traditional cultural expressions; weak community institutional linkages; inadequate capacities; intellectual property rights (GoK, 2009, p. 6).

The policy states five (5) objectives, thus (p. 7):

> provide a legal and institutional framework to support the integration of various aspects of traditional knowledge, genetic resources and traditional cultural expressions in national development planning and decision-making processes; promote the preservation, protection and development of traditional knowledge, genetic resources and traditional cultural expressions for multiple applications and use; promote and foster the documentation, use and dissemination of traditional knowledge, genetic resources and traditional cultural expressions with mechanisms to acknowledge, protect and benefit the sources and/or custodians; promote the protection of traditional knowledge associated with conservation and sustainable use of biological diversity and equitable sharing of accrued benefits; enhance collaboration and partnership in the generation, access to and utilization of traditional knowledge, genetic resources and traditional cultural expressions.

Gaps in the National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009

The policy was drawn in the pre-CoK, 2010 and thus is deficient of the devolve opportunities, such as administrative structure, that can be harnessed to promote the use of TK and TCEs associated with GR to develop SynBio innovations domestically. Secondly, the policy does not preempt utilization of genetic materials[16] or genetic resources[17] using more advanced biotechnologies such as SynBio. For this reason, biosafety, as well as biosecurity measures necessary for mitigating potential dangers of SynBio, are not preempted, neither are the programs to bolster utility of SynBio in transforming traditional knowledge and existing GR into industrial products are not thought or put into place. Moreover, the policy does not emphasize the risks management aspects of the interaction between TK, GR, TCE and IPR. For example, biosafety is only mentioned once in the entire policy while biosecurity is not mentioned at all. This is despite wide acknowledgement in the literature that SynBio technologies would have impacts on traditional beliefs and practices

[16] 'Any material of plant, animal, microbial or other origin containing functional units o heredity' (GoK, 2009).
[17] 'Genetic material of actual or potential value' (Ibid).

including on traditional economic practices (See Trump, 2017; UK Parliamentary Office for Science and Technology, 2015; Keiper & Atanassova, 2018; Reagan et al., 2022).

Thirdly, the policy's reference to Bonn Guidelines, Akwe-kon Guidelines, the CBD, Cartagena Protocol, Nagoya Protocol on Access Benefits Sharing (ABS) procedures and the International Treaty on Plant Genetic Resources for Food and Agriculture, the Global Plan of Action on animal genetic resources, have all been said (82nd CBD Technical Series on SynBio) to be inadequate to regulate SynBio sufficiently, hence the framework needs to be recast in order to cover the new debates about GR, PCE and TGK under SynBio debates. For example, concerns that SynBio products and components portend biosecurity threats have called upon national governments to reassess their policies and laws within the framework of Biological Weapons Convention and other relevant conventions within UN system in order to domesticate relevant biosecurity policies and laws.

Fourthly, concerning community settings, the policy does not propose or commit the government to establish community-based biosafety or biosecurity hubs for a) dealing with potential risks that may emerge as a result of the exploitation of TK and TCE associated with GR, b) that may serve as research hubs for SynBio, confining indigenous innovations[18] with closed set-ups that can reduce the risks related to Do-it-Yourself Biology (DITYB).

Lastly, community approaches to the protection of TK and associated GR are not elaborated. Although the policy document mentions that part of possible community approaches, that is, the utility models[19] can be derived from existing law such as the Industrial Property Act, 2001, no policy statement elaborates or aims at building communities capacity to protect their TK and associated GR. Moreover, Otswong'o (2011) has elaborated several intellectual property models (IPM) and non-intellectual property models (NIPM) that communities in Kenya can explore to protect their own TK and associated GR[20] from unprotected research or other forms of external

[18] According to the GoK (2009) this means ''any generation of new or improvement methods of using traditional knowledge''
[19] 'Utility models (UM) are petty patents that protect invention that are relatively obvious to people in the art. UMs are also granted at KIPI under the same Act of Parliament except that the knowledge may lack or consist of a less detail inventive step' (Otswong'o, 2011).
[20] IPM include: patents and utility models, plant breeders rights, trade secrets, trademarks and collective marks, industrial designs and copyrights are related rights. The MIPM include; TK Community registries, publications in journals as Prior Art, TK

exploitations of the GR. With these gaps, the policy is likely unable to facilitate the development of SynBio and ensure that is done in an environment that is prepared to counter its areas of potential risks. This means that the TAPIC principles are lacking in the policy, in as much as the development and regulation of SynBio is concerned. An expert argued in corroboration of these findings as follows:

> How exactly will SynBio capacities to utilize revered crops, and animals and other traditional artefacts be regulated? Are we aware of the extent of disruption of the ways of life of a cultures it will? While technology cannot be stoped in terms of its adoptions, we must be very vigilante how to mitigate these, especially as they remain a gap in the current National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009 (KII Interview with an Expert in African TRanditional Medicine).

The figure 8 below shows the survey rating of the sufficiency of the policy and reinforces the conclusion that the policy needs amendment in order to properly facilitate development and regulation of SynBio technologies within Kenyan communities. Majority of the expert sample 56.63% agreed it will be better if it is amended, 36.14% thought it cannot regulate at all and about 7% agreed it sufficient to regulate SynBio technologies.

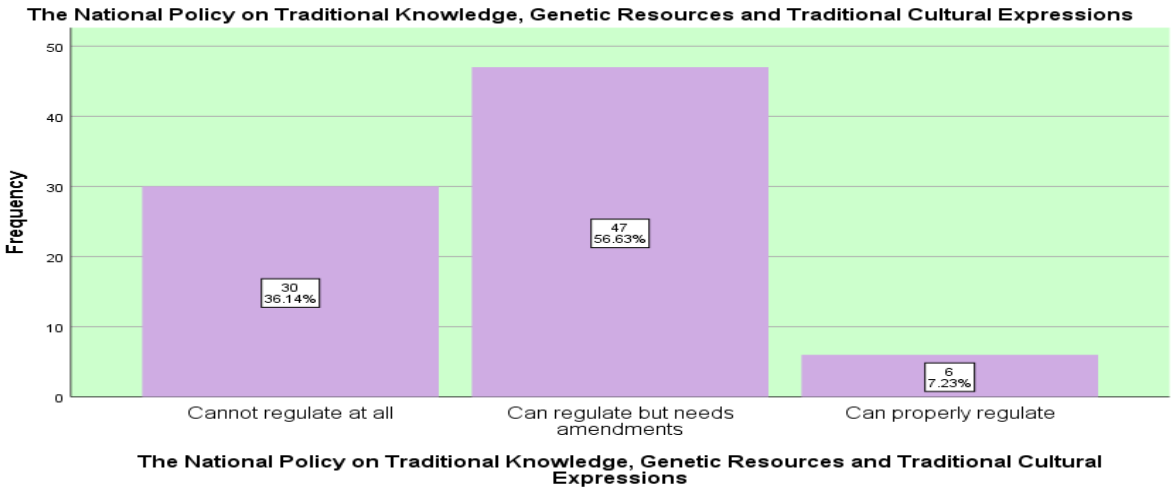


Figure 9: Sufficiency of National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009

documentation, using customary laws as protective mechanisms, Contractual Agreements, NEMA Access Permit, Access Permit and Licenses, invoking relevant policies to protect their TK and associated GR.

Source: Researcher (2022).

4.10. National Policy on Culture and National Heritage, 2009

The turn to inclusivism[21] as a panacea to sustainable development has bred the consideration that global and national progress is only sustainable when the human race and the problems they face are seen as happening across several cultures, national contexts, civilizations, population groupings and so on; so to sustainably get people out of poverty actors must ensure that the development process is inclusive of the many cadres of the human race. Global Development Blueprints such as Millennium Development Goals (MDGs) and Sustainable Development Goals (SDGs) (United Nations, 2015) have taken this notion to the next level by underscoring the transformative value of cultural inclusion and have set global targets for cultural development, as an aspect for human development (UNDP, 1994). While this is not new because cultural rights have been in existence, at a global scale, since 1948 when the United Nations Declaration on Human Rights (UDHR) was launched, it only recently that most states have put forth policies to safeguard against cultural discrimination and erosion of national cultures and heritages- particularly in the context of colonialism, neocolonialism, and so-called modernization.

Kenya's National Policy on Culture and National Heritage was formulated against this backdrop. The policy adopts the United Nations Educational, Social and Cultural Organization (UNESCO) definition of culture:

> "That whole complex of distinctive, spiritual, material, intellectual and emotional features characterizing a society or social group. This definition encompasses, in addition to art and literature, lifestyles, ways of living together, value accepted systems, traditions and beliefs" (UNESCO, 2001).

National heritage on the other hand is considered as; *the total of all the creativity in all its forms preserved, enhanced and handed over to future generations as a record of human experience and aspirations* (Ministry of State for National Heritage and Culture, 2009, p. 10). The policy aims at *creating the benchmark necessary for mainstreaming culture and heritage and setting standards*

[21] The set of ideas, beliefs and norms that have led to the notion that sustainable development cannot be achieved without inclusion of all categories of population, particularly those, hitherto, sidelined in mainstream development programmes.

as well as raising awareness and the capacity building necessary for infusing culture and heritage as integral parts of public policy and development plans (Ibid, p. 12). The policy statements and strategies aim to establish a systematic linkage between culture, heritage and sustainable development; cultural, heritage and economic development; culture and environment; culture and democracy; and culture and information and technology transfer. Elements of culture are also laid out and with policy statements on strategies to be pursued; including national dress, craft, visual art, health and medicine, food and drinks, historical sites, physical environment and monuments among others.

Gaps in the National Policy on Culture and Heritage

Firstly, the policy does not preempt the impacts of emerging technologies on cultural development and preservation. Although it speaks about the need to assess the impacts of information and technology transfer with regards to national development, there is no policy statement explicit on safeguards that would protect the Kenyan culture and heritage against adverse potential socio-cultural effects upon adoption and implementation of emerging and disruptive technologies such as SynBio.

For example, scientists interviewed project that in the next few years, there will not be need for livestock keeping because through SynBio, more nutritious and cheaper meat, completely synthetic, will be in the market produced through SynBio tools. If this happens in Kenya for example, cultural questions would emerge very strongly. For example, the nomadic pastoralists, such as the Turkanas, the Samburus, and other communities in Kenya, are traditionally livestock keepers and depend on the livestock for food and income to meet other needs. The level of socio-cultural and economic impacts that technology would have on such communities cannot be gainsaid. This is why the policy should cover, systematically, the impacts of SynBio so that programs of mitigation of such socio-cultural issues are planned. This would form a critical aspect of the anticipatory adaptive governance framework I argued in the theoretical framework of this study.

Thirdly, SynBio innovations can produce SynBio foods (such as golden rice), SynBio medicine (such as artemisinin), SynBio clothing through the production of SynBio cloth materials such as

SynBio wool, animals with edited genomes/and or DNA; all these will have impacts on the cultural setup of concerned Kenyan communities; the policy should be made clear on the particular remedies to affected communities and cultures that will be taken is the technology is adopted.

The survey (see figure 9) confirmed the need to revise the policy with 34.94% agreeing that it can regulate SynBio when it is amended, only 3.61% said it is properly equipped as it and 61.51% said it cannot regulate at all as it stands today, further reiterating the need to amend the policy accordingly. These gaps which emanate from the simple fact that the policy does not make the linkage between biotechnology and SynBio to national cultural heritage, implies that the policy cannot ensure an adaptive anticipatory governance framework and thus transform the country into a science superpower in the region.

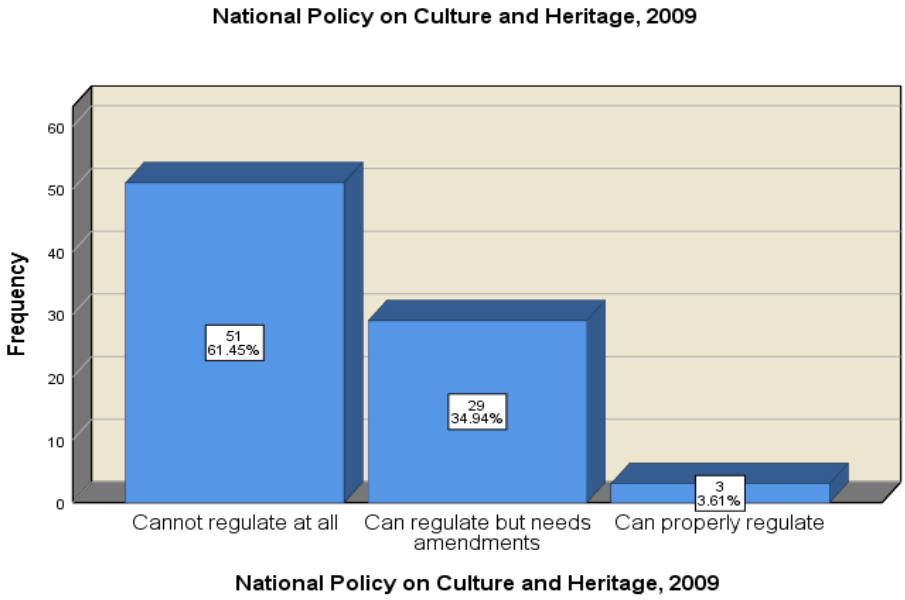


Figure 10: Sufficiency of National Policy on Culture and Heritage, 2009
Source: Researcher (2022).

4.11. Chapter Conclusions

In conclusion, this chapter presented the findings on the study objective one (1). The findings were heavily grounded on documentary analysis of 6 policy documents that are concerned with the development and regulation of Kenya's biotechnology and bioeconomy. This was corroborated with survey and interview results. The following conclusions can be made based on the findings and discussions made in the chapter.

Firstly, the biotechnology policy is the central policy governing the development and regulation of biotechnology in Kenya. It is at the same time, the immediate policy that will come into question when SynBio technologies and adopted and implemented in Kenya. For this reasons, the policy should be amended to capture the TAPIC elements of an effective emerging technology governance model. The policy should also be amended to cover the regulatory questions that SynBio is concerned with, such as biosecurity, socio-economic, bioethical and religious impacts, biodiversity and biosafety. While the policy makes provisions for biosafety and establishes the NBA, there remains need to ensure that these protocols are properly equipped to cover the magnitude of biosafety issues that come to question with SynBio. The NBA, and all other bodies established by the policy or linked to its work have no explicitly stated missions to promote the development and regulation of SynBio. Such an environment, is not suitable for attaining the TAPIC principles of an adaptive anticipatory governance. Otherwise the other four regulatory issues are currently not covered in the policy, and the onus lies with regulators and policy makers to ensure these aspects are explored and policy directions embedded in the policy for development and effective regulation of SynBio technologies.

The ST&I Framework Policy will also be a key policy in the development and regulation of SynBio in Kenya. The policy provides the general rationale for ST&I and necessitates the government to invest in and promote emerging and useful ST&I component to the national development. However, this policy is too general and while it enumerates biotechnology as part of the ST&Is it aims to prioritize, it does not provide the necessary justification for modern biotechnology and Synthetic biology, in particular. Like the Biotechnology Development Policy (BDP) it lays no specific development or regulatory foundations for SynBio technologies. As such, SynBio, TAPIC principles and the regulatory concerns of SynBio, its components and products should be mainstreamed in the amended version of the ST&I policy to position it as a guide for not just ST&I generically, but also SynBio in its developmental and regulatory manifestations.

The Food and Nutrition Security Policy, the National Environment Policy, National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, the National Policy on Culture and National Heritage are also important policies that will determine whether SynBio development and regulation in Kenya will be successful or not. However, these policies

are not clear on the role that biotechnology should play in the concerned sectors and consequently do not lay the regulatory frameworks for biotechnology. As Kenya moves in the era of SynBio technologies, SynBio should be mainstreamed into each of these policies with emphasis on bridging the TAPIC gaps, and providing guidelines for mitigating the regulatory issues concerned with SynBio.

CHAPTER FIVE

AN EXPLORATION OF KENYA'S BIOTECHNLOGY-RELATED LEGISLATIONS FOR ADOPTION AND IMPLEMENTATION OF SYNTHETIC BIOLOGY

5.1. Chapter Overview

This chapter presents the findings and discussions from the second objective of the study. Based largely on documentary analysis of 8 key legislations and interviews but also limited survey, the chapter explored the question; to what extent can Kenya's biotechnology legislations regulate the adoption and implementation of SynBio? The gaps were identified based on the TAPIC framework of analysis.

5.2. **Overall Robustness of the Biotechnology-related Legislations**

To understand the sufficiency of the current biotechnology legislation system[22], the study asked a general question. The researcher asked respondents to comment whether existing biotechnology and related legislations are sufficient to regulate SynBio technologies in Kenya. As the survey results show (figure 10) about 45% of the respondents had a fair opinion about the overall sufficiency of the current biotechnology legislations; about 29% had a favorable opinion while about 27% of the respondents expressed an unfavorable opinion on the sufficiency of current biotechnology and related legislations.

These results imply that overall, the legislations guiding biotechnology development and regulation and regulation are only fairly sufficient to facilitate the development and regulation of SynBio technologies. Work therefore still remains in order to ensure these legislations are revised accordingly to facilitate the adoption and implementation of SynBio within an adaptive anticipatory governance environment.

[22] The legislation system in this study refers to the all the (the seven selected) concerned biotechnology legislations and the programs implemented based on their provisions.

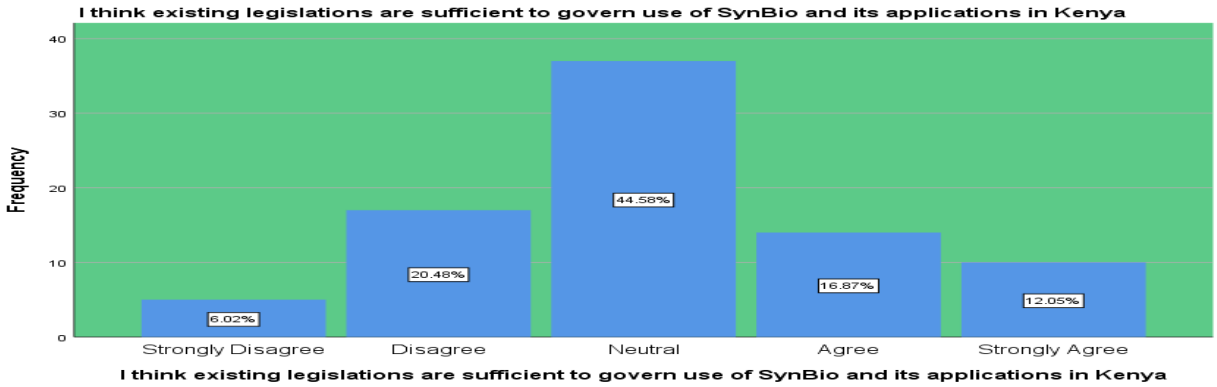


Figure 11: Overall Sufficiency of Biotechnology-related Legislations in Kenya
Source: Researcher (2022).

To understand the provisions of each of these legislations, and the gaps therein, the study analyzed 8 legislations. The findings are presented below. The analysis of the Constitution of Kenya, which is the supreme legislation sets the stage by pointing to the Government of Kenya's commitments to adhere to her obligations under the CBD framework. This is then followed with analysis of specific legislations.

5.3. The Constitution of Kenya 2010

The Constitution of Kenya [CoK, 2010] is the *supreme* law of the country (Article 2). As such any law and act that is inconsistent with its provisions is declared *void* and *invalid* respectively (Article 4). International law is considered part and parcel of Kenyan law and complementary to the Constitution through direct incorporation (Shelton, 2011 for the elaboration of this concept; see also Articles, 5 & 6 of the Constitution). The people of Kenya are the immediate and ultimate subjects of the constitution and their rights and duties as citizens are elaborated through the constitution (National Council on Law Reporting, 2010).

The CoK, 2010 is thus the basis for all development endeavors in Kenya. In light of the scope of this study, the following articles of the CoK, 2010 are key to understanding the basis for the adoption and implementation of novel emergent and disruptive technologies in Kenya, such as those of the magnitude of SynBio ((National Council on Law Reporting, 2010).

Debates surrounding SynBio have been discussed under the biological diversity of CBD's frameworks[23]. Articles 69 & 70 of the CoK, 2010 embed the obligations from such global institutions as part of Kenyan law and makes necessary recommendations for the formulation of environmental management law. Article 69 lays out the state obligations in respect of the environment; Article 70 adopts a human rights approach to environmental issues and lays forth the rights and duties of citizens and other concerned entities. Article 71 provides the grounds on which agreements leading to the exploitation of natural resources can be valid. Article 72 burdens the Parliament with the duty to enact relevant legislation to implement the provisions of these Articles (National Council on Law Reporting, 2010).

The CoK (2010) therefore, envisions the application of sustainable technologies and innovations for the conservation and management of the environment and natural resources. For example, Article 69(a) provides that the State shall *ensure sustainable exploitation, utilization, management and conservation of the environment and natural resources, and ensure the equitable sharing of the accruing benefits*. Through SynBio innovations such as those that produce, SynBio medicine e.g., Artemisinin, constructed through the SynBio of the genomes of the plant Artemisia growing naturally in Kenya, Gambia, Senegal and Tanzania (Akpoviri, 2018), can as well be an avenue for preserving this plant from extinction.

Moreover, with a proper and updated regulatory environment (as called for in CoK, 2010, Article 72) in place, the government can ensure a domestic approach to SynBio innovations development and regulation where appropriate structures are put into place to provide needed incentives and disincentives to researchers in Kenya to conduct laboratory experiments for production of SynBio products and systems. Benefits emerging from such locally-driven development and regulation of SynBio technologies can lead to increased environmental friendly industrialization and increased agricultural production and food security, and improved health systems (UK Parliamentary Office of Science and Technology, 2015; SBLC, 2016; 2021). These developments will therefore speed achievement of Kenya's Vision 2030. With surplus production of high-value SynBio products,

[23] These include CBD protocols and specialized fora such as the COPS, MOPS, AHTEG, and CBD Technical Series on Synthetic Biology and so on.

export to other countries will possible hence Kenya will position itself as a regional power, due to her improved national science capabilities enabled by SynBio.

The CoK (2010) thus provides the needed basic justification for adoption and implementation of SynBio in Kenya and its proper regulation. As argues one expert:

> The Constitution of Kenya has the basic rationale for the utility of modern biotechnology and Synthetic biology in Kenya. I think Articles 69, 70, 71, and 72 of the Constitution can be interpreted as not only allowing adoption of beneficial technologies in Kenya, it also encourages such innovations to take place from within Kenya rather than importing them. More importantly, the Constitution provides that appropriate regulation must be put in place to ensure that any technologies do not impact negatively on Kenyans and their environments (Excerpt from 4th FGD).

5.4. Biosafety Act, 2009

The Biosafety Act, Number 2 of 2009 was enacted in 2009 to implement the Biotechnology Development Policy. The Act is meant to *facilitate biotechnology research and protect humans and the environment from adverse effects of products of biotechnology* (PELUM, 2015). The Act gives the NBA the power to authorize the use and introduction of GMOs and prohibit any such activities by persons or groups without such authorization (The National Law Reporting Commission, 2009, Sections 18-22).

The Act lays out the process of authorization of persons who wish to work with or introduce GMOs in Kenya: a) the person should apply to the NBA; the NBA informs the public via two national newspapers; c) the public is given 30 days to respond by submitting their views within 30days from the date of posting the application; d) if the application is validated, NBA should conduct a risk assessment or audit the risk assessment that the applicant submitted to it (Section 27). The Act gives a latitude for the participation of other departments such as Department of Veterinary Services concerned with GMO animals, the Department of Public Health concerned with GMO foods as well as the Kenya Plant Health Inspectorate Service (KEPHIS) concerned with GMO plants. In section 28, the NBA is given the power to skip the risk assessment stage in a case where

it believes that there exists a shred of vast evidence to prove that the GMO to be introduced or used is safe (National Council on Law Reporting, 2010).

Gaps in the Biosafety Act, No. 2 of 2009

The Biosafety Act is a key legislation when it comes to the regulation of biotechnology is Kenya. It sets out the institutional frameworks needed to facilitate biotechnology development in Kenya and has the guidelines which spell the dos and don'ts in the biotechnology sector. The following gaps were identified from the analysis and expert interviews as it relates to regulating SynBio technologies in Kenya.

To begin with, the manner in which the Biosafety Act has implemented issues highlighted in the Biotechnology Development Policy, 2006 appears that it is limited to the regulation of GMOs/LMOs, i.e., it only covers plant and agricultural biotechnology. As such, as seen from the perspective of discussions in the section on global regulatory framework, the Act excludes those SynBio applications which are not based on a modification of LMOs that is advanced SynBio products and components. This therefore implies that TAPIC concepts, especially transparency, accountability and integrity are not possible to achieve under the current landscape of the biosafety Act.

Experts expressed for example, that while the Act has regulated plant biotechnology with some success, it would be difficult to apply it to issues concerning human health and enhancement, as well as well on other products of SynBio which are not compounds of GMOs. Reasons for this included concerns that human health and enhancement applications beg more ethical questions that will need to be captured very categorically in the Act through specific guidelines. Moreover, concerns were also raised that the current health policy and Act do not provide for clear guidelines for production of biotechnology health equipment, yet the country continues to import such products as Artemisinin which are examples of SynBio products. These complications further make the Biosafety Act insufficient to regulate non-plant health applications of SynBio and thus warrant it as a candidate for amendment within the TAPIC framework in order to establish an adaptive and anticipatory governance framework for SynBio in Kenya.

Secondly, the Act does not set a clear guide on public participation in the processes of validating an application of the use of, or introduction of a GMO. Even if the 30 days' notice is enough for GMOs, it cannot be enough for SynBio. As studies have shown in the USA (Hart Research Institute, 2010; 2013) SynBio still faces a serious lack of public awareness. This calls for more time, to not only enable the public to give their views on the possible risks of a proposed SynBio application but should also give space for public education so that they can give informed perspectives. One expert quite captured the need for public awareness during expert key informant interviews, thus:

> You cannot blame the public for not being aware. In fact in most of the biotechnology acts, one responsibility of actors is to ensure that the public understands all those things. But I have never seen even a campaign brought by the NBA educating the public on the basics of biotechnology and the differences between organic and genetically modified foods, this is worse situation with even a more advanced technology, Synthetic biology (KI Interview with Senior Lecturer in Biochemistry).

This therefore poke holes on the extent to which the bottom-up participatory framework laid out in Act will ensure proper public participation as a critical element of an adaptive anticipatory governance for SynBio. Moreover, the top-down participation framework is also unclear. The Act does not pronounce itself on the significance of a consortium of experts from academia, industry, government and private sectors that will act as independent body generating evidence and advising government and its stakeholders on appropriate ways for development and continued adaptation of the regulatory frameworks as SynBio innovations progress.

Thirdly, the Act's provision on risk assessment waiver in section 28 may be a loophole for exploitation particularly if there are no other controls on the NBA. This may be a more serious issue in the case of SynBio where potential risks are still very uncertain and public assessment capacities are null and void. In this regard, the Act needs necessary amendments for its risk assessment framework to be in light with regulatory discussions that have been raised at the global, regional and national scale concerning SynBio (Keiper & Atanassova, 2018).

The NBA as a regulatory institution whose legal establishment is based on the Biosafety Act is a central contribution of the Act whose robustness in terms of its mandate would have a great impact

on how SynBio biology technologies are developed and regulated in the country. The NBA's work therefore begs capacity questions of the TAPIC framework. The subject of capacity of as enshrined in the Biosafety Act is discussed in detail in chapter seven (objective four) where the NBA's mandate is juxtaposed and scrutinized alongside with its actual operations based on experts experiences.

5.5. The Science Technology and Innovation (ST&I) Act 2013

The Science, Technology and Innovation Act 2013 is the legislation enacted to implement the national commitments under the Science, Technology and Innovation Policy 2013. The Act establishes the NACOSTI, the Advisory Research Committees (ARC); the National Research Fund (NRF), and the Kenya National Innovation Agency (KENIA), all of which should play interdependent roles in the development and promotion of research and ST&I. NACOSTI is the overall ST&I institution and is charged to *regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto* (National Commission on Law Reporting, 2013b, Section 4). The NACOSTI is tasked with functions including:

> develop, in consultation with stakeholders, the priorities in scientific, technological and innovation activities in Kenya in relation to the economic and social policies of the Government, and the country's international commitments; lead inter-agency efforts to implement sound policies and budgets, working in collaboration with the county governments, and organizations involved in science and technology and innovation within Kenya and outside Kenya; advise the national and county governments on the science, technology and innovation policy, including general planning and assessment of the necessary financial resources; assure relevance and quality of science, technology and innovation programs in research institutes; advise on science education and innovation at both basic and advanced levels; in consultation with the National Research Fund Trustees, sponsor national scientific and academic conferences it considers appropriate; advise the Government on policies and any issue relating to scientific research systems; promote increased awareness, knowledge and information of research system (National Commission on Law Reporting, 2013b, Section 6).

The Act also lays out the process for licensing research in Kenya (Sections 12-15). It spells out the requirements to be met before research is licensed; the procedures, standards, ethics and guidelines for the conduct of research and research offences.

Gaps in the ST&I Act 2013

The ST&I Act is an important legislation that can be used to regulate and to promote SynBio adoption, implementation and development in the country. The institutions it envisages, and the research processes it establishes are key to promote SynBio adoption, implementation and development in Kenya. However, the following gaps still exist in the ST&I Act.

Firstly, the Act is too general; its coverage of ST&I issues and lack focus on ethics, standards, guidelines which target SynBio. Moreover, the biosafety law that it envisions to guide biotechnology-related research is deficient along the lines already identified, to deal with all risks issues particular to SynBio in the face state practices across the world (Trump, 2017). Without such an intentional focus on biotechnology, and SynBio, the Act therefore do not provide for guidelines that may be used to for the development and regulation of SynBio within a TAPIC environment.

Secondly, the Act does not lay out the participatory avenues that the government, industry and academia can cooperatively exploit to advance an emerging technologies (such as SynBio) agenda. Trump (2017) has shown that such cooperation is very necessary particularly for the governance of emerging technologies as it provides the necessary feedback that serves at least three important communication feedbacks necessary for policymakers and regulatory decision-makers: *(i) realistic risk and benefit outcomes posed by emerging sciences, (ii) societal perception and response to such sciences, and (iii) aligning incentives and research goals for developers moving forward concerning various areas of hazard, exposure, and consequence measurement for health risk (p. 1143).* From expert interviews, experts said that the ST&I institutions, such as the KENIA, have not had any focus for biotechnology and therefore making them unable to facilitate the development and regulation of SynBio which is more advanced.

> Because of the lack of focus on biotechnology in the country, even institutions such as KENIA which the ST&I Act established to reinvigorate national innovation through

research have sidelined biotechnology in their activities. But that is just one side of the coin, the other is that with my interactions with the person from KENIA, they don't appear to really understand what biotechnology is all about in regards to Kenya's industrialization and prosperity (Zoom KI Interview with Senior Environmental Scientist and Researcher).

The study findings from the survey confirmed these reservations about the robustness of the ST&I Act. As the figure 20 shows about 58% of the respondents agreed the act should be amended to properly cover SynBio issues; 8% thought it is good enough to regulate SynBio as it and the rest (34%) said it cannot regulate SynBio at all the way it stands now. There is need therefore to fill the gaps in the Act in order that it incorporates all SynBio issues along a TAPIC framework in order that an adaptive anticipatory governance environment is put into place.

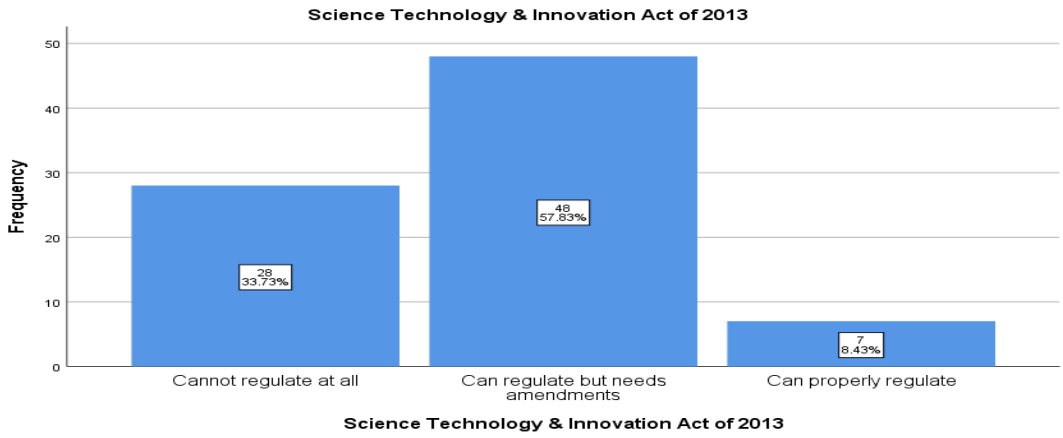


Figure 12: Robustness of the ST&I Act
Source: Researcher (2022).

5.6. Environmental Management and Coordination Act 1999 (EMCA) (Revised Edition 2012)

The EMCA was assented to in 1999 but became operational in 2000. The Environmental Management and Coordination Act (EMCA), Number 8 of 1999 is a legal instrument implementing the Environmental Policy, 2013 and other related policies. It is *an ACT of Parliament to provide for the establishment of an appropriate legal and institutional framework for the management of the environment and the matters connected therewith and incidental thereto* (National Commission on Law Reporting, 2012, p. 9). Although older than the policy itself, the Act has been updated through several recent issue-oriented regulations including Act No. 6 of

2006, Act No. 17 of 2006, Act No. 5 of 2007, and Act No. 6 of 2009. The Act incorporates as law many of the multilateral environmental agreements (MEAs) provisions including issues such as precautionary principle, sustainable development, strategic environmental assessment, environmental impact assessment, benefit-sharing, equitable biological/genetic resources exploitation.

The Act establishes three important institutions for the realization of a clean, safe and healthy environment, these: The National Environmental Management Authority (NEMA) *to exercise general supervision and coordination over all matters relating to the environment and to be the principal instrument of Government in the implementation of all policies relating to the environment (Kithika, n.d.).* The National Environment Council (NEC) provides policy formulation directions for the EMCA. It is also tasked to outline national goals and objectives, and to determine policies and priorities for the protection of the environment (National Commission on Law Reporting, 2012). EMCA also establishes the provincial and district environmental committees (P&DEC) which are tasked to undertake environmental management at the decentralized scales including provinces (now counties) and districts (now constituencies), and in the process increasing community stakeholders' participation. Finally, the Act establishes the Public Complaint Committees (PCC) which should provide the mechanisms for resolving environmental conflicts such as those arising from environmental harm. Section 58 of the Act crystallizes on this latter issue whereby any activities on the environment must be conducted only after the person or institution aiming to undertake such activity has satisfied the NEMA and any other institutions concerned which will then provide an Environmental Impact Assessment License (EIAL).

The EMCA provisions are furthered by issue-oriented regulations. These include EIA Regulations. Regulation 4 (3) of this regulation asserts that "no licensing authority under any law in force in Kenya shall issue a trading, commercial or development permit or license for any micro project activity likely to have a cumulative significant negative environmental impact before it ensures that a strategic environmental impact plan (SEIP) encompassing mitigation measures and approved by the Authority is in place" (National Commission on Law Reporting, 2012). Others include the Noise Regulation of 2009; the Wetland Regulations 2009; the Water Quality Regulations; the

Waste Management Regulations—this covers a range of wastes such as industrial, chemical, hazardous and toxic wastes, pesticides and toxic substances, biomedical wastes, radio-active substances. The Waste Management regulations spell out the requisites for handling, storing, transporting, and treatment/disposal of all waste categories and authorizes a NEMA licensed company to do the waste disposal.

Other regulations include Controlled Substances Regulations (primarily ozone-depleting substances) and; the EMCA (Conservation of Biological Diversity Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006; which provides that an environmental impact license is required to "engage in activities a) with an adverse impact on any ecosystem; b) lead to the introduction of any exotic species; b) lead to unsustainable use of natural resources, and further that any person who intends to access genetic resources in Kenya needs an access permit for genetic resources in Kenya with a certificate from national council for science and technology" (NACOSTI) (National Commission on Law Reporting, 2006).

Gaps in the EMCA 2012 (1999)

The EMCA is a key legislation in regards to SynBio development regulation because SynBio products and components in one way or another will end into the Kenyan environment and therefore will be subject to regulation by the NEMA provisions and guidelines. Experts reported that the EMCA (Conservation of Biological Diversity Resources, Access to Genetic Resources and Benefit Sharing) Regulations of 2006 is particularly very important in promoting or de-promoting biotechnology (and SynBio) as an aspect of ST&I in Kenya. Experts identified the following areas of gaps.

To begin with, NEMA, the main institution established under the EMCA Act has been playing a prohibitive role in regards to development and regulation of biotechnology, hence this would impede SynBio development and regulation. One of the key informant and a retired scientist who participated in the development of the country's GM maize argued that:

> …the regulators…regulation in any country, should be there to facilitate not prohibit research. That when a product is created, the responsible institutions should help explore best ways to go through the entire technology development cycle. But I think the approach

> that regulation and regulators have taken in this country has been really to prohibit. The way NEMA…you see, NEMA, if you walked into any rivers in Nairobi, the rivers are polluted, the polluters are there doing that every day and we don't see them taking any steps and clearly population is there. On the other hand, they have taken it upon themselves to block GM crops, any importation, or use of such crops, despite NBA approving them, there are even documents on the safety of the crops. They find it interesting and easier to block GM products than to follow with the industries and factories that pollute the rivers not just in Nairobi but across Kenya. The institution is unprepared to undertake SynBio research if fundamental revisions on its work and structure are done (KI Interview with a Plant Genetic Engineer).

This is an important point being made and speaks to the need to revisit the EMCA Act against the TAPIC framework. Secondly, the EMCA does not provide for stakeholders engagement platform that would see the coming together of the members of academia, industry, government and industry/business to explore best alternatives for the development and regulation of SynBio for the protection and sustainable utility of the Kenyan environment. Moreover the Act like the others already discussed do not spell out on the manner of stakeholders' participation: bottom-up or top-down that is necessary for maximum environmental benefits from SynBio technologies. For example, the Act due to its generality hence lack of focus on biotechnology and future advanced modern biotechnologies, does not outline any platforms when experts interact with the publics and regulators to put into place for mutual learning, information sharing and generation of important deliberations that should build up evidence for constructing an adaptive anticipatory governance environment. Marris & Calvert (2018) have called on UK policy makers to make similar considerations and result has been increased and intense engagements between academia (from the Innovation and Knowledge Centres [IKCs], such as SinbiCITE, the industry, and the government regulators. Together these are pushing the UK closer to being a global "science superpower". Such engagements are therefore key and should be a matter of law in Kenya if SynBio is to lead to the betterment of Kenyan's livelihoods and enhance Kenya's national power and middle income country.

5.7. Kenya Agriculture and Livestock Research Act, 2013

The Kenya Agriculture and Livestock Research Act, 2013 directly implements Agriculture and Livestock policies. It is one of the many approaches to realizing the long-held debates on the need to reform Kenya's agricultural system into a 'dynamic, innovative and a well-coordinated system' (National Council on Law Reporting, 2013a; Alila & Atieno, 2006). It is this Act that established the Kenya Agricultural and Research Organization (KALRO) with an autonomous corporate status. The Act elaborates on the work of the KALRO, its board, appointments to the board and Director-General of the organization. The Act also provides for the relationship between KALRO and the NACOSTI and empowers it to oversee research activities that are delineated toward agriculture and establishes Agricultural Research Fund (ARF) to mobilize resources towards agricultural research that aligns to national agricultural priorities. The object of the organization is to:

> Promote, streamline, co-ordinate and regulate research in crops, livestock, marine and fisheries, genetic resources and biotechnology in Kenya; promote, streamline, co-ordinate and regulate research in crops and animal diseases; and expedite equitable access to research information, resources and technology and promote the application of research findings and technology in the field of agriculture ((National Council on Law Reporting, 2013a, Section 5(1)).

The Act lists 13 functions of the KALRO in section 5(2). These include, among others:

> formulate policy and make policy recommendations to the Cabinet Secretary on agricultural research; prioritize areas for, and co-ordinate, agricultural research in Kenya in line with the national policy on agriculture; determine and advise the Government on the resource requirements for agricultural research in Kenya both at the national and county level; regulate, monitor and ensure that all agricultural research undertaken by research institutes and other institutions or persons undertaking agricultural research is consistent with the national priorities specified in the relevant policy documents; establish and exercise control over the research institutes, committees and research centres established under this Act.

Gaps in Kenya Agriculture and Livestock Research Act

Firstly, the Act may be deficient to regulate SynBio technologies such as genome sequencing and editing and DNA sequencing/reading and writing/editing[24] which are not part of what is regulated under the Biosafety Act, i.e., advanced non-agricultural and non-transgenic biotechnology. Biotechnology as conceived in Section 5(1) (a) of the Kenya Agriculture and Livestock Research Act, 2013, therefore, could only cover Living Modified Organisms (LMO) techniques which are less advanced than the mentioned SynBio technologies. For these gaps, most experts argued that the Act should therefore provide an appendix Guideline particular to SynBio techniques and methods as can be applied in agricultural research.

Another challenge faced by KALRO emphasized by the experts interviewed is the lack of public sensitization and awareness creation of their products and activities. Most respondents felt that even the anti-GMOs feelings from the public will not be there if KALRO considered public education, awareness creation and education as a critical step to public acceptance of biotechnology. One expert captured this as:

> You look at Kenya Livestock and Agricultural Research Organization (KALRO) it is rare for you to even find them in the villages training people about synthetic biology, or biotechnology or whatever it is called (KI Interview with a Senior Lecturer, Biochemistry).

5.8. Food and Nutrition Security Regulations

The food and nutrition security aspects elaborated in the Food and Nutrition Security Policy 2012 and regulated by a set of legislations spanning from the Biosafety Act, Public Health Act, Cap 242, the Food, Drugs and Chemical Substances Act, Cap 254, the Standards Act Cap 496. The Public Health Act aims at achieving good human health while the Food, Drugs and Chemical Substances Act aim to assure the safety of human food. The Standards Act gives the legal framework for food quality control and the Biosafety Act regulates the introduction or release of biotechnological commodities to protect human and environmental health.

[24] DNA sequencing is the process of determining the nucleic acid sequence – the order of nucleotides in DNA (Wikipeadia, 20222) https://en.wikipedia.org/wiki/DNA_sequencing.

Gaps in Food and Nutrition Security Regulations

a) The Food, Drugs and Chemical Substances Act, Cap 254 does not link food safety to modern biotechnology and does not therefore lay out biotechnology development and regulation guidelines for food, drug and chemical substances.
b) The Public Health Act, Cap 242, does not regulate health risks that can emerge as a result of the use of emerging bio-medical innovations. Social, environmental and cultural issues linked to biomedical innovations are also not properly considered. Additionally, the Act does not provide for protocol for research and development of medical equipment or drugs in Kenya. A KU-based scientist argued that:

During the peak of COVID-19 I lead a team of scientists who wanted to develop ventilators. I tell the Government has no proper directions on how such an activity should be registered until the products are commercialized. We went to several institutions and everyone was confused than us whether it was within their mandate to allow the production. Thy hard to tell u to develop some protocol and share with them, before the commencement of the study. I think with SynBio innovations, for you to produce human health equipment and drugs, it will be more complicated and confusing to undertake (KI Interview with Public Health Expert & University-based Researcher).

c) The Standards Act Cap 496 does not make provisions that cover social, ethical and economic concerns that come to question with the development and regulation of SynBio.
d) The institutions established under these Acts do not lay the needed stakeholders' engagement frameworks that will promote sector-based discussions and deliberations to inform continuous adaptation of the regulatory environment to a TAPIC framework that will guarantee optimal gain from SynBio within an environment where its potential negative impacts are possible to mitigate.

5.9. Agriculture Act, 2012

The Agriculture Act 2012 implements the Agriculture Policy and sets the regulations that aim to protect and promote the agricultural sector to make Kenya a food and nutrition secure country. The Act outlines the regulations for: pricing and marketing of agricultural products; establishes agricultural committees and boards; provides the rules necessary for the preservation of soil and its fertility; outlines the mechanisms and the regulations thereof for the development of land. Part

VIII outlines the mechanisms and regulations that should lead to sufficient food crops for Kenya's food requirements; the Act declares essential crops in Kenya, provides for guaranteed minimum returns, grants and advances in regards to the essential crops (National Council on Law Reporting, 2012f).

Gaps in the Agriculture Act, 2012

The Agriculture Act does not appreciate the contribution of emerging technologies, particularly bio-innovations as an avenue for efficient agricultural production leeway to food and nutrition security (National Council on Law Reporting, 2012f). This lack of recognition of biotechnology implies that the Act is insufficient to guide application of biotechnology development. As SynBio is a more advanced technology from biotechnology, the Act is therefore incapable to facilitate its development and regulation. Following in this argument, the Act falls short of the TAPIC elements and requires appropriate revisions. The revisions for this Act are necessary most importantly because agriculture remains the backbone of this country.

5.10. Seeds and Plant Variety Act, Chapter 326 of 2012

The Seeds and Plant Variety Act, Chapter 326 of 2012 is the legislation regulating all matters relating to seeds and plant varieties in Kenya and is, therefore, central legislation in the Agriculture sector. The Act outlines seed regulations such as civil liabilities of seed sellers; procedures and regulation thereof of seed testing; regulations to control imports of potentially deleterious seeds and cross-pollination; and plant breeders' rights. Part VI of the Act also establishes the Seeds and Plants Tribunal to resolve conflicts related to seeds and plants varieties.

Gaps in the Seeds and Plant Variety Act, Chap 326 of 2012

First, the Act does not acknowledge the indispensable role of biotechnology in the development and management of seeds and plant varieties. For example, the word biotechnology is not mentioned anywhere in the Act and bio-innovations, or bio-based techniques to seeds and plant varieties innovations are not considered as substantive regulatory issues. This is true therefore for SynBio, as its techniques build and go beyond those of biotechnology. Yet upon adoption, SynBio would have the power to transform the manner of doing business in the seeds and plant varieties sectors, by availing, as Jayanti (2020) discusses, opportunities to construct new forms of seeds and

plants from synthetic techniques – whose benefits would be: cheaper and highly efficient than naturally occurring seeds, and plant varieties.

Secondly, the Act makes no regulations for the utility of emerging technologies in the development and management of seeds and plant variety issues in Kenya. The participation of actors in this regard is also not considered. For example, the National Trials Performance Committee and the National Variety Release Committee; established to foresee seeds and plant varieties trials and release respectively, have no provisions that the membership of experts (from both academia and industry) from the fields of biotechnology or SynBio. The major shortcoming of the Act is therefore the lack of acknolwdgement of biotechnology in the processes of seeds development and regulation. An expert in plant engineering pointed out serious issues that emerge from such gaps, including participatory approach to biotechnology governance and consolidating research and regulation of biotechnology to solve issues of disjointed research and regulation as witnessed with GMOs and as both Mugo et al. (2017) and Pauline (2006) have given an account. The expert narrates, thus:

> Seeds and Plant Varieties Act is as important to food security in this country as other agricultural related Acts. Yet like those others, the Act is not framed within a modern biotechnology framework. As such linkages between seed and plant varieties institutions and actors is not established yet this is key, going forward to SynBio era, because actors from all concerned sectors must have a duty clearly spelt out. This will also help solve issues of disaggregated regulations and research (KII with a Plant Genetic Engineer, Nairobi University - December, 2021).

5.11.Chapter Conclusions

Based on documentary analysis and expert interviews, this chapter has highlighted the provisions and gaps therein of important legislations to the development and regulation of SynBio technologies. The Constitution of Kenya provides the general legal justification for adopting and using SynBio for national development and enhancement of livelihoods. The Biosafety Act is a key legislation as it establishes the NBA. The NBA is in effect to ensure that any biotechnology products are risk-free before they released into the environment. For the regulation of SynBio, the Biosafety Act and its NBA are deficient to ensure that SynBio products will be developed and

regulated within a TAPIC environment. It's too oriented toward biosafety yet SynBio begs biosecurity questions which requires NBA's mandate to be expanded or an institution dealing with biosecurity issues be established.

The ST&I Act is another important legislation that provides for a mandatory investment of 1% of the Government GDP to ST&I. It also establishes the NACOSTI and expands its mandate as the regulator of all research studies and the government advisor on ST&I needs. The Act lacks in focus and does not make any specific provisions on biotechnology. It therefore does not make any pronouncements for development of SynBio technologies, neither does it spell out on the provisions concerning social, ethical and economic impacts, biological diversity and biosecurity measures needed to be in place to ensure a TAPIC framework is in place.

The EMCA is key to the regulation of SynBio technologies but the institution it establishes, the NEMA, is riddled with several challenges that compromise its potentials to regulate SynBio within an adaptive anticipatory governance framework. The KALRO Act established the KALRO which has been undertaking agricultural biotechnology in Kenya. The KALRO, however, cannot as it is. The Food, Drug and Substances Act does not make any linkages between these three items and bio-innovation. As such, the framework that ensues from the Act can only facilitate the development and regulation of SynBio technologies if revised along the TAPIC elements of an adaptive anticipatory governance. This is the same to the Agriculture Act.

Within such a framework that cannot properly facilitate the development and regulation of SynBio, adoption and implementation of SynBio technologies in Kenya may not be smooth, and consequently may not lead to the dreams of bettering of Kenyans Livelihoods and enhancing Kenya science capabilities, hence national power.

CHAPTER SIX

AN EXPLORATION OF THE SCIENCE, TECHNOLOGY & INNOVATION (ST&I) THEME IN KENYA'S DEVELOPMENT PLANNING FOR SYNBIO ADOPTION AND IMPLEMENTION

6.1. Chapter Overview

To attain her Kenya Vision 2030, ST&I must be at the base of Kenya's transformative agenda. But how can this possible be if development planning is not driven by the notion of an ST&I/knowledge-based-driven economy?

This chapter sought to explore the question: to what extent is the theme of ST&I embedded into selected Kenya's national development plans (NDPs) and can that create a platform to mainstream SynBio into national development planning? Based on the findings, the chapter argues that sustainable implementation of SynBio in Kenya will depend, other than a robust policy and legislative environment, on whether the country's development planning is driven by an ST&I- and further whether development plans are receptive to emerging technologies like SynBio. The premise of the argument is that if Kenya's development plans have embedded ST&I as a driver for development, that can be a ground to justify investments in SynBio as an aspect of ST&I which will in effect provide a ground for SynBio mainstreaming into national development plans, something that will have varied positive ripple effects on the bioeconomy sectors such as health, manufacturing, environmental protection, among others [as discussed under the Big Four Agenda section in this chapter]. The chapter is largely based on documentary analysis but triangulation of secondary data is skillfully done with results from survey, KIs and FDGs. This complemented documentary analysis with fresh primary data, enabling the researcher to put documentary findings on contemporary context.

6.2. Overall Perspectives on ST&I Embedding and Synthetic Biology Mainstreaming

The study sought to understand the extent to which the theme of ST&I is perceived as an important development enabler in Kenya by conducting a document analysis of four key development plans relevant to this study, while corrobating that with fresh data from interviews and surveys. The study found that the theme of ST&I, has been an issue for political rhetoric, rather than a practical development agenda – reflected in real transformational, programs for more than 3 decades now

(The Government of the Republic of Kenya [GoK], 2007; Ministry of State for Planning National Development and Vision 2030, 2012). However, as an issue for national planning and an enabler for economic development and prosperity, it was only in 2013 that the Government committed to mainstream ST&I in her development approach. This was marked by the launching of the ST&I Act of 2013 (discussed in chapter five). When the researcher assessed respondents' perspectives on the extent to which ST&I is embedded in key national development blueprints and whether that can provide a fertile ground to mainstream synthetic biology in national development plans, most (82%) respondents reported that the development planning environment was moderately favourable for ST&I and would thus to some extent be modertately favouarble for SynBio. The survey result were as in figure 12 below.

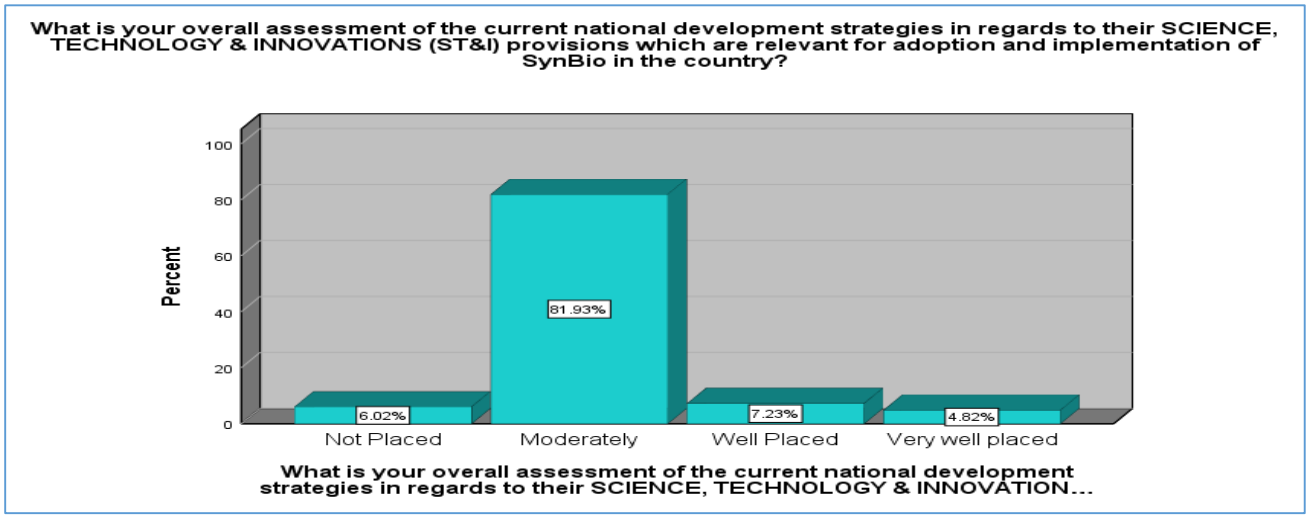


Figure 13: Overall Perspectives on ST&I Embedding and SynBio Mainstreaming
Source: Researcher (2022).

From figure 12 above, about 82% of the experts surveyed said ST&I embedding in NDPs was moderate to allow mainstreaming of SynBio, only 6% said it was not well placed, 7.23% said they were well placed and only 4.82% agreed that ST&I was well very well placed in NDPs in a manner that would enable adoption and implementation of SynBio and its mainstreaming in national development plans. From further exploration of this question during FGDs and KIs in order to understand and put survey statistics into perspective, it emerged that Kenya has a long history with talks - especially by politicians to the youthful voters - about ST&I as a driver for economic development. However, implementation through transformative ST&I projects have been

hampered due to five main issues: lack of political commitment, lack of support local scientists and biotechnology related fields, policies which do not explicitly make programmatic commitments, and lack of a political leadership that understands the importance of biotechnology for Kenya's development. A scientist and former biotechnology regulator at the national level argued to complement this assertion as follows:

> I think… ST&I in Kenya, there has been a lot of thinking and I think a lot is written and that's why the idea of NACOSTI was conceived and implemented. But what lacks in Kenya is something called political will…because what we should be seeing is that the same way ST&I is praised in policy, we should be seeing support, not just written but also demonstrated. Where we should be seeing support in youth being encouraged and scientists being encouraged to discover new things, but we tend to ask them to discover almost duplicates in the science that is already known. We tend to be in principle, supporting the need to go out of the box in terms of ST&I. At the same time, we openly fear it because of lack of political will to support it. That's why right from the beginning of GMO science I think in early 2000s, as early as 2001, I was able to bring in GM Maize, but only to test leaves in the laboratory which we demonstrated that it works, but up to today which is 20 years later, we are still saying that we don't know how safe it is. So I really don't know where political will fits into the policy but I think that's what needs to be addressed because by now we would hearing users of GM crops and other biotechnology products. But we are still in the realm where up to now it is the developers who are talking about them. So we don't allow the user who would be the farmer and the consumer to be giving us feedback instead we only have the developers (Key Informant Interview with Government Regulator & Former Plant Biotechnology Researcher, 13th Feb 2022).

It was thus necessary for the researcher to try and explore these overall assements of ST&I in NDP using certain key NDPs and scrttizing them through an impartial technique – document analysis and corrobating that with fresh data. The discussion that ensues covers four key NDPs beginning with the Kenya Vision 2030. Intension was to highoight ST&I pronouncements within these docuemnts and see what happenes in practice based on experts' experiences.

6.3. Kenya Vision 2030

This study conducted an analysis of 5 key Development Plans currently guiding Kenya's development, key among which was the Kenya Vision 2030. Results from documentary analysis were triangulated by survey and qualitative results. This specific sub-section presents findings from on how Kenya Vision 2030 has embedded the theme of ST&I and the extent to which it serves as a ground for adoption and implementation of SynBio.

Kenya Vision 2030 (or Ruwaza ya Kenya 2030) is the country's current overarching development blueprint formulated to guide Kenya's development, 2008 up to 2030. It was formalized on 10th June 2008 by President Mwai Kibaki (Ministry of State for Planning National Development and Vision 2030, 2012). Its goal is to transform Kenya into a "newly industrializing, middle-income country providing a high quality of life to all its citizens by 2030 in a clean and secure environment" (*Ibid*). The Vision is founded on three (3) pillars: Economic, Social, and Political. Its adoption was motivated by the shooting of the country's GDP from 0.6% in 2002 to 6.1% in 2006 under President Kibaki's Economic Recovery Strategy for Wealth and Employment Creation (ERS) which expired on 31 December 2007 (*Ibid*). Replacing the ERS, the Vision is to be executed in progressive five-year plans, beginning 2008–2012. It was believed that the Vision would help Kenya attain the Millennium Development Goals by 2015 (*Ibid*), and now that the MGDs is a gone story, it is believed that through the Vision will help Kenya attain the Sustainable Development Goals (SDGs) which is the very global foundation for Vision.

6.3.1. ST&I Theme in the Kenya Vision 2030

According to the Sessional Paper No. 10 of 2012 on Kenya Vision 2030, the Kenya Vision 2030 aims to transform the country via three main pillars: the economic, social and political (Ministry of State for Planning National Development and Vision 2030, 2012). The visions set to be achieved in every pillar is based on a philosophy that perceives technological innovation as a central enabler of an efficient and cost-effective socio-economic transformation. Chapter Two of the said Paper outlines technological innovation among the 7 outlined enablers upon which Kenya's socio-economic transformation can be achieved. The Paper makes the following linkages between science, technology and innovation (ST&I) and Kenya's socio-economic transformation.

> The Vision recognizes the role of science, technology and innovation (ST&I) in a modern economy, in which new knowledge plays a central role in boosting wealth creation, social

> Welfare and international competitiveness. Four elements allow effective exploitation of knowledge:
>
> (a) An economic and institutional regime that provides incentives for the efficient use of the existing knowledge, the creation of new knowledge, and the flourishing of entrepreneurship;
>
> (b) An educated and skilled population that can create, share and use knowledge well;
>
> (c) A dynamic information and communication infrastructure that can facilitate processing, communication, dissemination; and finally
>
> (d) An effective innovation system (i.e. a network of research centers, universities, think tanks, private enterprises and community groups) that can tap into the growing stock of global knowledge, assimilate and adapt it to local needs, while creating new knowledge and technologies as appropriate (Ministry of State for Planning, National Development and Vision 2030, 2012, p. 21).

The excerpt above, explicitly states the central role the ST&I has to play if the Vision 2030 is to be achieved. The concept of knowledge-driven economy, and an effective innovation system directly implicate that ST&I is at the heart of the Vision. Further, the Sessional Paper appreciates the lessons from countries such as China, Chile, South Korea, Malaysia, Finland and Ireland where the knowledge-led economy has not only spurred economic development but also human wellbeing which have been achieved after relatively short periods due to coherent strategies that built these countries capabilities to create, access, use and innovate knowledge. To place ST&I as the basis for an innovation-led economy, the Government commits through the Sessional Papers:

> Science, technology and innovation will be mainstreamed in all the sectors of the economy through carefully targeted investments. This will create a strong base for enhanced efficiency, sustained growth and promotion of value addition in goods and services. To achieve that objective, the additional investment must be made in ST&I, sectors that lag in the application of ST&I must be exposed to its benefits, there must be better coordination of Kenya's multiple institutions dealing with research and development, and Kenya must adopt a better ST&I dissemination strategy (*Ibid*, p. 21).

The commitments above have seen the formulation of both the ST&I policy and Act in 2013 and where the government commits to set aside 1% of its GDP annually to ST&I. To actualize her ST&I commitments under the Vision, the Sessional Paper outlines four broad strategies to promote ST&I. First, the paper commits the government to strengthen technical capabilities for ST&I development and enhancement; this should *focus on the creation of better production processes, with a strong emphasis on technological learning* (*Ibid*, p. 22). The second strategy is a commitment to the development and retention of highly skilled human resources that aims at *improving the national pool of skills and talent through training that is relevant to the needs of the economy* (*Ibid*, p. 22). The third strategy commits the government to intensify innovation in priority sectors to *increase funding for basic and applied research at higher institutions of learning and research and development in collaboration with industries (Ibid, p. 22).* The last strategy stated in the Sessional Paper is a commitment to creating ST&I awareness through deliberate efforts to promote awareness of discoveries in the fields of ST&I among the public.

6.3.2. Kenya Vision 2030 and SynBio Mainstreaming

SynBio is a globally recognized highly disruptive and significant bioinnovation (Glovall, 2015; WEF, 2012). It is ranked among the top world's most important emerging technologies (Bojar, 2018) and is perceived to be at the core of the so-called knowledge bio-based economy (Albretch et al., 2010). Kenya has already accepted the importance of this technology as a critical component of its ST&I and as both an end and means to the attainment of its Vision 2030. The country has commissioned and allocated a novel amount of resources--human and monetary—to SynBio research through the National Research Fund SynBio Project to develop two pioneer SynBio innovations, rapid diagnostic kits for detection of Cholera-causing pathogen and SynBio-based biosensors for detection of Potato brown streak disease (PBSD). These commitments have a global dimension and arguably are global in origin. Kenya is key player in the CBD processes through NACOSTI has been a very actors in SynBio-COP discussions. The study established that:

> What is going in the country is actually an implementation of global calls at the CBD and its expert groups recommendations for countries to explore best ways to adapt SynBio in well governed environments (KI with a focal Person at NACOSTI, July 2021).

Based on the analysis of the Vision 2030 Sessional Paper and follow-up discussions with experts, the Kenya Vision 2030 appears favorable for the adoption and implementation of SynBio in the following ways;

a) Experts engaged during the study asserted that the Paper provides a special place for ST&I and commits the government to make necessary interventions to facilitate the development of discoveries. As an emergent technology, SynBio fits within this commitment. Experts who are part of the NRF SynBio Project asserted that it on these grounds of the Vision 2030 that President Uhuru Kenyatta's government was able to allocate funds for the project.
b) The stakeholders' roundtables revealed that the Paper provides for mainstreaming of ST&I into all sectors where applicable. SynBio makes important contributions directly to all sectors of the bioeconomy[25]. It is prudent thus that this step is taken to deliberately mainstream SynBio into policies, legislations and even ongoing programs so that the technology can make an optimal contribution to Kenya's knowledge-led economy.

c) All the four strategic steps for developing and enhancing ST&I provided in the Sessional Paper can be applied to particularly support innovations in SynBio. The government can make necessary deliberate efforts to define and support government-academia-and-industry forums (or SynBio Consortiums) that aim at human resource development, developing and innovating techniques and applications and providing advisory functions to government MDAs, among other functions as may be defined. The government can also promote SynBio awareness among the general public and identified key stakeholders through a defined SynBio communication strategy. This final suggestion will ensure that the alien concept of SynBio is dissected to the public which may increase their awareness and enhance their support for SynBio R&D, include update of SynBio products as final consumers.

[25] In their "The Knowledge Based Bioeconomy (KBBE) in Europe: Achievements and Challenges", Albretch et al. (2010) defines the concept as *The bioeconomy is the sustainable production and conversion of biomass, for a range of food, health, fibre and industrial products and energy, where renewable biomass encompasses any biological material to be used as raw material*."

The favorable environment for mainstreaming SynBio into NDPs as provided by the Kenya Vision 2030 itself was reflected also from the study survey (figure 13). The researcher asked respondents to comment on whether Kenya Vision 2030 was not favorable at all, or moderately favorable or very favorable to facilitate adoption of SynBio. The results show that majority of the respondents said the document was moderately favorable (71%), 28% agreed that it was very favorable for mainstreaming SynBio into other NDPs and only 1% said it was not favorable at all. The survey results were thus in tandem with documentary analysis that the Vision 2030 is to a greater extent a good justification for Kenya's investment in SynBio but needs to go further and make specific recommendations touching on SynBio. The FGDs and KIs findings were also in tandem with the analysis.

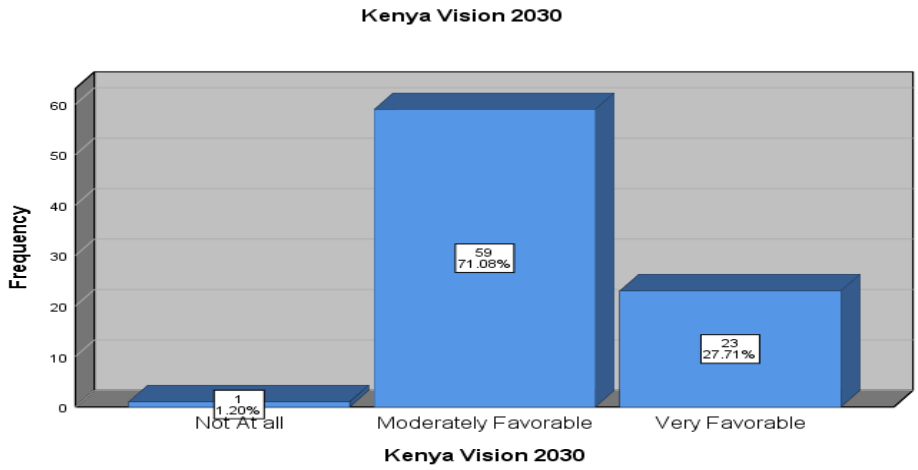


Figure 14: ST&I in the Kenya Vision 2030 and the Mainstreaming of SynBio
Source: Researcher (2022).

Gaps in the Kenya Vision 2030

Within the TAPIC framework, however, the Kenya Vision 2030 still has certain gaps that will need to be addressed for systematic mainstreaming of SynBio into national development planning. Firstly, the Kenya Vision 2030 contains ideas conceived before the formal acceptance of the techniques and methodologies referred jointly as SynBio in Kenya. In as much as the ideas, particularly those related to ST&I are very favorable for the adoption and implementation of SynBio as highlighted above, going forward, future Mid-Term Plans (MTPs) need to embed, explicitly, SynBio and make SynBio-specific provisions rather than considering it as fitting in the

ST&I framework. This will support specific funds allocations and programs for SynBio in the various sectors of the bioeconomy. Explicit recognition of SynBio in upcoming MTPs will enhance TAPIC. Currently the first elements of TAPIC are not achievable in the document. Capacity (the last element) is better because through the Vision, the government has funded a SynBio project, implemented in a PPP framework, and there reported cases of donor funded biotechnology projects (see Mugo et al., 2017), even as it remains challenging to the government when it comes to building capacity of biotechnology and biosciences.

6.4. "The Big Four Agenda"

The second NDP analyzed was the 'Big Four Agenda' (herein after called the Agenda). The researcher analyzed the document through vantage point of Parliamentary Budget Office (2018), the only piece of work that exists as an independent critical analysis of the Agenda. Literature on global commentaries on the matters concerning the agenda were also analyzed. Because the Big Four is ideally an implementation of the Kenya Vision 2030, the researcher assumed it's based on the very ST&I foundations highlighted by the Vision 2030. In the same breadth, the researcher then juxtaposed the aims of the Agenda against the potentials of SynBio borrowing from global applications of the technology. The presentation of findings that follow are a triangulation of the documentary analysis, survey and analysis of results from interviews.

The Agenda is the current government's development banner. Its implementation did not only coincide with the first budget (2018/2019) of President Uhuru's second term but also, its set timeline (2018-2022) coincided with the Medium-Term Plan III of the Kenya Vision 2030 (National Treasury and Planning, 2020). According to the Parliamentary Budget Office [PBO] (2018) the Big Four Agenda if implemented to its letter, can transform the country's economic performance and improve human wellbeing of millions of Kenyans. PBO (2018) argues that the challenge with it is that its implementation was predicated on post-election budgeting. *The challenge of post-election budgets is that they are typically expected to deliver too much, too soon and can end up being 'broken promises' budgets* (PBO, p. 7).

Under the Agenda, through the national budgets of 2018/2019, the government committed itself to support investments in value addition with four interdependent broad visions: raise the share of

the manufacturing sector to 15% by 2022; enhance food and nutrition security of all Kenyans by 2022; provide universal health coverage (UHC) of all Kenyan as a guarantee of quality and affordable healthcare; and, lastly, to provide decent and affordable housing for all Kenyans—not less than 500,000 such houses by 2022 (the Republic of Kenya, National Treasury and Planning, 2020; PBO, 2018).

6.4.1. The Place of Science, Technology and Innovation in the Big Four Agenda: Potentials for Synthetic Biology

The Big Four Agenda's: 100% food and nutrition security, UHC, value addition as an enabler to 15% GDP increase and decent and affordable housing require a business as an unusual approach to economic and human development on a macro and micro scales. For this reason, and like Vision 2030, ST&I would play a critical enabling role if these visions are to be achieved. The following discussion highlights the challenges the Big Four Agenda aims to solve through its four pillars (agenda) and how SynBio can make such interventions a reality in a cost-effective, efficient and environmentally friendly pathway. Three pillars; manufacturing, food and nutrition security and universal care, all of which relate to bioinnovation, are selected to put the point across.

6.4.1.1 Manufacturing

Due to its strong forward and backward linkages to other sectors of the economy, the manufacturing sector is important to job creation and stabilizing the country's economic performance. The main products from the sector include; leather, agro-processed products, textiles, construction materials and machinery (PBO, 2018). The sector is dominated by Small and Medium Enterprises (SMEs) which are largely low-skilled. The sector's contribution to the national GDP has been unstable since 2011 and this is the same for real value addition (*Ibid*).

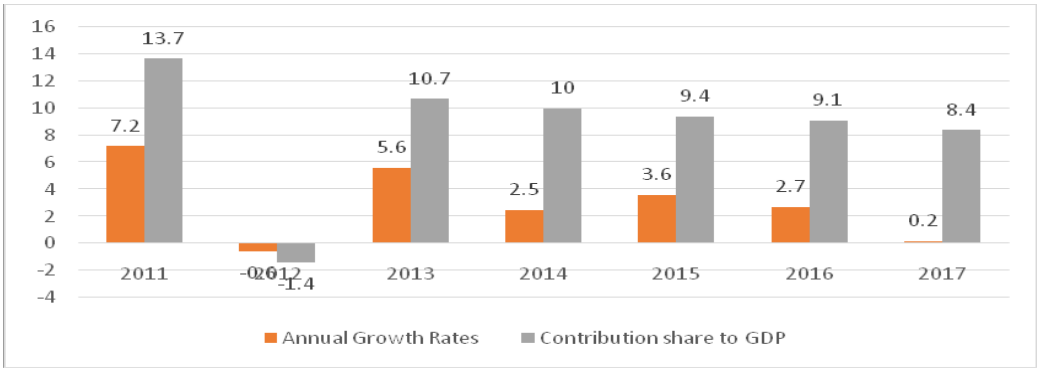


Figure 15: Manufacturing Sector Annual Growth Rate and its GPD Share (2011-2017).
Source: Kenya National Bureau of Statistics (KNBS) (2017).

From figure 24, it is evident that the sector contributed 13.7% to the GDP and that has been sustainably decreasing reaching 8.4% in 2017. At the same time, value addition in the sector has stagnated for over a decade at an estimated value of USD 5billion (Figure 25) accompanied by very low growth (PBO, 2018). Such is associated with factors such as increase in the cost of doing business—including costs of essential factors of production such as electricity, and labor. This has witnessed economic boosters of Kenya's GDP such as key foreign businesses as Procter and Gamble and Reckitt Benckiser relocating from Kenya (*Ibid*, p. 18).

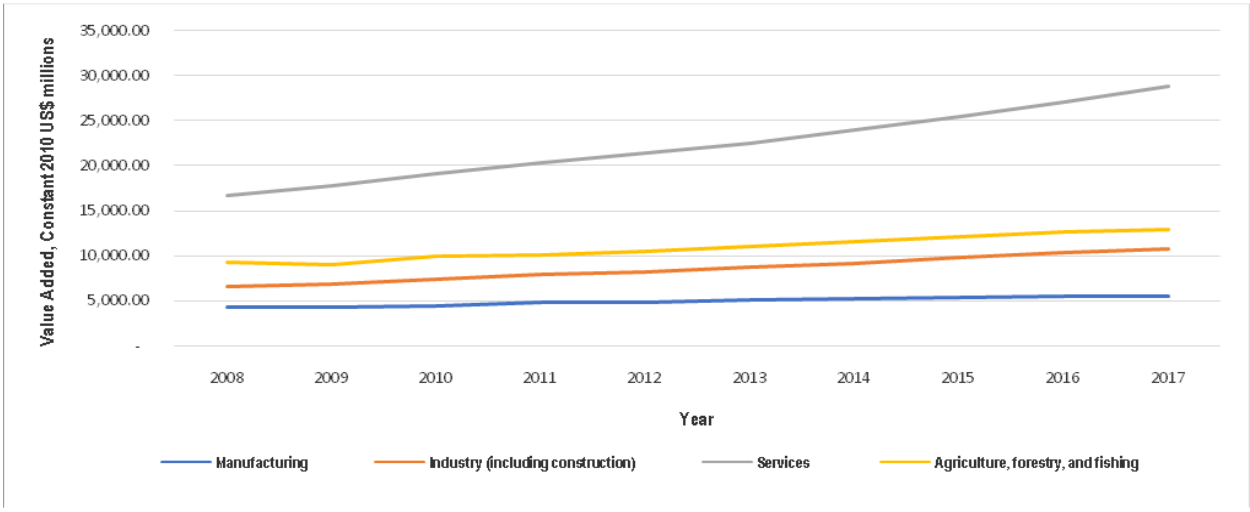


Figure 16: Value Additional per Sector (2008-2017)
Source: World Bank (2018).

In the Big Four Agenda, the government has laid out new projects and allocated funds to support ongoing important projects to the achievement of manufacturing goals under the agenda and to remedy the foregoing economic stagnancy situation. Such projects include Kenanie Leather Industrial Park, modernization of Rivatex, Athi River Textile Hub which are all co-opted projects from the Kenya Vision 2030 which were already ongoing before the launch of Agenda. These projects have been facing financing challenges that must be dealt with under the Agenda flagship (PBO, 2018).

SynBio adoption and implementation and it's mainstreaming into the manufacturing sector processes could be a critical booster to finding solutions to these problems facing the manufacturing sector. Its innovations can create alternative cheap energy and reduce dependence on expensive and business-unfriendly sources such as those from biomass (see Bojar, 2018). Such clean and cheap energy will not only promote value addition and jobs creation for innovators and new employees into thriving new entrant industries as it has done in the UK (UK Parliamentary Office for Science and Technology, 2015). It will also provide an avenue to deal with climate change by reducing greenhouse gases (GHG) emissions (SBLC, 2016) as well as conserve biological diversity. For example, by providing alternative sources of energy, clean bio-fuels, SynBio can help secure Kenya's water sources which provide 57% of the electricity used in the country (African Conservation Centre [ACC] & African Centre for Technology Studies [ACTS], 2010). Other possible contributions of SynBio to the manufacturing sector include the production of SynBio agro-products which will not only be cheaper and promote businesses especially agricultural-based SMEs, it also will enhance biological diversity conservation; increase the availability of agro-products through such technologies as gene editing (the targeted replacement of unproductive genes with productive synthetic gene forms) which will ensure improved animal and plant production.

6.4.1.2 Food and Nutrition Security

Agricultural performance has been cited in the Agenda as a key driver of economic growth (PBO, 2018). The sector accounted for 31.5% of the GDP, 75% of the labor force and over 50% of total earnings from export (*Ibid*). Despite this empirical value of the sector, it has been on a downward trend decreasing by 1.6% in 2017 from 5.4% in 2013 (MOA, 2016). This is due to a reduction in food production, marked by reduced production of critical foodstuffs such as maize. The Ministry of Agriculture (MOA) estimates for example that maize production reduced from 40 million bags in 2013 to 35.8 million bags in 2017 (MOA, 2016). Such reductions, according to PBO (2018, p. 21), are facilitated by a conglomerate of factors including *drought, limited agricultural land expansion, low and declining soil fertility, inadequate use of quality seeds, delayed supply, high fertilizer cost and Pests such as the Fall Army Worms.*

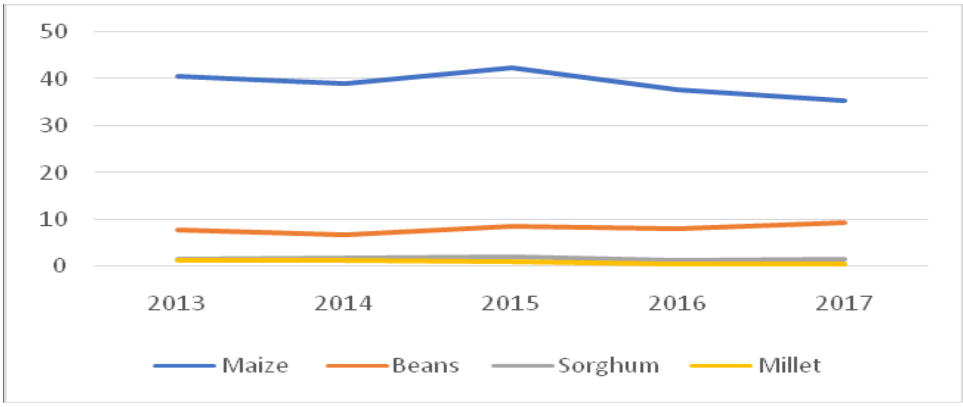


Figure 17: Estimated Production of Selected Agricultural Commodities
Source: KNBS (2017).

Moreover, in both 2017 and 2020, (the latest available statistics) Kenya was ranked by the global food index as food insecure[26] coming at number 86 out of 113 countries in both years (The Economist Intelligence Unit [EIU], 2017; 2020). According to PBO (2018), Kenya compensates for this insecurity by importing most of its foodstuffs such as milk, potatoes, beans, rice, maize and wheat. For example, the share of imports on key grains was 25% in 2010, increased by 7% in 2015 and was suspected to reach 36% in 2016. This trend could increase further because a) Kenyan population continue to grow (KNBS, 2019), climate change continues to exacerbate, and land-use practices and land under agriculture continue to shrink (Ministry of Agriculture [MOA], 2016; EIU, 2020).

In the backdrop of these challenges, through the Agenda, the government has an ambitious aim of achieving 100% food security by 2022 for all Kenyans. Measures to realize this include increasing the production of critical foodstuffs such as maize. This include increasing maize production from 40 million bags annually to 67 million bags by 2022; increase rice production from 125, 000 metric tons (MT) to 400, 000 MT by 2022; increase potato production from 1.6 MT to 2.5MT. Other efforts pursued under the spirit of the Agenda including promoting agriculture from a subsistence activity to commercial activity by for example allocating good sums of money to support nationwide irrigation projects. For example, in the 2018/2019 fiscal year (FY) the government allocated 17.9 billion Kenyan Shillings to nationwide irrigation projects (PBO, 2018).

[26] This report measures food security using three variables: affordability, availability, quality and safety and natural resources and resilience.

These efforts and more, targeted at finding solutions to agricultural problems facing Kenya and related problems can be bolstered by the adoption, implementation and mainstreaming of SynBio into new and ongoing food and nutrition security policy, programs and projects. Based on the lessons already learnt from the USA (see, e.g., Jayanti, 2020; Trump, 2017; Synthetic Biology Project 2010; Pauwels, Stemerding & Vriend (nd), US Bioeconomy Strategy, 2012Singapore and the UK (Trump, 2017; Kolodziejczyk & Kagansky, 2017; EU, 2012; Giese & Gleich, 2015; Gronvall, 2015; Joyce & Kendall, 2013; Kuiken, 2015) where SynBio has been promoted as part and parcel of bioeconomy development processes; the technology can avail several cost-effective, easy to use and environmentally friendly food and nutrition security products and foodstuffs. For example, SynBio technologies have been used to impart favorable traits into plants and animals that can make them more productive and resilient to droughts, pests and diseases. The technology can also produce artificial cell systems such as biosensors and bio-based rapid diagnostic kits which can detect impending crop, animal and human diseases before they materialize hence increasing plant, animal and human diseases surveillance systems enabling early warning and early mitigation measures to be taken by the concerned citizens (ISAAA AfriCentre, 2020). This assertion is complimented by the following excerpt from a key informant of the study;

> We expect that by constructing the biosensor for PBSD we are proving a cheap means of detecting this common disease affecting our Kenya staple food. Farmers will be able to use it without any needed expertise, and it will be cheaper than currently existing biosensors. We believe it is a step towards the food and nutrition goals of the Big Four Agenda (KI with a Researcher and PI in the NRF SynBio Project).

Moreover, such SynBio products are cheaper than naturally occurring ones or those manufactured from natural products (*Ibid*; Jayanti, 2020). FDG results supported this assertion that:

> This way, applications such as biosensors once commercialized, can be availed to smallholder farmers who can then use them to make farming decisions that will reduce losses, increase returns on incomes, and enhance their livelihoods and wellbeing; in the process promoting national food security and agricultural share of the GDP

As has been realized in countries like Singapore and the UK and USA (Trump, 2017).

6.4.1.3 Universal Health Coverage

Through the Big Four Agenda the government aims to achieve 100% universal health coverage (UHC) by end of the year 2022. This is through ensuring that barriers to equal healthcare access are eradicated in order to improve health outcomes. Because inequality to healthcare access is largely a matter of health security which means that everyone has the capability to access quality healthcare, the Government aims to achieve its UHC agenda by up-scaling the uptake of National Hospital Insurance Fund (NHIF) (PBO, 2018). In fact, there are talks that the Governemnt of Kenya will soon make NHIF a mandatory issues for all Kenya (Tuko.co.ke. 2022). World Health Organization (WHO)[27] defines UHC as a situation

> Where all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardships.

According to PBO (2018) analysis of the Agenda vis-à-vis budgetary allocation 2018/2019, the WHO definition of UHC embodies three related objectives namely: equity in access to health services - everyone who needs services should get them, not only those who can pay for them; The quality of health services should be good enough to improve the health of those receiving services; and People should be protected against financial-risk, ensuring that the cost of using services does not put people at risk of financial harm (PBO, 2018, p. 25-6).

The Government of Kenya has proposed the following initiatives to achieve UHC (PBO, 2018, 26):

a) Driving NHIF uptake through enlisting 37,000 banking sector agent network, leveraging on self-help groups and religious groups for advocacy;
b) Enlisting 100,000 Community Health Volunteers to each recruit 20 households; Expansion of the 'Linda Mama' programme to mission hospitals;
c) Legal reforms to align NHIF with the UHC;
d) Adopt new health care financing models that include gradual increment of budgetary allocation to health from 7 percent in 2017 to 10 percent in 2022,

[27] http://www.who.int/health_financing/universal_coverage_definition/en/.

e) Introduction of Robin-Hood taxes on Real Time Gross Settlements (RTGS), mobile money transfers, and airfares;
f) And Adoption of new low cost service delivery model that leverage on technology such as e-Health for telemedicine, m-Health, and e-Hubs collection and dissemination of information (p. 26).

The UHC agenda has been hampered by the glaring challenges facing the health sector, which include, physical-those which relate to actual availability, location and conditions of healthcare facilities; human-those which relate to human resources needed to attain 100% access to universal healthcare; and healthcare equipment-those which relate to the availability of the requisite healthcare provision tools such as diagnostic kits, medicine, and others (PBO, 2018).

6.4.1.4. SynBio as a Means to Attaining UHC

Synthetic biology can act as an enabler to attaining quality healthcare in Kenya. Learning from the UK (see e.g., UK Parliamentary Office for Science and Technology, 2015), the technology provides a wide range of applications to the health sector. These include synthetic medicine such as artemisinin for treating malaria, a common drug which Kenya continues to import at tunes of millions while malaria disease continue to be top ten most killer disease in Kenya (KI with a Principal Investigator, NRF SynBio Project). While the UK has been able to produce this drug for both local and international consumers, Kenya, upon adoption of SynBio can consider locally producing this drug to save on costs of importing it as is the case currently, while also reacting to the disease which kills millions of her population annually (Ministry of Heath, 2019).

Other application include diagnostic kits for human disease-causing pathogens and biosensors for crop-disease causing pathogens. These two applications are already under construction by Kenyan scientists under the NRF SynBio Project. The scientists, funded by the Kenyan Government aim to construct a rapid diagnostic kit for *Vibrio cholera* which is the disease-causing pathogen for Cholera in a water surface. Cholera is one of the most common diseases and during 2015-2018 invaded several parts of the country on a back-to-back basis (see, e.g., ISAAA AfriCentre, 2020). Upon successful experimentation and field tests for safety, the application should help detect Cholera outbreak in good time hence help the country make necessary preparations to prevent its outbreak. On the other hand, the biosensor being constructed under the said project should serve a

similar purpose as the diagnostic kit but in plants, especially by detection PBSD using potato leave pigments.

Such detection will enable farmers to know of impending PBSD outbreaks long before it occurs and affects the potato roots, thus helping them to avoid loses and keep their agricultural livelihoods on an upward trend upward. These two applications of SynBio are said to be efficient, effective, cheaper, and easy-to-use relative to those currently in the market. The diagnostic kits can be produced cheaply and in large scale for use in community health facilities across the country where Cholera detection has been very poor. The biosensors on the other hand will be used by the small-scale farmers as well as commercial farmers, directly, unlike the current approach where the target is largely commercial farmers who are able to hire agricultural extension workers (MOA, 2018), and the small-scale farmers who while they constitute the largest percentage of the farmer community, are unable to access current biosensors due to their high costs and the need for expertise to operate.

These tools and others, enabled by SynBio techniques, are revolutionary to the conduct of medicine and health in plans and animals. In fact, as SynBio research gets advanced, scientists are soon going to be able to create customized drugs which will treat cancer and other death-warrant diseases (Pauwels, Stemerding & Vriend, 2011). These will not only be possible if SynBio becomes embedded into NDPs going forward. Such NPDs as the Big Four Agenda may do better in facilitating Kenya's gains from SynBio when the technology is explicitly considered, and specific programs to be achieved set for each of the priority sectors such those of the Agenda.

6.4.2. Gaps in the Big Four Agenda

As discussed in this sub-section, SynBio is an important enabler to achieving the Agenda. This, however, is only possible if the Agenda makes deliberate efforts at considering SynBio contributions categorically into the agendas. Although the Agenda is coming to an end by end of 2022, the gaps it exhibits in regards to facilitating mainstreaming of SynBio into NDPs, should inform next Government on what and how to plan with SynBio for national development. These gaps are identified as follows:

Firstly, from the expert interviews and stakeholder roundtables, it was reported that the Agenda does not recognize SynBio as part of the so-called key enablers for the Agenda and therefore no special allocations, for example, were made particularly for advanced technologies key to achieving a knowledge-based bioeconomy. On this ground all aspects of transparency as conceived in TAPIC framework are difficult to achieve in a systematic manner. Moreover, even integrity and participation elements are difficult to realize without an explicit recognition of the value of the technology. This is so because without explicitly mentioning SynBio, issues of biosafety, biosecurity, bioethics, and socio-economic issues are not systematically considered, implying that even capacity questions of the TAPIC framework are unconsidered. These are issues that whatever plan that will replace the Agenda may need to consider for continuity in the work already started concerning SynBio.

Secondly, the programme consequently fails to acknowledge the need for the involvement of knowledge-based bioeconomy stakeholders to promote new technologies R&D in the bioeconomy. As has been discussed in chapter four, government commitments to develop an environment for a thriving biotechnology development in the country has been hampered by among other things, mainly the disconnect between biotechnology education and the biotechnology industry. The Agenda, while it is a short term political plan, should be succeeded by a more robust framework that will enlist specific avenues for modern biotechnology development which values biotechnology education, and research, particularly providing industry opportunities. In effect realizing the participation element of the TAPIC framework. A participatory framework that brings industry, academia, government and the private sector in a common platform of discussion and dialogue on best paths to pursue for a biotechnology development that will propel economic growth and dispel of the negative politics that has hampered it over twenty down the line.

Nonetheless, as documentary analysis revealed, the challenges that the Agenda aims to mitigate are so linked to SynBio hence justifying its adoption in Kenya, not just as an area of practice but most importantly as a driver of national development mainstreamed in key NDPs. This notion of the technology was also asserted by the study survey results. From (figure 17), majority (74.70%) of the respondents reported that the Big Four Agenda was moderately favorable for mainstreaming

SynBio. Only 17% were pessimistic about the Agenda's agenda for ST&I and SynBio and 8% said it was very favorable. These survey findings reinforce the point already made: the Agenda, is a good plan which should be revised going forward with explicit consideration of SynBio and specific allocations for SynBio Projects under each of the pillars of the Agenda or the new substitute that would be put into place by the next Government.

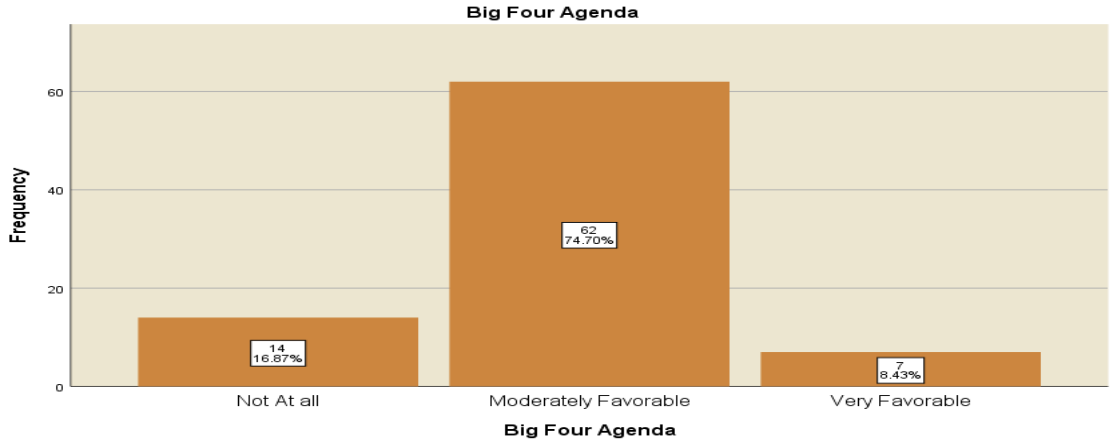


Figure 18: ST&I in the Big Four Agenda and Mainstreaming of SynBio
Source: Researcher (2022).

6.5. Kenya Biodiversity Status Review Reports

One of the most critical sectors in Kenya is the environment. The environment is mother of the bioeconomy where ST&I particularly, SynBio makes the most of contribution is as much as national development is concerned. Against this background the researcher selected Biodiversity status review report of the documents of analysis and for empirical study.

Kenya is party to the CBD and all its protocols as well as other environmental and climate change international regimes. In the backdrop to her international commitments to sustainable development and sustainable use of her natural environment, Kenya has been submitting her National Biodiversity Reports (NBR) to the CBD. The 6th NBR is the latest of such reports and updates COPs on the state of Kenya's biodiversity under her commitments to such international regimes such as Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Cartagena Protocol on Biodiversity and its Nayoya-Lumpur Supplementary Protocol on Redress and Liability, the Aichi Biodiversity Targets (ABTs), and the CBD Strategic Plan 2011-2020 (KI with a Biodiversity Expert, NACOSTI).

The (6th) report elaborates on the institutional structures and policy and regulatory measures taken by Kenya to realize ABTs and CBD Strategic Plan. It elaborates on the biodiversity goals and successes under Kenya Vision 2030; CoK 2010, the Blue-economy Strategy, Climate Change related policies, and other sectorial mechanisms that relate to biodiversity conservation and management. The report also enumerates the 20 ABTs and their mainstreaming into national targets and Chapter 5 outlines a national assessment on these targets.

6.5.1. Kenya Biodiversity Status Review Reports: Science, Technology and Innovation and the Synthetic Biology Mainstreaming Gaps

The role of ST&I in Kenyan biodiversity conservation and management cannot be gainsaid. The 6th NBR asserts strongly that the 5th NBR did not achieve the ABTs partly due to a lack of the requisite ST&I infrastructure to facilitate the process. Moreover, the Report acknowledges that it has put into place a Biosciences Policy and Bill, Nanotechnology Policy, among other policies as achievements under the ST&I sector in light of her commitments to both Aichi and national biodiversity targets. Upon adoption and implementation of SynBio, Kenya will need to mainstream the technology into the NBR process. This may mean having a SynBio policy and Act which should specify the role of the technology in various sectors of biodiversity and other aspects of sustainable development and its role in realizing Aichi and national biodiversity targets. As the reporting happens to-date, neither ST&I nor biotechnology/SynBio is appreciated as key holders to unlocking biodiversity goals in Kenya. For this reason, a TAPIC framework analysis reveals that the biodiversity status reports fails on all elements of the TAPIC; it doesn't recognize SynBio, it thus does not provide the avenues for realizing a transparent, accountable, participatory, integrity and capacitated biodiversity management and conversation system that utilizes SynBio as a central driver. One expert in an FGD augmented this assertion as follows:

> It is true as it happens today, the way we do biodiversity reporting does not point to the manner in which we utilize the bioinnovation. While may not necessarily mean that we don't, it is as well a pointer that we have not thought of the important role of bioinnovation, especially those advanced like SynBio in making biodiversity conservation processes cheaper and efficient (1st FGD).

6.6.Kenya National Climate Change Action Plan (NCCAP) 2018-2022

The researcher also analyzed Kenya's climate change action plan. The plan was selected due to the importance of climate change to the Government of Kenya which keeps on saying in international climate change Conferences, that Kenya, like other developing countries is among the most hard hit by the impacts of climate change despite Kenya and other low and middle income developing countries being least contributors to GHG (Ministry of Foreign Affairs Facebook Page, 2022).

Kenya has long recognized the impacts of climate change on her development and the wellbeing of her population. The country is a State Party to the UNEP and became a State Party to the United Nations Framework Convention on Climate Change (UNFCCC) on 27th January 2017. The country is also an active participant in climate change-related regimes such as the COPs. The NCCAP and other related plans are therefore a domestication of Kenya's obligations under international law of treaties and a reflection of Kenya's international relations with other members of the family of nations.

The country has in place a Climate Policy and legislation and has in place 'the National Climate Change Response Strategy (2010), National Climate Change Action Plan [NCCAP] (2013-2017), National Adaptation Plan (NAP 2015-2030), Kenya Climate-Smart Agriculture Strategy (2017-2026), Climate Risk Management Framework (2017), Sessional Paper on National Climate Change Policy (2016), and National Climate Finance Policy (2018)' (Ministry of Environment and Forestry, 2018). All these policy instruments should ensure coordinated climate change adaption and mitigation. The Climate Change Act No. 11 of 2016 commits the government to draw a five-yearly national climate change action plan to guide the mainstreaming of climate change mitigation and adaption into the operations of sectors within national and county governments. The NCCAP 2018-2022 was formulated in this regard, replacing the NCCAP 2013-2017.

The NCCAP 2018-2022 has the objective of furthering Kenya's development goals by providing mechanisms and strategies for achieving low carbon climate-resilient development with special priority on adaptation measures as opposed to mitigation. This is because Kenya contributes very little to global climate change, less than 1% of global Green House Gas (GHG) emissions (Ministry of Environment and Forestry, 2018). Building on the first Action Plan (NCCAP 2013-2017) the NCCAP 2018-2019 provides a framework that should help Kenya achieve her Nationally

Determined Contribution (NDC)[28] under the Paris Agreement implemented by the UNFCCC. The Plan is aligned to the priorities of the Kenya Vision 2030, especially under Vision 2030's MTP III thus mainstreams climate change adaptation and implementation into national development priorities pursued under the Kenya Vision 2030. The plan also aligns with the Big Four Agenda priorities of 2018-2022 and is, therefore, to be pursued within its framework.

Based on the Kenya Vision 2030's MTP III and the pillars of the Big Four Agenda, the NCCAP outlines strategic actions for climate change adaptation and mitigation in seven areas: disaster management in drought and famine scenarios; food and nutrition security; water and blue economy; forestry wildlife and tourism; health, sanitation and human settlements; manufacturing, energy and transport. Seven (7) coinciding strategic objectives are also enumerated in the plan.

6.6.1. The place of Science Technology & Innovation National Climate Change Action Plan 2018-2022

The role of ST&I is appreciated in the NCCAP 2018-2022 in chapter four which lays out the supposed enablers necessary for the achievement of the targeted adaptation and mitigation measures in the NCCAP 2018-2022. The Plan commits the government to support sectors and counties to promote the needed technologies and innovations that will help in the realization of strategic actions to climate change adaptation and mitigation such as improved water harvesting, enhanced climate information services (CIS) and clean technologies (Ministry of Environment and Natural Resources, 2018, p. 103).

The Plan outlines five ST&I action plans to promote ST&I development as a requisite to climate change adaptation and mitigation. The main action plan is to build the capacity of key institutions such as the Kenya Industrial Research and Development Institute (KIRDI), KALRO, Kenya Forest Research Institute (KEFRI), County Governments and their institutions such as the Council of Governors (CoG) academic institutions and private institutions to promote, upscale and disseminate climate change-related ST&I. A special mention is accorded to the KIRDI as being the National Designated Entity (NDE) for the Climate Technology Centre and Network (CTCN)

[28] Under the UNFCCC Kenya seeks to abate GHG emissions by 30% by 2030 relative to the business as usual scenario of 143 MtCO2eq in the six areas set by UNFCCC; agriculture, energy, forestry, industry, transport, and waste. MtCO2eq 'is an abbreviation for million tons of carbon dioxide equivalent, or the amount of GHG emissions expressed as an equivalent amount or concentration of carbon dioxide*' (Ministry of Environment and Natural Resources, 2018, p. xiv)*

under the UNFCCC (Ministry of Environment and Natural Resources, 2018, p. 103). Other action plans for ST&I development and utility in climate change interventions are*:*

> Provide climate information services (CIS), including information to help farmers manage risk, inform early warning systems, and inform decision making for organizations, businesses and households; establish a sustainable consumption and production networking facility for micro, small and medium enterprises (MSME), with an emphasis on women KIRDI and youth; promote gender-responsive climate technologies and innovations in the private sector through the provision of financing, capacity building, and start-up/scale-up of services. encourage youth innovation through outreach programs with schools, universities, and organizations of the youth; identify policy and fiscal incentives to promote the uptake of climate-friendly technology (such as tax incentives, reduced energy tariffs, low-interest loans, and public-private partnerships) action continues from NCCAP 2013- 2017: finance (p. 103-105*).*

6.6.2. National Climate Change Action Plan 2018-2022: Gaps in regards to Synthetic Biology

The following are the gaps in the NCCAP 2018-2022 that may hinder the smooth incorporation of SynBio into national climate change adaptation and mitigation planning within a TAPIC framework of analysis.

Firstly, the plan does not foresee the utility of technology of the magnitude of SynBio and as such does not lay the basis for its development. For example, the 'policy and regulatory framework' (p. 101) enabler does not consider the policy gaps that exist in current policies about the utility of emerging technologies in climate change adaptation and mitigation. The technology and innovation (p. 103) enabler on the other hand, only considers low knowledge-intensive technologies such as cooking stoves and does not outline explicitly the possible roles that emergent technologies such as nanotechnology, Artificial Intelligence and SynBio, among others, can play in the climate change interventions, and consequently how they can be developed, adopted and implemented as safe avenues to low-carbon climate-resilient development. The lack of official recognition of SynBio in such a key climate change plan implies TAPIC elements cannot be

realized when SynBio is applied without its systematic mainstreaming into national climate change processes.

Secondly, the needed incentives for adoption and implementation of SynBio, and their possible utility in climate change interventions are not considered. According to a respondent in one of the FGDs:

> These include, official allocations targeting SynBio projects that will contribute to national climate change adaption processes, commitment for academic and innovative forums, such national symposiums to sponsor activities meant to explore SynBio projects tailored towards climate change adaptation and mitigation; government commitment to policy making and legislating processes for bolstering the development a SynBio system that links climate and environmental programs and other related development planning to SynBio technologies (FGD 2).

The national development planning under NCCAP 2018-2022 does not, therefore, possess a suitable environment for SynBio adoption and implementation. This so because it fails to recognize SynBio subsequently fails to lay out or make linkages with concerned institutions and policies, on to realize the TAPIC elements while SynBio is utilized for climate change adaptation and mitigation interventions in Kenya.

6.7.Agricultural Sector Development Strategy

Agriculture is another sector which lies at the heart of Kenya as shown statistically in sub-section 6.4.1.2. For this reason, the Agricultural Sector Development Strategy (ASDS) became a candidate for analysis in this study.

This National Strategy for Agriculture builds from and expands the Strategy for Revitalizing Agriculture (SRA) and the Economic Recovery Strategy for Wealth and Employment Creation (ERS). It also takes cognizance of Kenya Vision 2030 MTP I and particularly agricultural priorities under the economic pillar. Building on these and revising SRA, the strategy sets new agricultural sector development strategic objectives within the new governance dispensation of the devolved system of government under the CoK 2010. It also aligns to regional and global agricultural development regimes such as the Comprehensive African Agricultural Development Programme

(CAADP), and MDGs, particularly the poverty and hunger targets hence is a domestication of Kenya's global obligation under agricultural sector (Government of the Republic of Kenya, 2020).

It outline of the nature of the agricultural sector, namely on areas such as land and resource base, agricultural systems, production scale, agricultural commodities and enterprises-such as aquaculture, forestry, wildlife, livestock production, and crop production; and issues related to cooperatives. It expounds on agricultural services in Kenya spanning agricultural research, agricultural extension, training and information services, marketing, credit inputs, pests and disease control in fish, crops, and livestock to statutory boards and development authorities for the advancement of agricultural sectors strategies (Government of the Republic of Kenya, 2020). ASDS focuses its interventions on five sub-sectors: crops and land development, livestock, fisheries, cooperatives and private sector participation. It then spells out the production factors strategic interventions in such factors as Arid and Semi-Arid Lands [ASAL], forestry and livestock resources, river basins and large water resources, environmental and natural resource management, land use-related factors and water and irrigation productive factors (PELUM, 2021). Six enablers are considered in the strategy for its realization, including, inter alia, education, training, science and technology (Government of the Republic of Kenya, 2020).

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6.7.1. Agricultural Sector Development Strategy: Science Technology & Innovation and Synthetic Biology Adoption

Agriculture is not only Kenya's greatest contributor to the GDP (Government of the Republic of Kenya, 2020), it is also at the base of a knowledge bio-based economy. Therefore, ST&I has a greater role to play as both a cause and effect for the realization of the goals of agricultural sector development planning. This fact is appreciated in Chapter 7 of the ASDS where Education, Training, Science and Technology is considered among the six listed enablers for agricultural sector development. The ASDS reiterates the ST&I visions of Kenya Vision 2030 by appreciating the linkage between agricultural performance and an educated, innovative and knowledge-creating population. However, in regards to SynBio adoption, implementation in a TAPIC/adaptive anticipatory governance environment, and possible utility in the promotion of agricultural sector development, the ASDS has the following gaps.

The ASDS makes no specific measurable strategic objectives that can be pursued to ensure ST&I is utilized to solve the numerous agricultural challenges it enumerates hence fails on grounds of transparency, integrity and accountability in so far TAPIC framework is concerned. Thirdly, there is no linkage between ST&I and the productive factors, sub-sectors, and the obtaining characteristics of the agricultural sector. One key informant pointed that:

> For example the chapter on enablers (paragraph on Education Science Technology & Innovation) lists no specific area of STI&I that the government aims to utilize to enhance for the achievement of the strategy. This accounts for the lack of specific objectives and explicit linkages between ST&I and the achievement of the issues laid in the Strategy (KI with a Scientist from KALRO).

Despite these gaps, the ASDS is good national plan as it appreciates, at the general level the possibilities of utilizing ST&I in agricultural sector development but fails to consider specific latest technologies as drivers of agricultural development. Its lack of clarity on how advanced technologies like SynBio should be applied to agricultural sector development was also reflected in the study survey findings (figure 18) which sought to understand the extent to which embedding of ST&I in the ASDS may help the mainstreaming of SynBio into agricultural development plans with only 13% of the experts agreeing that it had provisions that were pro-ST&I hence pro-SynBio adoption. It was observed that 42% of the respondents said the strategy cannot favor SynBio mainstreaming at all, 45% said it is moderately favorable and only 13% supported that the strategy was very favorable in terms of enabling mainstreaming of SynBio into the agricultural development programs in Kenya. These and the expert interview and stakeholders roundtables leads us to the conclusion that the ASDS requires to be revisited with the aim of integrating SynBio into it in order that the technology is mainstreamed into agricultural programs.

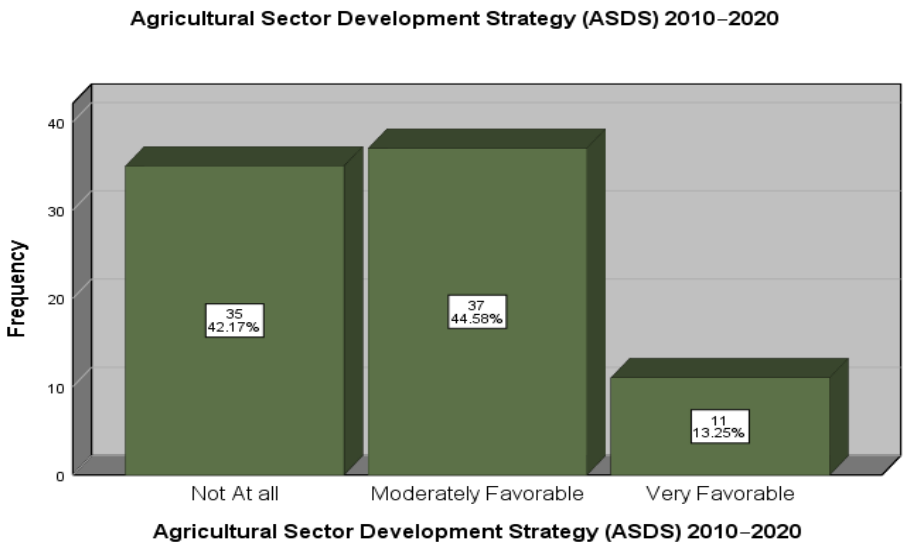

Figure 19: Sufficiency of the ASDS 2010-2020
Source: Researcher (2022).

6.8.Chapter Conclusions

This chapter aimed to explore extent to which ST&I drives Kenya's development as evident from selected key national development plans, as a ground to gauge whether SynBio can be adopted and mainstreamed in NDPs to bolster Kenya's bioeconomy. Based on the triangulation of the data from FGDs, KIs and documentary analysis and gaps analysis based on TAPIC framework, the following chapter conclusions can be made. Firstly, national development planning in Kenya is based on the country's international commitments, which have been domesticated according to the needs and unique contexts surrounding development in Kenya. Secondly, ST&I as a theme for national development has been considered an enabler to the achievement of national development objectives in two key NDPs, namely Kenya Vision 2030 and the Big Four Agenda but is not clearly evident in the other four NDPs analyzed. However, in both Vision 2030 and the Agenda (which expires by the end of 2022) and the other four NDPs, it is difficult to say that TAPIC elements would be adhered to upon adoption because SynBio is not explicitly mentioned neither are there policy and programmatic commitments on bioinnovation/SynBio that would facilitate the development of SynBio in an adaptive anticipatory governance environment.

Lastly, the lack of recognition of SynBio or proper recognition of modern biotechnology which preceded it (see SCBD, 2021) as a central driver of the bioeconomy implies that environmental, health, and socio-economic regulatory issues that come to play when SynBio is mentioned such as: biosecurity, biosafety, bioethics, and social and economic impacts of SynBio are not conceived and mitigation measures put into place. This further reveals that the extent of ST&I utility in NDPs may not be taken as favorable to adoption, implementation and mainstreaming of SynBio into NDPs. This is mainly because specific regulatory issues are not currently embedded in NDPs, hence, the need for further discussions and policy initiatives on how this can be done to facilitate an adaptive anticipatory governance of SynBio upon adoption in Kenya.

CHAPTER SEVEN

AN EXPLORATION OF KEY STAKEHOLDERS' PERCEPTIONS ON SYNTHETIC BIOLOGY AND ITS ADOPTION AND IMPLEMENTATION IN KENYA

7.1. Chapter Overview

This chapter explored the question: what are expert stakeholders' perspectives and expectations on current biotechnology regulatory and development gaps in regards to adoption and implementation of SynBio in Kenya? The assumption made in the chapter was that it is the Kenyan experts that have dealt in biotechnology research, regulation, reporting, and so on, and have the necessary capacity to point to the regulatory and development gaps that my hinder adoption and implementation of SynBio. Their perspectives and expectations on current biotechnology regulatory and development trajectory. The chapter served to complement issues not tackled in chapters 4, 5, & 6 which primarily depended on documentary analysis.

This chapter was grounded largely on quantitative data from survey, but FGDs, KIs and secondary data also came in handy. Expert perspectives and expectations were explored along four thematic areas, namely; SynBio research and development and perspectives on policy processes and SynBio regulatory. At the end of presentation and discussions of each thematic category, a summary is given; whose intension is to interpret the ensuing findings per thematic category into a TAPIC analysis framework. The presentation and discussion format is in a manner that follows after the sub-themes that emerged during FGDs and KIs (interviews), structured as sub-headings.

7.2. National Capacity, Perceived Safety and Risks and Economic Justifications for SynBio technologies

This first thematic category explored regulatory gaps along six sub-themes: 1) capacity of Kenyan Scientists, 2) safety of SynBio Products, 3) SynBio Risk Impressions, 4) Would-be Impacts of SynBio on Religious Belief Systems, 5) Confidence in SynBio as Critical Tool for National Economic Development, and 6) whether investment in SynBio is a Priority relative to other aspects of ST&I. Results from the survey are thus presented and discussed through FGDs and KIs findings.

7.2.1. Capacity of Kenyan Scientists

The first thematic category of questions aimed at establishing expert perspectives on the capacity of Kenyan scientists to undertake SynBio research in a globally competitive manner. As the results show in figure 29; majority (90.16%) at least agreed that the Kenyan Scientists possess the needed

expertise to produce SynBio products for both local and international consumption. 6% had a fair opinion and about 3% at least disagreed on the preparedness of Kenyan Scientists to produce SynBio products of global standards.

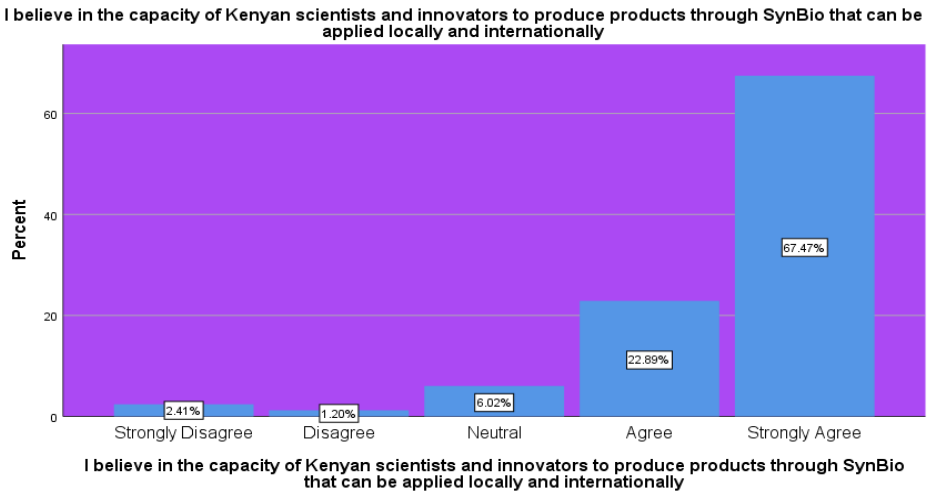

Figure 20: Capacity of Kenyan Scientists

Source: Researchers (2022).

The interviews revealed that there is an ongoing biotechnology work which led to production of three GM awaiting commercialization these include, Bt Corn/Maize, *Bt* Cotton, and lately Cassava which have been successfully produced through Kenyan scientists, proving that have the needed capacity even to produce SynBio products and components. However, most interviews also revealed that biotechnology research and development (R&D) in Kenya has not been driven from within and that experts have only been involved for their expertise by the external funders. This occurrence, respondents felt has contributed to the slow pace of biotechnology development as well as slow pace local capacity building because projects have not been born from within and only a handful of scientists have been engaged in the few projects.

Two important demerits of an externally driven biotechnology research expressed by most experts were: first that this has always led to conflicts of interest between the Government and donors where the Government has been emphasizing public interest such as safety of products while donors have been interesting in facilitating quick production and commercialization of GM products. Secondly, interviews revealed that donor-driven biotechnology R&D has led to a

situation where local expertise has not been properly developed because there have been at any given time only a few or one mega biotechnology study going on. This is despite the fact that Kenya produces thousands of biotechnology and related graduates yearly. In this regard, experts were overly in support of the ongoing NRF SynBio project, funded by the government and implemented 100% by Kenyan scientists through a public-private partnership arrangement, through the ISAAA. One interview excerpt captures this quite aptly:

> ….I think this is why we have very brilliant scientists in biosciences in the country Kenya but whose names cannot feature anywhere in terms of original thinkers or innovators. Maybe the NRF SynBio Project is an opportunity and place Kenyan scientists on the global biotechnology radar (Key Informant Interview with a Biochemistry Lecturer, 12th Dec 2021).

These findings are in tandem with Pamela (2006) who while studying the possibilities and limits in the regulation of GMO in Kenya and South Africa found that the two countries have legal and policy frameworks but GMO research as often as not funded from the outside. This way, donors tend to push for their interests which usually is to ensure that GMO studies are done very first, tests done and commercialization done which often is in contrast to the needs of the government through her regulators which must follow due process, which is obviously marrerd with slowness.

To ensure that this overwhelming support for local capacity is turned into opportunity for adoption of SynBio, the government will have to put into place policies and legislations that psell our the allocations it needs to spare for SynBio, so as to limit the challenges owing from externally funded biotechnology projects. This way, the GoK will be able to take charge of her bio-innovation, and produce even in surplus to meet external market in the process enhancing her GDP, and bridging current gaps in developing funding which forces her to borrow from developed countries. Trump (2017) makes this point when he asserts that in countries like Singapore, the government plays a key role in funding multiple SynBio projects, symposium and discussions. This way, Singaporean Governemnt has gain dominance in SynBio market and has been able to export her expertise to other small countries through funding, hence gaining allies for furture trade in SynBio products.

7.2.2. Safety of SynBio Products

Other than capacity as a determinant of current biotechnology development, the study also explored the perceptions and expectations of experts on the safety of SynBio products. After such

general exploration, the researcher then narrowed down to NRF SynBio Projects. The findings revealed that most respondents, 88%, had reservations concerning the safety of SynBio products. From FGDs and KIs study revealed two important aspects of safety. Firstly, experts said that SynBio is still new and there is no existing database from which the real risks can be known and mitigation mechanisms put into place. On this, most expressed that the "precautionary principle" which is called for in the Kenya Biotechnology Development Policy, can be applied. Nevertheless, experts expressed that much still need to be done even with precautionary principle as it exists in the Biotechnology Development policy. One expert argued during an FGD:

> Even with the application of the precautionary principle, study showed that TAPIC elements, especially would not be realized unless a policy and a legislation on SynBio are put into place to guide to its R&D (3^{RD} FGD).

Secondly, experts argued that there is need to adopt a case-by-case approach in speculating about safety of SynBio products. These arguments from FGDs and KIs reveal a more cautious notion on safety of SynBio products in contrast to the outright (88%) fear from the survey that these products may not be safe during the survey.

During the qualitative research, the researchers took a keen interest on the SynBio products being constructed the NRF Project (biosensor and rapid diagnostic kit). Study found out that there are no safety issues regarding the two SynBio products; the rapid diagnostic kits and the biosensor. This is because these products are only testing tools and so have no genetic interactions with the surfaces they will be introduced to. The issue of case-by-case regulation, or safety considerations emerged, however, when experts expressed that other products of SynBio which are to be introduced into the human beings, or plants, or into the environment generally, in the form of medication, food, biological systems, or any other, may portend several safety implications because there is possible of the components of the products interacting with the biological components of the new environments they would be introduced to. There is need thus for regulators to have reference data on such potential risks and lay the needed mitigation measures in place, this way, a TAPIC environment would be created where procedures and institutions concerned with SynBio exist as a matter of law and policy with clear regulations. From secondary data, the UK Parliamentary Office for Science and Technology (2015) points to the need for Kenya to learn from global practice even as it explores an adaptive anticipatory governance framework for SynBio. It argues

that in the UK, risk assessment is based on a precautionary principle laid out in two key European Union (EU) Directives: Directive 2009/41/EC, Off. J. Eur. Union, 75–97, 2009 and Directive 2001/18/EC, Off. J. Eur. Communities, 2001. Three concepts driving risks assessment of SynBio products in the UK include:

a. Case-by-case approach. All activities that involve GMOs are considered on a case-by-case basis depending on the scale of the activities, the nature of the manipulation and the specifics of the environment.
b. Step-by-step principle. This is applied where the ultimate application of an organism involves its release to the environment. It involves gradually reducing containment and increasing scale when evaluation of human and environmental health indicate it is safe to do so.
c. Comparative analysis. For release to the environment, the novel organism is compared against a 'wild-type' (non-GM) comparator in order to determine if there is a possibility of increased risk. For contained use, the characteristics of the parent organism and any introduced traits are used to estimate a risk level for the novel organism and select an appropriate level of containment (UK Parliamentary Office of Science and Technology, 2015, p. 3).

7.2.3. SynBio Risk Impressions

The researcher followed up the question on safety with the question: "what is your impression about the risks and benefits of SynBio". As summarized in figure 20, somewhat diverging findings emerged relative to the safety question above. While it would be expected that because majority had safety concerns they would agree that risks outweigh benefits, the reverse was true with 57.8% agreeing that SynBio benefits outweigh its risks, while 32.5% and 9.4% said "benefits equal risks" and "risks outweigh benefits", respectively.

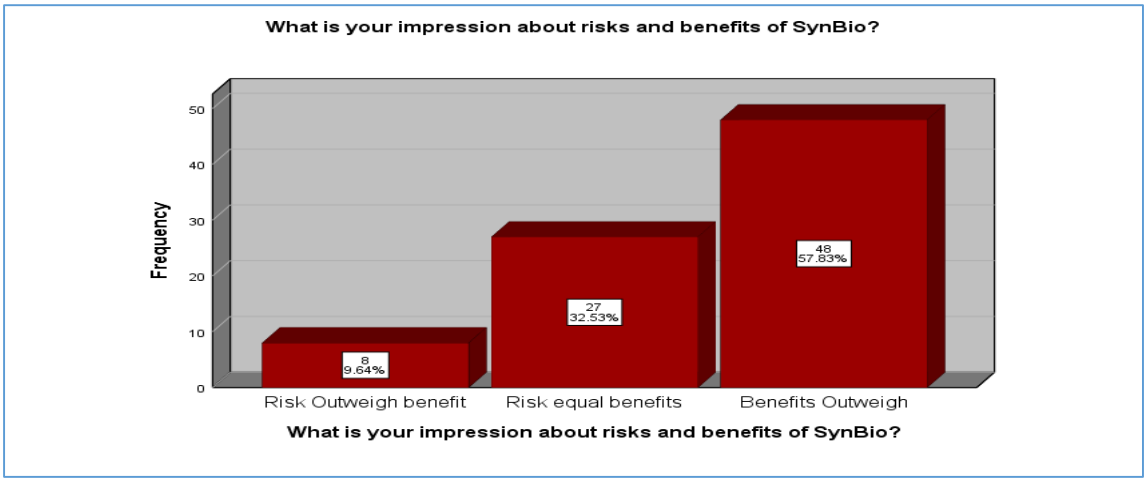

Figure 21: Expert Impressions on Risks & Benefits of SynBio
Source: Researcher (2022).

This question revealed a more optimistic attitude towards SynBio R&D. While it is important to note that the key informant interviews were based on an experts sample and may not reveal the perspectives of the general public (those who are unaware of the technicalities of SynBio), it can be can deduced nonetheless, that because the R&D of SynBio in Kenya will first and foremost be determined by the perspectives of expert stakeholders from academia, policy, regulatory, governance, industry, media and communication, medical and other key sectors, the optimism should be welcomed. Also key to policymakers, from this finding, is the fact that there is still need to identify and reduce to negligible levels the fears concerning safety and risks of SynBio because those pessimistic attitudes can negatively affect adoption, implementation and further R&D of SynBio.

This could have an implication for R&D of SynBio because if more people have safety reservations about the technology, they would likely not support its adoption an implementation or take part in related research studies. On the other side of the argument, if more people report that they feel the benefits of the technology outweigh its risks then it could be a pointer to smooth adoption, implementation and further investment in R&D of SynBio in Kenya, because this could imply that

the technology may make tremendous contributions to the many challenges facing Kenya's bioeconomy sectors[29].

7.2.4. Impacts on Religious Beliefs and Practices

The study also explored respondents' perspectives on the implications of SynBio on their religious belief systems. Across the globe, there have been claims that SynBio presents an opportunity for scientists to "play God" by "creating life" which is a reserve only for God (see, e.g., Andy, 2020). While scientists-especially genetic engineers, have responded to these claims by differentiating between the concepts creating and constructing (*Ibid*), by asserting categorically that they are not creating but "constructing life" for the betterment of humankind which is the primary intension of the creator, who is God himself, religious suspicions still remain high on what exact impact complex SynBio innovations such as the notion of "designer babies" (Jayanti, 2020), "synthetic pigs" or customized (DNA-sensitive medication and pharmaceutical products) may mean for the supernaturalness* of God (see, e.g., EU, 2012). The study explored this question to understand how such notions and grounds for anti-SynBio debates play out in the Kenyan context, within the prism of regulatory gaps. As the figure 21 shows, cumulative percentage of 59.04% of the respondents at least agreed that in one way or another their religious beliefs are at stake when SynBio is adopted and implemented in Kenya.

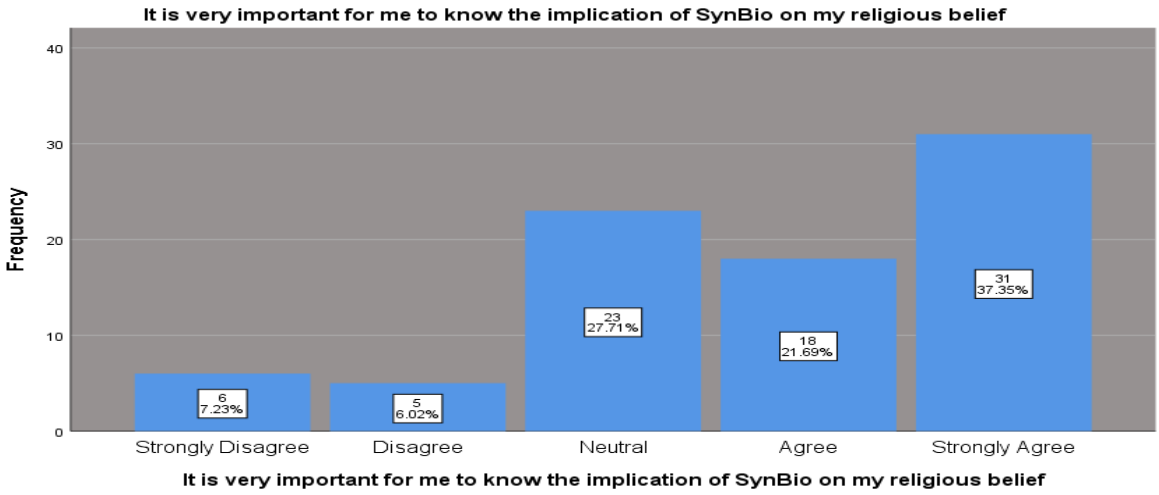

Figure 22: Implications of SynBio on Religious Beliefs

[29] In their "The Knowledge Based Bioeconomy (KBBE) in Europe: Achievements and Challenges", Albretch et al. (2010) defines the concept as The bioeconomy is the sustainable production and conversion of biomass, for a range of food, health, fibre and industrial products and energy, where renewable biomass encompasses any biological material to be used as raw material."

Source: Researchers (2022).

The message to policymakers and regulators from this finding is that the religious community is an important stakeholder in SynBio R&D. As a matter of fact, a senior scientist from private research institution expressed:

> The religious community cannot be ignored. In fact when it comes to issues of biotechnology, is you ignore churches like the Catholic Church, you may do all your things in the laboratory but end up with them rejected by the public primarily based on the anti-science perspective perpetuated by the Church. What we have been doing and what policy makers and Kenyan regulators should do is to involve them from the very beginning of such studies (Key Informant Interview with a Senior Research Scientist from a key International Research Institution based in Kenya, 18th Feb 2022).

The message to policymakers and regulators from this finding is that the religious community is an important stakeholder in SynBio R&D. As a matter of fact, a senior scientists from private research institution expressed to us during the study:

> The religious community cannot be ignored. In fact when it comes to issues of biotechnology, is you ignore churches like the Catholic Church, you may do all your things in the laboratory but end up with them rejected by the public primarily based on the anti-science perspective perpetuated by the Church. What we have doing and what policy makers and Kenyan regulators should do is to involve them from the very beginning for such studies (Key Informant Interview with a Senior Research Scientist from a key Research Institution based in Kenya, 18th Feb 2022).

7.2.5. Confidence in SynBio as Critical Tool for National Economic Development

To further explore the first thematic area, the study explored expert perspectives and expectations on whether SynBio was a really needed technology and an indispensable component of Science Technology and Innovation (ST&I) whose investment should not considered an opportunity cost. As summarized in the figure 22 below, there is a tremendous support that SynBio is a tool for

economic development in Kenya. An overwhelming 89% (74/83) of the respondents expressed a favorable opinion on the matter, 6% had a fair opinion and about 4% at least disagreed.

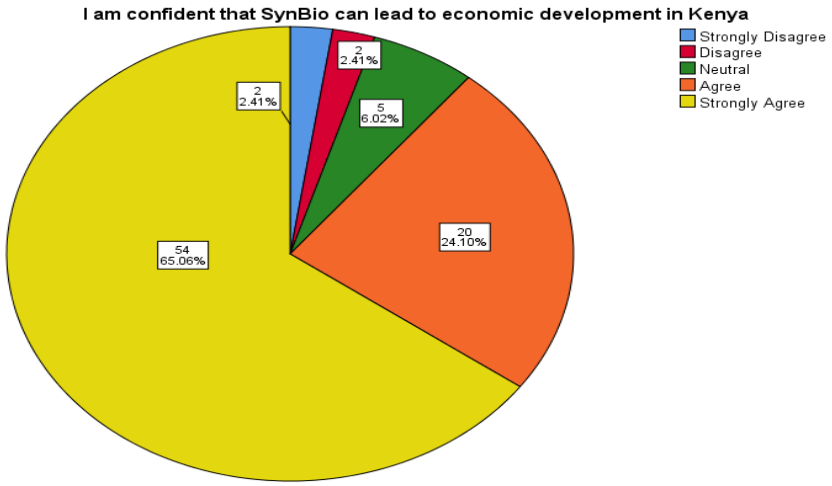

Figure 23: Confidence on SynBio as a Tool for Economic Development

Source: Researchers (2022).

Experts further revealed in the qualitative discussions that SynBio has multiple applications to several sectors, ranging health, agriculture, energy, climate change and environmental management among others. Experts argued that these sectors face serious challenges most of which may not be solved if the country fails to adopt SynBio. Such benefits have been extensively discussed in chapter in light of objective three.

7.2.6. Necessity of Investing in Synthetic Biology

To wrap up this thematic category, the study explored the question on whether investing in SynBio is a priority relative to other aspects of ST&I, such as nanotechnology, artificial intelligence, Information Communication Technology (ICT) among others. The results were very encouraging and pointed to an absolute support by the study expert sample for Government investment in SynBio, not just for the sake of it, or because it is the new normal, as a "goldmine" technology with multiple application to multiple sectors. As evident in figure 23 below, the histogram representation of the findings is skewed to the left, implying most respondents disagreed with the statement that government should invest in another technology and let SynBio be an opportunity cost; connoting that the Government is justified to invest in SynBio. This points to a very important

point: that Kenyan biotechnology experts feel that SynBio is a priority ST&I and which the government should consider in its annual funding. These are in tandem with Reagan et al. (2022) which established that SynBio portends immesnse potenatial for the transformation of developijng countries, especially those that have GMO frameworks such as Kenya and South Africa, and whose main task should be to understand the current gaps in existing regulations and ensure that needed technology investment mechanisms are put into place.

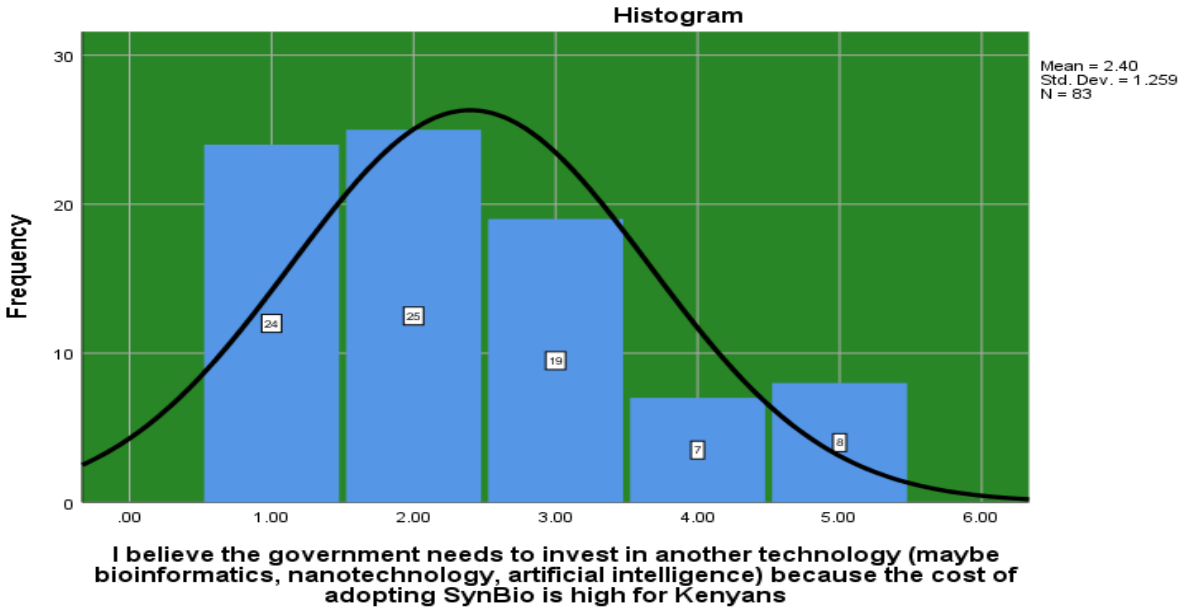

Figure 24: Support for Investment in SynBio

Source: Researchers (2022)

Summarily, this first sub-thematic area explored questions relevant to capacity aspects of the TAPIC environment. Generally, the study revealed that biotechnology development is not where it is because of lack of qualified Kenyans but due to other factors. There is a good support (over 90%) that Kenyan scientists have produced biotechnology products are can produce SynBio products. The second sub-thematic area touched on transparency, accountability and integrity questions of the TAPIC framework. It revealed the feeling that safety issues would be at stake (88%) upon adoption and implementation of SynBio everything remains constant. The finding reinforces the findings on chapter four and five which showed that regulatory issues (biosecurity, biosafety, bioethics, and socio-economic impacts) of SynBio are currently not covered within the existing policies and laws regulating biotechnology hence the feeling by experts that this leaves

room for concerned institutions, actors and processes to be regress integrity, practice lack of transparency, and be unaccountable to the public for their actions.

Sub-theme 3 (impressions on risks) is a further ground calling for the need for legislations and policy which clearly states what risks would emerge from what case of SynBio products and what mechanisms would be applied by whom (transparency) and who will they be answerable to (accountability). The sub-theme on religious believes cuts across capacity and participation questions of the TAPIC. On one hand, it points to lack of capacity of the current regimes to project Kenyans against negative impacts of SynBio on their religious belief and practice systems. On the other hand, it points to the need for policy makers and regulators appreciate the significance of religious constituency in SynBio processes, or else such processes meet with unimagined opposition due to fears of technologies negative impacts on religious practices and beliefs.

7.3.Synthetic Biology Policy Process and Role and Significance of Actors

On this sub-section, study aimed to explore expert perspectives and expectations on policy processes and role and significance of actors. The section explored experts' perspectives and expected content of a SynBio policy and role and significance of five actors: experts, government sponsored experts, politicians, business/industry community and the research community. The presentation and discussions are made under the following sub-headings. The section also explored experts' perspectives and expected content of a SynBio policy.

7.3.1. Conception of Policy Content

The first question explored the kind of vision respondents had regarding the form of public policy the government should adopt to ensure effective and efficient adoption, implementation, and further R&D of SynBio. The respondents were presented with a list of public policy definitions adapted from Anyebe (2018). According to Anyebe (2018) public policy studies is a challenging task, first and foremost due to a lack of a clear conception of the concept and what its subject matter is or at least should be. He asserts that whatever definition or understanding of public policy a government adopts leads to the actual things that government ends to do. It is important there, according to Anyebe (2018) and in the context of the study, that favorable understanding of public is adopted. Anyebe (2018) then proceeds to evaluate several definitions of public policy and arrives at the conclusion that public policy should *be actual resource allocation presented by projects and programs designed to respond to perceived public problems and challenges requiring government*

action for their solution. This and other definitions criticized by Anyebe (2018) were given as the choices for respondents. The results were as summarized in the figure 24 below.

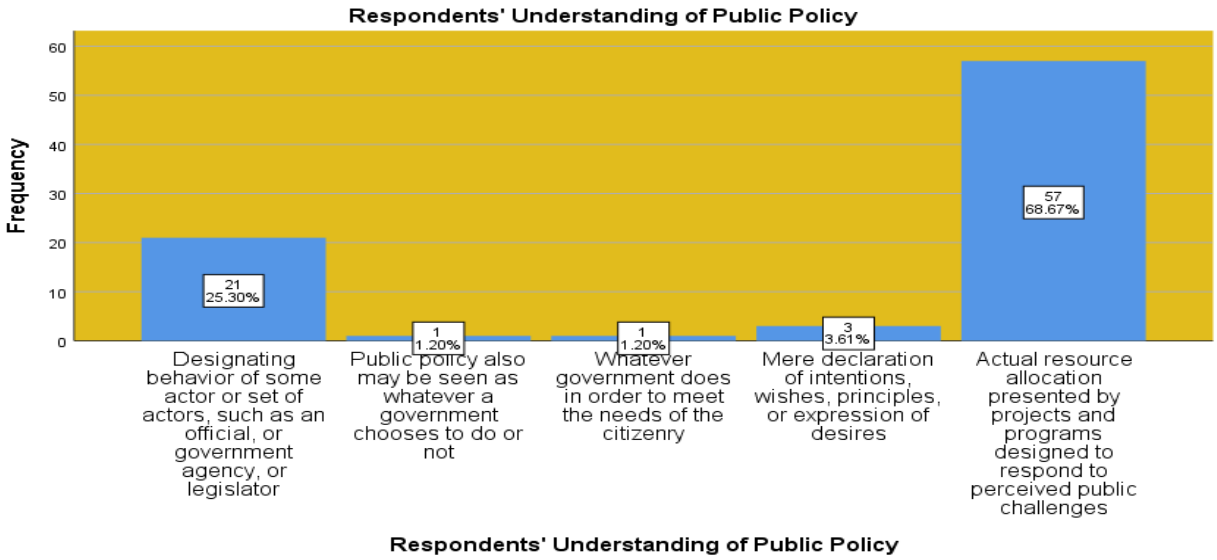

Figure 25: Respondents' Understanding of Public Policy

Source: Researchers (2022).

The figure above shows that a majority (68.7%) (57/83) of study sample agreed with the most correct conception of public policy as argued by Professor Anyebe, that public policy in the context of formulating a robust SynBio policy should: "designating behavior of some actor or set of actors, such as an official, or government agency, or legislator". And only about 6% chose other definitions as correct. Two implications for this finding are as follows: a) most of the respondents chosen understood what public policy is and what it should involve within the context of SynBio. b) Respondents conception of the most suitable public policy conception to facilitate adoption and implementation of synthetic biology and bolster its further R&D is that which will ensure that the Government of Kenya goes beyond the policy pronouncements about SynBio to set aside funding for projects and programs that will implement the concerned policies, legislations and development plans.

One participant from the FGDs reinforced this as follows:

> For Kenya to realize her ambitions with the SynBio technologies, words must be changed to actions. Commitments must be practiced. Even if this study led to formulation of a

SynBio policy, if the document is not practical with specific programmatic recommendations, nothing different will happen from what we have observed with current biotechnology development in Kenya (3rd FGD).

7.3.2. Role and Significance of Actors

The study also explored the perspectives of the sample on the significance of different actors in the making of a public policy for SynBio. The researcher began by exploring opinions on the role of Kenyan biotechnology policy experts as players when it comes to making SynBio policy. As the figure 25 below shows, study revealed that only 27.7% had a favorable opinion that public policy making is a domain for experts only. The greatest number (44.6%) had a fair opinion to the statement and another 27.7% at least disagreed that public experts had no role whatsoever in SynBio policy making.

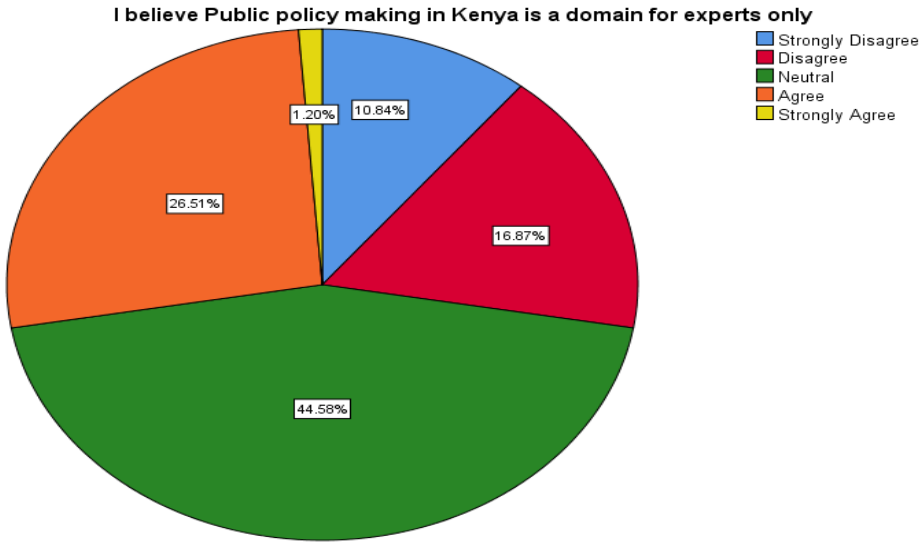

Figure 26: Respondents' Understanding of Public Policy

Source: Researcher (2022).

The second question of role and significance of actors explored the role and significance of government-sponsored experts as the only key players in policy processes of SynBio. As summarized in figure 26 below, the results revealed that only 12% had a favorable opinion about government experts' role and significance SynBio related policy. 43% had a fair opinion while a majority (44.6%) at least disagreed that only government experts should play a role in policy processes concerning SynBio.

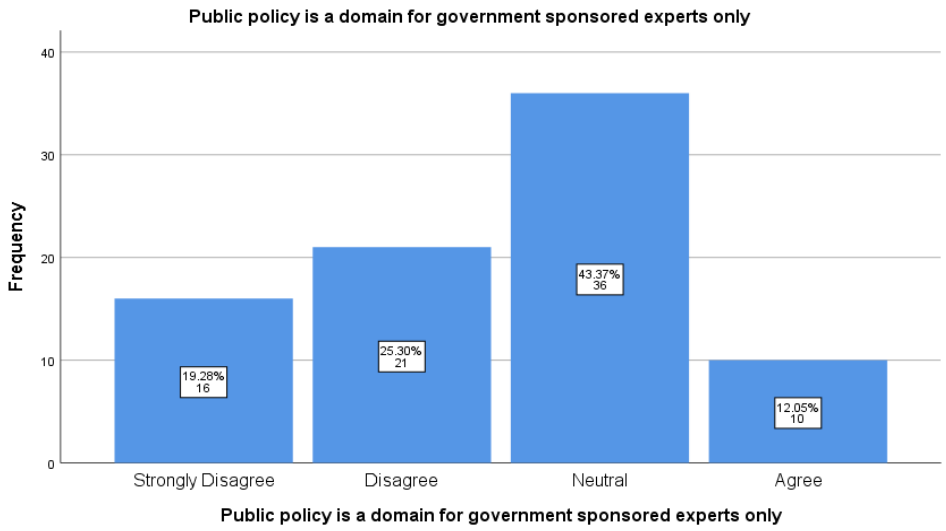

Figure 27: Government-sponsored Experts in SynBio Policy

Source: Researcher (2022).

The implications of the first two questions are as follows: that majority of respondents thought public making process for SynBio does not just concern experts only but also the general public. One interview captured this assertion succinctly, thus:

> We should never think that the technology only concerns the experts. Yes the experts will play a key role, but if we stop there, we shall have done nothing because where are we taking the products to? It is the general public (Key Informant Interview with Regulatory Personnel).

Therefore, it is important for the regulators, policy makers and government communication departments to have a concrete outreach tool to the general public, first to educate and raise their awareness and secondly to involve their participation in the policy formulation processes concerning SynBio. This will not only boost the acceptance of the final products which can be produced through SynBio. It will also ensure that there is a clear connection between the researchers, the policy makers and the consumers, who are the general public. An expert in plant and genetic engineering captured this notion as follows:

> What has affected commercialization of GM crops in Kenya is, in part, the disconnected way of doing things. The researchers, the policies and policy makers, the mainstream

academia, and the consumers operate in their own worlds, with the consumers the most forgotten. This must stop. We must work together, we must involve everyone, including the citizens who do not even know what the science means (Key Informant Interview with a Plant Genetic Engineer).

The study explored the significance of the role and significance of politicians as an actor in SynBio policy processes. As evident in figure 27, a more similar trend was observed. Only 18% had a favorable opinion that politicians in deed would play a role in policy processes concerning SynBio, majority (43.3%) had a fair opinion, and a cumulative 38.6% expressed an unfavorable opinion about the role of politicians in SynBio related policy processes.

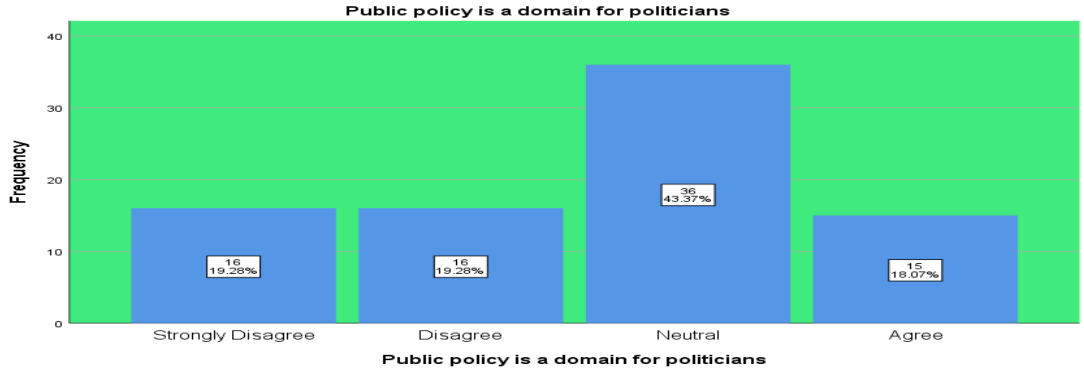

Figure 28: SynBio Public Policy Making as a Domain for Politicians

Source: Researcher (2022).

This finding is rather alarming because while public policy making is first and foremost the role of the political leaders, since political will is critical element as already revealed in the first thematic category. The study explored this contradiction further through interviews. What emerged was that the history of biotechnology in Kenya has been mired with policy red tapes and what some experts called "unnecessary regulatory bureaucratic bottlenecks". Study found that situation this as due to policy gaps in the Biotechnology Development Policy where politicians roles are not well provided for yet these politicians or political appointees such as cabinet secretaries have the final say on whether a GM crop gets commercialized in Kenya or not. Explaining the history of the GMO import ban in Kenya which was effected in 2011, one key informant expressed that:

> …take for example, we have had challenges with the commercialization of GM crop despite completed field tests and environmental impact assessments done by experts that proved the products to be safe. This is partly because the biotechnology policy does not come clear on the extent to which key political actors such as the Minister for Public Health can or should play. Concerning the GMO import ban which we operate under to date, it was the cabinet minister who due to lack of knowledge on GMOs as a political rather than an expert appointee to the docket of a Cabinet Secretary of Health imposed a ban based on an invalid journal paper which tried to prove that GMO foods caused tumors in rats. The paper was later removed from the journal because it was unscientific. So politicians have actually been creating "unnecessary policy and regulatory bureaucratic bottlenecks" instead of supporting biotechnology development in Kenya (Key Informant Interview with a Plant Genetic Engineer).

As the country moves on from GMO 1.0 to GMO 2.0 or SynBio era (TWN, 2018) such lessons learnt brought traditional and modern biotechnology should inform the formulation of robust policies and laws that will be devoid of regulatory dilemmas, by spelling out very clearly the roles of individual institutions on the specific stages in the life cycle of SynBio products development.

The study also sought to explore would-be role and significance the business community could play in policy processes concerning SynBio. Unlike politicians and experts, the study revealed a tremendous support to the leadership role that the business community can bring on board. As shown in table 7, only 2.4% disagreed or strongly disagreed with the statement, 13.41% of the respondents had a fair opinion, and an overwhelming 84.1% had a favorable opinion that the business community can play a lead role in SynBio policy processes.

The business community plays a lead role in policy

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Strongly Disagree	1	1.2	1.2	1.2

	Disagree	1	1.2	1.2	2.4
	Neutral	11	13.3	13.4	15.9
	Agree	38	45.8	46.3	62.2
	Strongly Agree	31	37.3	37.8	100.0
	Total	82	98.8	100.0	
Missing	System	1	1.2		
Total		83	100.0		

Table 7: Role of Business Community in SynBio Policy Making

Source: Researcher (2022).

From interview results three main reasons were suggested as an explanation to the significance of the business community or the industry in policy processes of SynBio namely:

i) Experts reiterated that biotechnologists and researchers and academicians and the related industries have been working in a vacuum. Hence, study revealed that the lack of involvement of the business and industry sectors is a key issue and the "missing link" to unlocking biotechnology potentials in Kenya. SynBio policy and related processes, this should involve the business/industry fields as key actors.

ii) The business community understand the real gaps about innovative solutions to solving societal problems. They should actually be ones pushing for the adoption of SynBio and other bio-innovations as opposed to researchers whose objectives are usually short-term, ending as soon research funding is depleted.

iii) That working with the business community will solve the challenges of the many unemployed and wasted students graduating with biotechnology, genetic engineering, and related fields but end up working in the supermarkets and other unprofessional fields because there are no industries to absorb them. One expert said:

> Involving biotechnology related industries and businesses, and building their capacity will create job opportunities and enhance innovativeness of biotechnology

students and experts to pursue product development pathways which are businesses/industry oriented (1ST FGD).

Lastly, the study explored the role and significance of the research community as a player in SynBio policy processes. As presented in 28 figure below, 90.36% had a favorable opinion that the research community should play the primary role in the provision of the needed evidence to inform policy making and implementation; 6.34% had a fair opinion and 1.20% had an unfavorable opinion. Compared to the other actors, this was the highest rating on actor role and significance recorded by the study. This shows the key role that Kenyan researchers have to play in giving direction and working collaboratively with other categories of stakeholders to define an adaptive anticipatory governance environment through evidence-based policy making, and programming for SynBio.

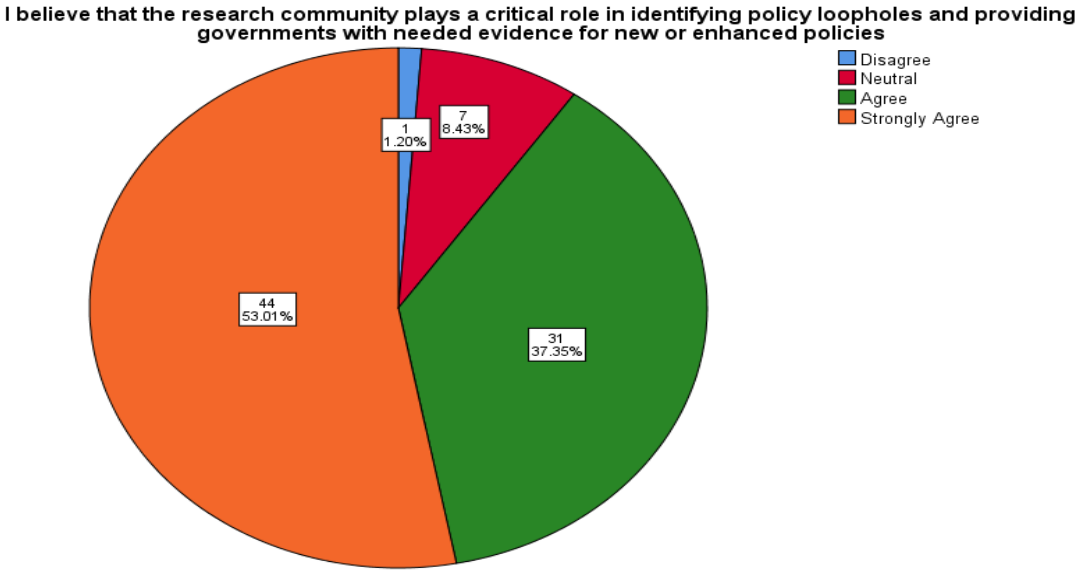

Figure 29: Role of research community in SynBio Policy and Regulation

Source: Researcher (2022).

To sum up, this thematic category aimed at exploring the conception of public policy deemed as appropriate for SynBio is a new context like Kenya, and to explore role and significance of different actors/stakeholders in SynBio policy processes. As results showed; research community received the highest rating at (90.36%), followed by the business community at 84%, expert (27.7%), then politicians (18%) and government-sponsored experts at 12%. These findings reveal

current underlying regulatory and policy gaps in biotechnology development in Kenya since actors (such as the politicians) which should play their role in a facilitative manner have in certain instances failed to act as facilitators of biotechnology development but turned into stubbing blocks to successful biotechnology projects. These are important lessons as the country moves from modern biotechnology/GMOs into the phase of SynBio. Actors should be engaged in a TAPIC environment where the rules of the game are clear in policy and law, and the functions of the institutions concerned are clear and collaborative in a stakeholders' dialogue framework as outlined in the UK Synthetic biology strategic plan (SBLC, 2016).

7.4.Robustness of Current Biotechnology Research and Regulatory System

Under this third thematic category, the study explored experts' perspectives on the overall sufficiency of regulatory institutions currently concerned with biotechnology regulation and research; hence would be the primary institutions for research and regulation of SynBio. The institutions included NBA, NACOSTI, and NEMA and KALRO, KEMRI and Kenya Plant Health Inspectorate Services (KEPHIS) as key research institutions.

In this regard the study first explored general confidence on the sufficiency of current regulatory systems on SynBio. As is observable from the figure 29 below, most (48.19%) had a fair opinion, on the statement; 24.09% expressed a favorable view on the overall sufficiency of the regulation systems; and 27.71% expressed an unfavorable view on the overall sufficiency of the current biotechnology regulatory systems. This implied that generally the regulatory systems are fairly prepared to regulate SynBio. Further analysis therefore explored capabilities of specific institutions to the regulation of SynBio.

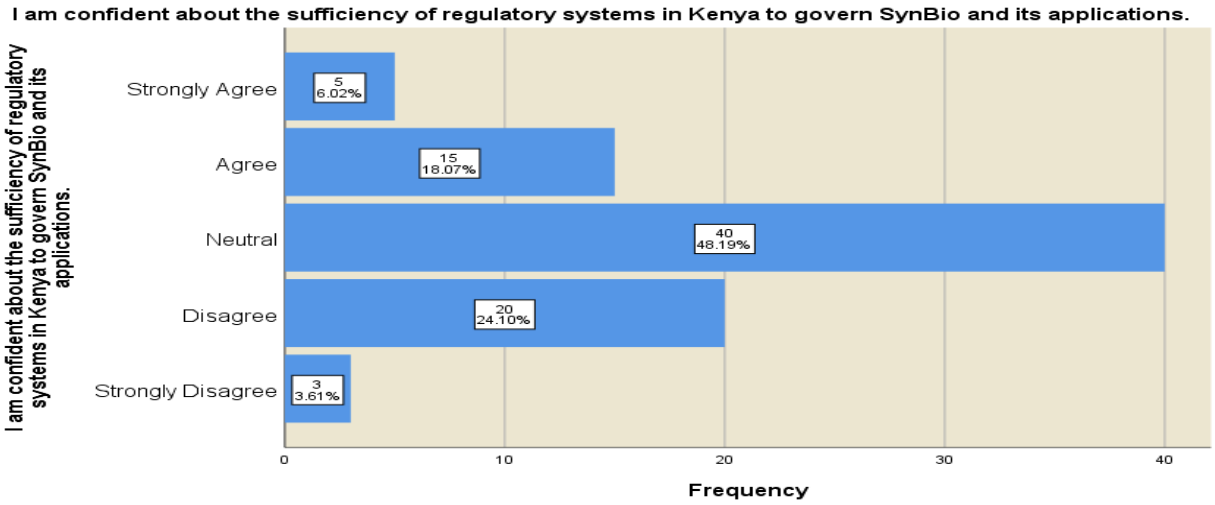

Figure 30: Overall Sufficiency of Biotechnology Regulatory Frameworks
Source: Researcher (2022).

According to the figure 30 below, (86%) had a favorable opinion about the preparedness of NACOSTI to regulate SynBio research, a meagre 3% had an unfavorable opinion and 11% remaining had a fair opinion. NACOSTI is the national research regulator established under the ST&I Act 2013. Other than regulating all types of tertiary research, the institution is a key advisor to the Kenyan Government on matters ST&I and the kind of priorities which the country should pursue. Accordingly, the institution is currently the focal point for global and national SynBio discussions and deliberations and hosts the Kenyan representative to the COP and other international fora on SynBio.

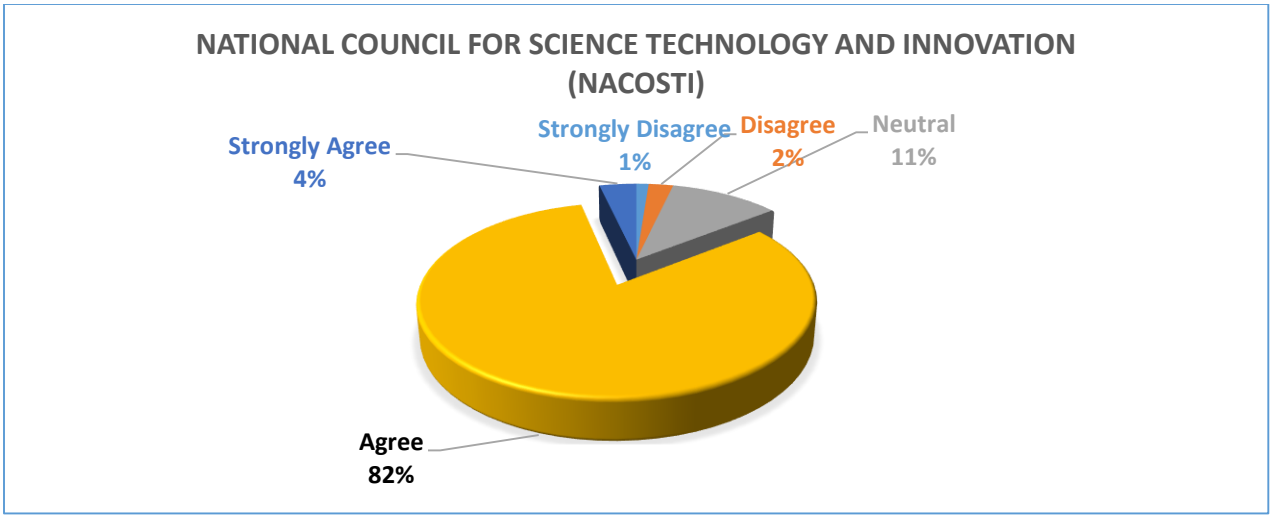

Figure 31: Overall Sufficiency of Biotechnology Regulatory Frameworks
Researcher (2022).

Through interviews the study sought for explanations for the overwhelming support for NACOSTI's capacity to regulate SynBio research. The main reasons were as follows.

i) NACOSTI has several departments and experts leading those departments including for biotechnology. For this reason, NACOSTI may only need to rearrange her departments and fit and equip a SynBio department.

ii) Within the NACOSTI, there is already an expert who represents Kenya to the global debates about SynBio within the frameworks of the CBD. This expertise makes NACOSTI a unique entity because the regulatory and R&D issues, which are still alien to even many of the biotechnologists, and biotechnology research and regulatory institutions, are well known to the NACOSTI.

iii) One interviewee asserted: "On the question of where or who should host a SynBio, I think NACOSTI stands in a better position compared to other institutions. First and foremost because it is within the NACOSTI (of cause through discussions with private sector and researchers) that this idea of SynBio Project was birthed."

The third institution the study explored its preparedness in terms of facilitating research in SynBio was KALRO. As summarized in the figure 31 below, 67.47% held a favorable opinion about KALRO's preparedness, 24.10% held a fair opinion while 8.43% said KALRO was unprepared, i.e., had an unfavorable opinion. From the interviews with KALRO-based experts and from other

institutions revealed similar trend with NACOSTI, and IPR. One key informant's response captures the gist of experts' perspectives on KALRO. She explained:

> I think generally speaking, KALRO is very well equipped to take the work it has been doing with agriculture and livestock biotechnology to the next level. SynBio builds from biotechnology work, and because we have been doing that for quite sometimes now, we have some tools, we have over 2000 employees' researchers, and whatever is still missing is what we can get to spearhead the new area-SynBio… as we speak, there is an ongoing collaborative study with an external university and funders which entails gene editing, though the gene editing is done outside Kenya... (KI with KALRO-based experts).

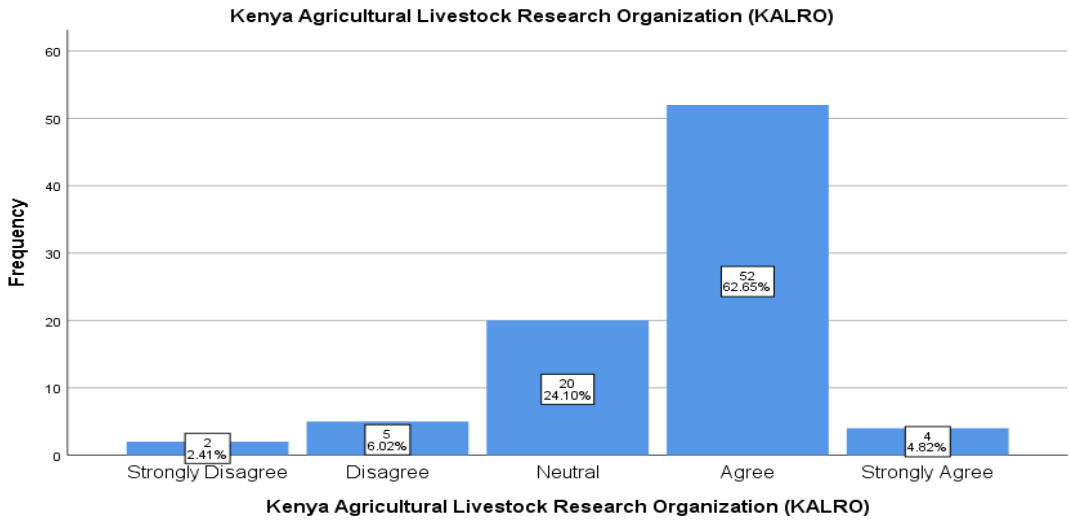

Figure 32: Robustness of KALRO's Current Mandate
Source: Researcher (2022).

Another institution whose preparedness was investigated was NEMA. As the national environmental protection agency, the institution is concerned with any biotechnology (and therefore SynBio) products which would be taken into the environment. It is charged, under the EMCA Act, 2012, to undertake environmental impact assessment of all products going in the Kenyan environment, in effect rejecting or allowing the introduction of those products into Kenya's environment. As such it will be a key regulatory institution in the regulation of SynBio upon its adoption in the country. Whether it is fully prepared or not will thus affect SynBio adoption and implementation. For example, if NEMA lacks the needed capacity to undertake ERA

of SynBio products but still goes ahead to undertake such tasks, the decisions may be unscientific and either way may lead to introduction of unsafe products into the environment or the disallowing of SynBio products which can help solve Kenya's challenges leading to economic development. The respondents' perspectives about NEMA (figure 32) revealed reservations about the NEMA's sufficiency to facilitate successful research and commercialization of SynBio products upon adoption.

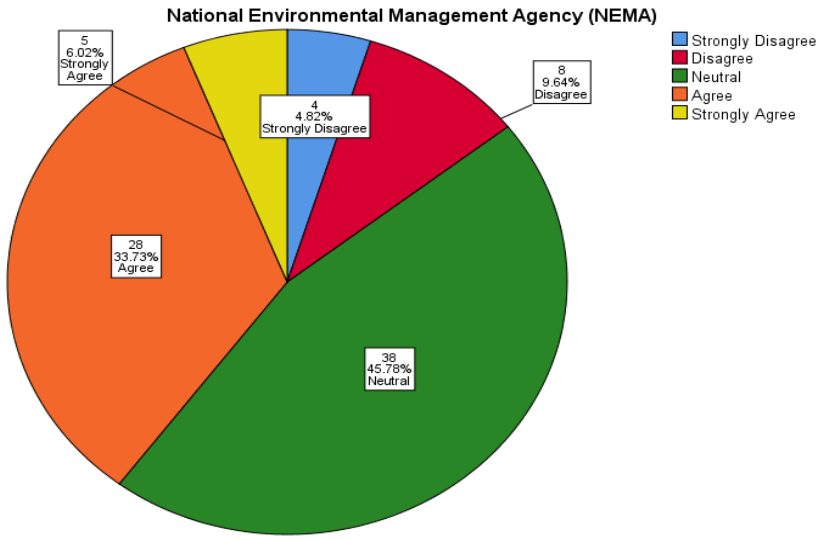

Figure 33: Robustness of NEMA's Current Mandate
Source: Researcher (2022).

A whole 45.78% expressed a fair opinion, 39.75% had a favorable opinion about the preparedness of NEMA while the rest (14.46%) held an unfavorable opinion, rejecting that NEMA was preparedness to guide environmental management issues concerning SynBio. The relatively (compared to KALRO and NACOSTI) low rating for NEMA is also in tandem with Hart Research Associates (2010) that established that the American public's confidence in the various concerned institutions with the regulation of SynBio was lowest for Environmental Protection Agency (EPA) rated at only 36% (closer to the study finding which is 39%) relative to USDA (60%), FDA (57%), and US Department of Energy (52%).

The second last institution the study explored her preparedness was KEMRI. KEMRI is a critical health and medical research institute in Kenya. The institution engages in multimillion projects many of which are closer to SynBio research (3RD FGD), and for example is currently undertaking

studies around malaria, cholera and tuberculosis detection, treatments and even diagnostics. It also hosts nearly all international medical collaboration studies hosted in Kenya. For example it is currently hosting the PRiSMA study which aims to detect pregnancy related diseases using the placenta of a newly born child and through which it is also monitoring pregnant mothers from conception to delivery (KI with a KEMRI-Attaché). This places the institution as a would-be key player in SynBio research especially those that would concern medical and health aspects.

The survey results showed that 60.24% had a favorable opinion on KEMRI's preparedness at, 32.53% expressed a fair position while 7.23% expressed an unfavorable opinion, asserting that KEMRI is unprepared to undertake the kind of research involved with SynBio on medical and health issues. Conclusively, the study thus revealed an above average support for KEMRI's capability to undertake SynBio research.

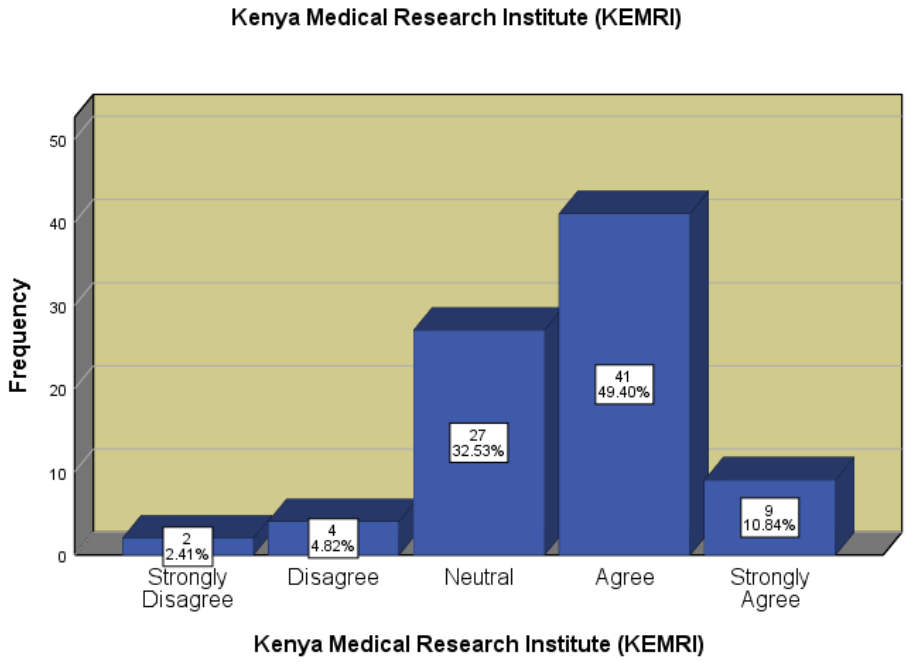

Figure 34: Robustness of KEMRI's Current Mandate
Source: Researcher (2022).

The very last institution whose robustness of current mandate to regulating SynBio research was explored was the National Biosafety Authority (NBA) established under the Biosafety Act, 2009. The institution is charged with regulating biotechnology research and development in terms

overseeing the bio-safety of biotechnology products before they are commercialized. As summarized in figure 34 below, which represents quantitative rating of the NBA's mandate, most (60.24%) experts had a favorable opinion on the robustness of NEMA's preparedness to regulate SynBio technologies, 28.92% had a fair opinion and about 11% said NBA is not prepared to undertake SynBio regulation.

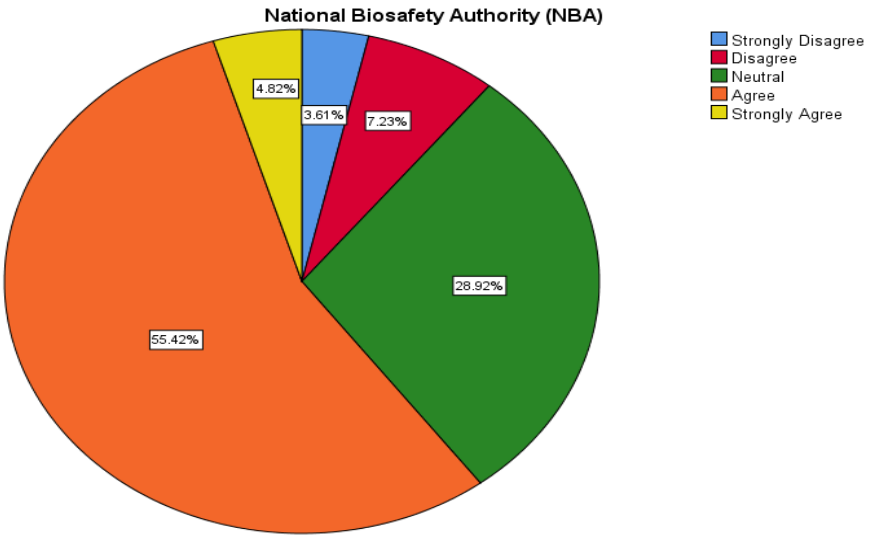

Figure 35: Robustness of NBA's Current Mandate
Source: Researcher (2022).

To put these quantitative results into their qualitative context, the researcher explored the question through FGDs and KIs. A dual approach was adopted to help understand both the perspectives of the high raters as well as of those who had fair and unfavorable opinion. On the first angle (reasons for high rating on the robustness), three reasons emerged. Firstly, experts expressed that the NBA is the only organization which deals directly with GMOs and their biosafety. Hence, because SynBio is primarily a modification or an advancement from GMO science, the institution has a better standing to regulating and facilitating development of SynBio technologies.

Secondly, experts also emphasized that the NBA has been very prompt in clearing up biosafety tests, a role it should play under the Biosafety Act. On this, most respondents compared NBA against NEMA. About the latter, it emerged that it has been acting as a stumbling block to successful commercialization and release to the public of GMO products, despite NBA clearing them. Moreover, NEMA processes are said to be too long hence cause delays to researchers, and

achievement of national goals such as food security when promising GM crops are not commercialized. Thirdly, most experts interviewed emphasized that unlike other relevant bodies to the biotechnology regulation in Kenya, NBA has been effective largely because the top employees have been those who qualify, i.e., have been properly trained on issues biotechnology, bio-engineering, bio-chemistry and related fields.

On the second dimension of the question (reasons for lack of 100% agreement that the NBA mandate was properly equipped), two reasons emerged. Firstly, most respondents argued that the NBA has not been keen on awareness creation and public education. One respondent summarized this point, thus:

> It is the NBA, they have a big role in regards to public awareness creation but they just seem not to know what they are supposed to do. They should create awareness of these things. That awareness should involve telling the population what the technology is about, why is the technology important, what are its harmful sides and how significant is the harmful sides (KI Interview with Animal Genetic Engineer).

This is an important point to note going forward (moving from traditional biotechnology into SynBio). There should be a clear framework of public awareness creation and education for what exactly SynBio is, what products can it lead to and what facts and myths accompany the public perceptions about the technology. While the country has the Biotechnology Awareness Strategy, experts felt that this strategy has not led to any concerted efforts by the Government to promote education and awareness on biotechnology issues, and much of the publicizing work has only been done by the private sector. Additionally, experts emphasized awareness and sensitization about biotechnology and now synthetic biology is not and should not simply be targeted at the general public or consumers. This is because most critical persons in other relevant Government departments and even agencies who should promote biotechnology in the country. An expert explained this as follows:

> I have had several interactions with most of the lead officers in government agencies like public health, KENIA, and many others. One thing which I know for sure is that the level of awareness of biotechnology (let alone SynBio which is now new) is very low. This has affected biotechnology development because key people who should support

> biotechnology ideas from private scientists and even government-donor collaboration projects have stood against those projects and are simply disinterested. That is why one policy maker burned GMOs in 2011 without any scientific foundation (KI Interview with an Expert from Program for Biosafety Services).

Another expert expressed during one FGD that such key person should be the target especially if SynBio is aimed to facilitate radical changes in Kenya's bioeconomy. He argued:

> What should be done before even we think of educating and creating awareness to the public is to sensitize this critical population and win their support. Awareness and support at this level is what will count because the public are actually looking up to these people, if they believe in the myths surrounding SynBio and biotechnology and they take negative positions such as the GMOs import burn, we can only expect that the public will not accept the technology as well (Zoom KI Interview with Senior Environmental Scientist and Researcher)

The second loophole experts reported affects NBA work and would affect it with the regulation of SynBio was that as it is today, it concentrates only on plant and agricultural biotechnology. A key informant said:

> What is happening is that the Biosafety Act was enacted with only plant and agricultural biotechnology as the priority biotechnology areas. So if the NBA was created by the Act, it cannot perform more than that. This will affect SynBio development and regulation because SynBio cuts across plant, animal, and human, and we cannot say that the NBA is prepared to cover these other areas of biotechnology (KI Interview with Senior Environmental Scientist and Researcher).

Related to the issues of concentration on agricultural biotechnology is the theme of biosecurity. Under this sub-theme most participants reported that the Biosafety Act covers GMOs within the understanding that these are safe products once the cycle of testing and other procedures are met. In regards to SynBio, however, experts expressed fear that risks go beyond just biosafety to include biosecurity; that synthetic biology products and components can be used by careless scientists as weapons of mass destruction. This is also a recurrent theme in SynBio regulation literature (Trump,

2017; National University of Singapore, 2015; Kuiken, 2015; Marris & Calvert, 2018; TWN, 2017; Wikmark et al., 2017; Kolodziejczyk & Kagansky, 2017). Hence a serious task for policy makers in order to mitigate this challenge in Kenya is to lay anticipatory mechanism to mitigate biosecuty risks when they rise. Reinforcing such a need, a university-based academic asserted that:

> So am saying when I think about the Biosafety Act, I feel like there is a problem in Kenya because it only covers biosafety as it relates to plants-agriculture. But laboratory biosafety which involves SynBio generally is not covered. It is not covered under the biosafety act, it is covered under the bacteriological weapons convention (BWC). So for that reason in terms of the regulation when you want to regulate SynBio I don't know which one now will be revised, the act alone or the others too, and then I don't know if we have a domesticated version of BWC and that is an area that is in dire need. Yes. It is true Kenya has acceded to those but we don't have an act, so we are likely to create a new act and anchor all these biosecurity issues related to SynBio (KII with a Biotech & Public Health Lecturer, Kenyatta University).

7.4.1. Perceptions and Expectations on Institution (s) to Host Synthetic Biology

From the discussions on the theme of robustness of regulatory institutions, a sub-theme, what institution and/or sector of the economy should host SynBio, emerged whereby most experts expressed that it is the Ministry of Industrialization, Trade and Enterprise that should host and spearhead the SynBio agenda. The reasoning given was that this is a global practice, where countries advanced in SynBio have created linkages between innovators and researchers and the business and industry. In the UK for example, the industry sector do not only play a critical role in implementation of SynBio ideas but is was and remains a key partner in policy making as evidenced during the processes leading up to SynBio Strategic Plan inaugurated in 2016.

A second perspective supported the Institute of Primate Research (IPR) as better placed to spearhead SynBio. The experts from IPR pointed to the milestones they have made in SynBio-related studies and the collaborations which they have managed to foster with external and internal donors and researchers. A third perspective justified NACOSTI (for reasons already discussed). Within the scope of this study, the main contribution is the revelation that there exist divergent views on who is prepared to undertake SynBio research as the primary referent institution, a subject which should be a function for further national debates and discussions.

Conclusively, this thematic category explored institutional capacities of three regulatory institutions (NACOSTI, NBA and NEMA), and two research institutions (KEMRI and KALRO) and these five institutions are vital for both research and regulation of SynBio in Kenya. Based on the presentation and discussion foregoing, it is clear that that institutional preparedness in terms of what these institutions currently do or should do, there is the requisite capacity for them to undertake research and regulatory of SynBio. That is to say, NEMA rated at 45.78%, all other were rated at above 60% whereby NACOSTI (86%), KALRO (67.47%), NBA (60.245), AND KEMRI (60.24%). However, based on a TAPIC interpretation of current work of these organizations, viewed holistically and informed by findings from previous chapters, gaps still exist which need be filled for these institutions to function properly as they research and develop SynBio technologies, tools and products as well as regulate SynBio processes. Based on the 14 questions derived from the TAPIC framework (refer to section 1.7.1) the following analysis is made.

To begin with, on transparency, it is clear from chapter 4 and 5 that no SynBio policies currently exist with clearly stated scopes (Q1), hence these institutions are not guided by any specific rules related to SynBio research and regulation (Q2), and there are division of labor on what which organization should play in regards to research and regulation of SynBio (Q3).

Secondly, concerning accountability questions, it is clear that because SynBio is not currently explicitly regulated by any of the biotechnology regimes, these organizations cannot be held accountable for their actions or inactions concerning SynBio (Q4). However, existing procedures such as those from NBA and NEMA may be modified or adapted, but still cannot be applied raw particularly for those SynBio products which are made from compounds of GMOs (Q5) (see SCBD, 2021 under literature review).

Thirdly, based on the participation element of the TAPIC framework, currently, there are no forums within these organizations that bring together people from academia, industry and government and private sectors to discuss and advice the government on the best pathways to pursue in R&D of biotechnology, hence SynBio (Q6) as is the case in the UK (SBLC, 2016). Accordingly, on integrity, none of these institutions have in place clearly stated performance standards guiding neither research nor regulation of SynBio processes and products (Q8) and none has a stated mission directly linked to SynBio regulation and research (Q9) however, activities

undertake n by these organizations relate to some processes involved in SynBio such as IAE undertaken by NEMA, or ERA undertaken by NBA, and research activities undertaken by KALRO and KEMRI.

On the element of capacity, the study revealed a rather good score on all the questions particularly on NACOSTI which had the highest rating. NACOSTI scored on first capacity question (Q11) because it is part of the NRF SynBio Project; it also scored on the second (Q12) because it implements the said project on behalf of the government through a partnership with ISAAA. It was however, not clear whether it scored on the third question because the NRF SynBio project, the first ever of its kind in Kenya, is funded by the government not a donor. On the fourth capacity question, which is also the last TAPIC question (i.e., Q13) NACOSTI stilled scored because as has been presented, there is already qualified expertise on several elements of the modern biotechnology, including on SynBio which a focal person for the country domiciled and NACOSTI is both Kenyan and African representative at the relevant CBD platforms.

7.4.2. Typology of Regulation

The study also explored the types of policy and/or legislation that respondents envisaged as appropriate for regulating SynBio technologies. As summarized in the figure 35 below, majority (81.93%) had a favourable opinion in support of the view that a new policy/legislation is the most suitable for SynBio regulation. This reveals a tremendous support for drawing a SynBio policy, legislation, and development plan, from some sort of scratch.

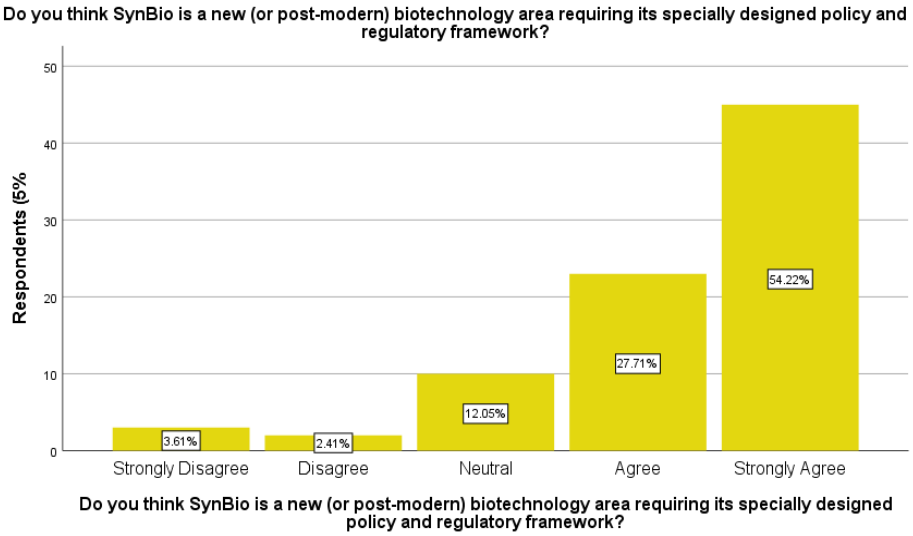

Figure 36: Perspectives on Sui-generis Vs. Adapted SynBio Regulation
Source: Researcher (2022).

However, a more or less different view emerged during the interviews when most respondents thought the policy, legislative and development plans currently in place are a good place to start and that SynBio processes, and programs should simply be mainstreamed into the already ongoing work and existing regulatory mechanisms, without necessarily starting all over again. From the literature (Trump, 2017) there are two approaches to regulating SynBio; sui-generis (formulating regulatory guidelines from scratch), or modification and adaption of existing biotechnology regulatory mechanisms to the SynBio procedures. In the USA, largely those mechanisms that apply to chemical substances have been modified and adapted to SynBio while in the Singapore and European Union nations, biotechnology regulatory guidelines, policies, development blueprints have been modified and adapted to the regulation of SynBio (*Ibid*). The global practice is thus recommended by experts, albeit qualitative findings contrast the survey results.

7.5.Government versus Private Regulation

Under this thematic category the study sought to explore the main regulator of SynBio technologies upon its adoption in Kenya. As shown in the figure 36, the respondents paved a rather gloomy image of the private sector's role in the regulation of SynBio. 34.94% had a favorable opinion about capacity of private institutions and actors, 19.27% had unfavorable opinion while a 45.78% expressed a favorable opinion.

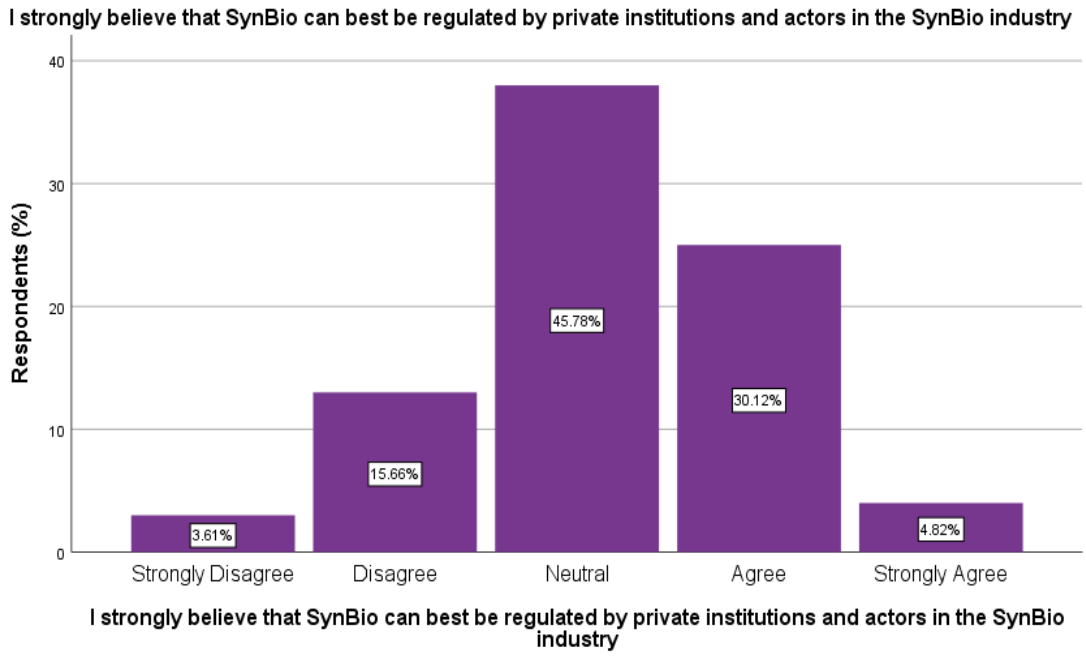

Figure 37: Perspectives on Private Sector's Capacity to regulate SynBio
Source: Researcher (2022).

Nonetheless, the private sector was acknowledged as already playing a key role in the regulation of biotechnology mainly through acting as policy brokers, a fact that Hall & Kingiri (n.d) have extensively delved into within the Kenyan biotechnology regulation dynamics. Outside Kenya, the private sector also plays a critical role. For example, Voluntary protocols laid out by institutions dealing in DNA Synthesis have laid out the so-called Harmonized Screening Protocol which sets provisions aimed at stopping the sales of DNA synthesis to individuals who may reuse them as biological weapons by ensuring that customers and persons making orders are properly screened and their details documented. Across the world, 80% of the high profile DNA Synthesis private, public and public-private organizations have subscribed to be bound by the guidelines (UK Parliamentary Office for Science and Technology, 2015). The role of the private entities cannot be gainsaid, even in Kenya as evidenced by the tremendous support for the role of business and industry in SynBio processes as revealed by the sub-section on actors roles and significance.

Lastly, the study explored a reverse question as the above. In contrast to findings on the role of private sector, the study revealed an overwhelming (86.75%) support for Government as the key

regulator of SynBio. Only 8.43% expressed a fair opinion, and meagre 4.82 had an unfavorable opinion.

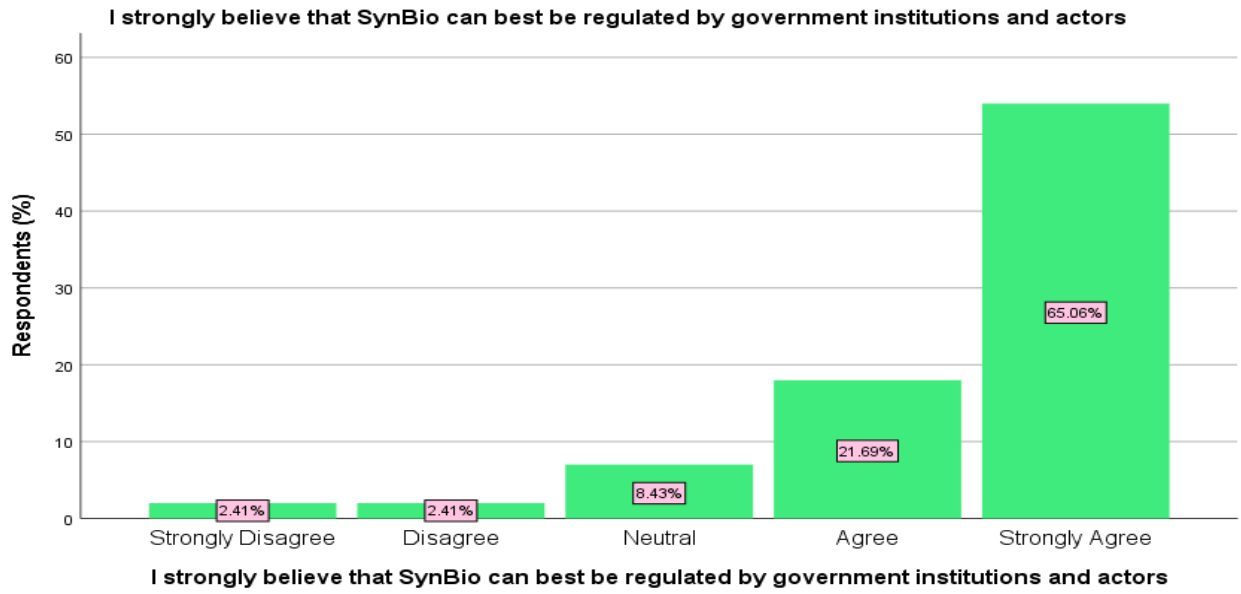

Figure 38: Perspectives on Government's Capacity to Regulate SynBio
Source: Researcher (2022).

This overwhelming support for government actors as the best regulators for SynBio was a recurrent finding during the interviews. Most interview respondents reported reasons such as a) there too many security issues about SynBio that only the government is in a position to check and prevent. These security issues include biosafety, biosecurity, and bioethical concerns (Trump, 2017; Jayanti, 2020; Supan, 2014; Mandel & Marchant, 2014; Douglas & Stemerding 2014; Fatehi & Hall, 2015; Keiper & Atanassova, 2018; SCBD, 2021; Marris & Calvert, 2018) about SynBio as was discussed in detail in chapter two of this thesis. The findings on high confidence in government as the key regulator of SynBio is also in tandem in with previous studies. In their findings, Hart Research Associate (2010) found that 52% of their sample population supported a regulation-led by the Federal Government Agencies as opposed to only 36% who supported that voluntary guidelines and private actors could properly regulate SynBio.

The government and private sector are two key actors in the R&D of synthetic biology. This has been evidenced in the UK where the numerous synthetic biology establishments work hand in hand with the government in ensuring that a responsible research and innovation environment with;

> "…the aim should be for broad awareness and mutual understanding of synthetic biology across public and stakeholder groups, and for research and innovation communities to build public trust through being open about their motivations and aims" (SBLC, 2016, p.23).

Such engagements will ensure that the research, industry, government and private sectors work hand in hand as they explore best options to adapt existing policies, laws, and programs and to mainstream SynBio into national development policies and programs; in the process setting up an infrastructure that is grounded on the TAPIC culture.

7.6.Chapter Conclusions

This chapter has highlighted on the state of biotechnology regulation and development in Kenya along 4 major thematic issues which border adaptive anticipatory governance for SynBio in Kenya. It has identified gaps and certain opportunities in the current biotechnology regulatory and research through the lenses of experts' perspectives and expectations. Attempts have been made to place these gaps within a TAPIC analysis framework at the end of end of presentation and discussions of each thematic category. The chapter findings point revealed:

a) That Kenya possess the requisite human resources,

b) There exists institutions whose work is directly related to SynBio technologies research, regulation and development. However, these institutions work are not aligned as yet to the specific research, development and regulation of SynBio technologies, hence the need to extend the mandates along TAPIC principles to capture SynBio issues.

c) There is an overwhelming support from experts that SynBio is a gold mine for Kenya's bioeconomy.

The evidence from the study therefore is encouraging because experts' assessments of the different issues that concern SynBio regulation are fairly above average. Nonetheless, there is still gaps which largely relate to mainstreaming SynBio into the work of current biotechnology institutions, ST&I, and ongoing biotechnology research. In the final analysis, the Kenya would be able to attain her coveted national science power and sustainable livelihoods when these gaps are filled, and opportunities reinforced through explicit policy and programmatic mainstreaming of SynBio technologies into bioeconomy development and regulation.

CHAPTER EIGHT

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

8.1. Overview of the Thesis

This study was conducted between March-2021 and July-2022. The main study objective was to explore whether Kenya possess the requisite regulatory environment for adoption and implementation of Synthetic biology. To achieve this, four specific questions were pursued using an exploratory sequential mixed-method design. Qualitative research involved the utility of both primary and secondary data. Primary qualitative data was collected from 4 FGDs and 22 KIs with purposefully selected experts sampled from a stratified population encompassing academia, media & communications, medical, regulatory, policy and governance bodies, and research and industry fields. Secondary data involved the analysis of purposefully selected biotechnology-related policies, legislations, and development plans. Quantitative research involved a sample size of 83 experts representing the mentioned sectors whose opinions were gathered using a Likert scaled and non-scaled questionnaire. The qualitative results were analyzed through thematic analysis and presented through text narrations and verbatim excerpts. Quantitative results were analyzed through SPSS v.26 and presented through frequency tables, pie charts and bar graphs with text interpretations. The study findings will inform policy and programmatic initiatives concerned with biotechnology development and regulation within the framework of Synthetic biology technologies.

8.2 Summary of Findings

This study had four objectives. The first three objectives were largely grounded on analysis of secondary materials, purposively selected to answer the research questions. The last objective on the other hand was grounded on quantitative findings from expert survey. Nonetheless all the objectives benefited from the mixed-method approach where both qualitative and quantitative data was used to answer research objectives. Analytically the first three explored the extent to the current biotechnology regulatory environment is transparent, accountable, participatory, and base on the integrity and capacity principles. In other words, first three objectives were guided by the first four principles of the TAPIC framework. Last objective explored questions related to the capacity principle. Summary of the thesis findings is given below along the objectives.

The first research objective explored biotechnology-related policies. The study found that Biotechnology Development Policy [BDP] (2009) is the focal policy for the development and regulation of biotechnology, hence would be the primary policy on matters SynBio development and regulation. However, the policy needs certain amendments in order to ensure that it is in line with the principles of adaptive anticipatory governance of SynBio. Overwhelming majority of the respondents (82%) felt that such amendment will streamline the policy to the regulatory issues particular to SynBio and facilitate its smooth adoption and implementation; hence enhance Kenya's science capabilities and improve the livelihoods of her citizens. The other policies, national food and nutrition security, national environment policy, national policy on ST&I, National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009, and National Policy on Culture and National Heritage, 2009 are all very important policies touching on various aspects of biotechnology, but as study revealed, they lack in terms of the first four of the TAPIC principles and therefore needs systematic amendment to cover the regulatory issues concerning SynBio.

Objective 2 of the study explored 7 important pieces of law that are concerned in one way or another with biotechnology development and regulation. The study found that the Constitution of Kenya provides an important ground and implies that all ST&I adopted in the country should adhere to the principle of responsible research and innovation, and not have any adverse effects on the Kenyan environment and health. The Biosafety Act (2009) which implements the provision of the Biotechnology Development Policy, 20226, is the focal legislation on matters biotechnology in Kenya. It legalizes the NBA operations, and defines the scope of BDP as constrained only within GMO biotechnology as relates to plant agriculture. The study thus revealed that the Biosafety Act was limited in scope and as such was insufficient to cover matters such as biosecurity, social-and-economic impacts, ethical and biological diversity questions that are specific to SynBio. More than half of study respondents (60%) of experts surveyed therefore supported the need to amend the Act and realign its provisions and the mandates of its institutions to these regulatory concerns for smooth adoption and implementation of SynBio.

The study further found that the ST&I Act, while is another critical legislation to the regulation of SynBio particularly on financial justifications for investment in SynBio, is too general and lacks any substantive focus on biotechnology and hence SynBio. Experts asserted that the legislation

needs further work to make necessary SynBio-specific guidelines, and link the technology to business and industry. The other legislations analyzed though not directly concerned with biotechnology development, experts expressed that they would be critical to the successful implementation of SynBio and that the Government and her partners needed to look into them and make necessary adjustments along the TAPIC gaps identified through targeted mainstreaming of SynBio programs.

The third objective explored the question of whether biotechnology-related development plans in Kenya are driven by ST&I, especially biotechnology hence providing an environment for adoption and implementation of SynBio. The study found that ST&I is an important part of national development planning and has been embedded into long-term plans such as Kenya Vision 2030 as well short-term plans such Big Four Agenda. The Big Four was rated at 74% moderately favorable for adoption of SynBio while 71% said Kenya Vision 2030 was moderate in terms of supporting ST&I in line with SynBio technologies adoption and implementation. This requires that not only biotechnology but also SynBio as an advanced form of ST&I should explicitly be mainstreamed in the NDPs in a manner that adheres to the principles of TAPIC in order to ensure that development planning appreciates and makes provisions on the utility of SynBio technologies in pursuit of Kenya's development agendas. Moreover, the study found that biotechnology as a component of ST&I has not received much attention in sectorial NDPs, despite it being "at the heart of bioinnovation" (SBLC, 2016). In this regard, the study revealed that biotechnology, and ST&I generally, have not been systematically mainstreamed in bioeconomy sectorial plans such as biological diversity, climate change adaptation, and agricultural sector strategies. Such an environment should be transformed to provide a ground that perceives SynBio technologies as a key driver of bioeconomy.

Lastly, objective four of this study explored expert stakeholders' perspectives and expectations along six thematic categories. This objective explored themes which relate largely to the principle of capacity as conceived in the TAPIC framework. Under the first theme: National Capacity, Perceived Safety and Risks and Economic Justifications for SynBio technologies:- the study revealed an overwhelming (90.16%) trust in the capacity of Kenyan scientists to undertake SynBio research; 88% asserted that there are safety concerns about SynBio that concerned stakeholders must consider going forward as they innovate an adaptive anticipatory governance for SynBio

technologies; 57.83% agreed, however, that benefits of the technology still outweigh its risks; 59.04% expressed fear that their religious beliefs may be at stake upon adoption of SynBio in Kenya; an overwhelming 89% (74/83) supported the adoption of SynBio technologies because of its potential contributions to the economic development in Kenya; and lastly, more than average of the study sample (62%) support investing in SynBio technologies is a viable relative to other ST&I aspects.

The second thematic area, SynBio policies, role and significance of actors, the study found that most (68.67%) agreed that for proper adoption and implementation of SynBio technologies, the Government of Kenya, should initiate policy processes that will ensure *actual resource allocation presented by projects and programs designed to respond to perceived public problems and challenges requiring government action for their solution* which are achievable through SynBio. Additionally, the study found that research community should play the most (90.36%) important role in formulation of policies related to SynBio technologies development and regulation; this was followed by the role of business and industry (84%), and finally politicians (18%).

The third theme explored the robustness of current biotechnology regulatory and research system through the lens of institutions concerned. The study found that the institutional mandates of the institutions studied were rated as above 50% favourable except for NEMA. NACOSTI was rated at 86%, KALRO at 67%, NBA at 60%, KEMRI at 60% and finally NEMA at 46%. The study, however, found that the institutions had specific gaps in their mandates in the regulation and development of biotechnology. Such gaps, require an adaptive governance framework in order to adapt current mandates of these institutions to SynBio technologies regulation and development. The study also found that there is no consensus among on what institution or sector of the Kenyan economy should host SynBio and spearhead its development in the country upon adoption. Key institutions suggested as capable were NACOSTI, IPR, and Ministry of Industrialization with experts making justifications for each choice. The study further found that most (81.68%) respondents support a sui generis approach to SynBio policy, legislation and development plan/strategy formulation.

The last thematic category explored whether private or Government sector actors and institutions were the best placed to regulate SynBio. Findings revealed a tremendous positive case for

Government as the key regulator of SynBio products and processes with a rating of 86.75% against only 34.94% supporting private sector.

8.3. Thesis Conclusions

A question that need to be asnwre in this section is what the study contribute to knowledge in IR. This study revealed the extent to which current biotech governance in a developing country like Kenya can regulate a technology of transnational significance like SynBio. As highlited within the Subsidiary Body on Science Technology and Technical Assistance of the Convention of Biological Diversity, and other technical working groups dealing in Synthetic Biology, effective global governance of SynBio technologes requires proper regulation at the national scales. Evidence on opportnties and gaps in Kenya, are thus a critical tool for bridging regulatory gaps within new come states like Kenya whose actions in regards to import and export of SynBio products may cause challenges (refer to this discussion from the first section of the literature review). The empirical evidence resulting from this study will therefore inform debates of global governance of SynBio at Convention on Biological Diversity (CBD) and beyond. The findings also point to Kenya what she needs to do adopt SynBio technologies as an opportunity to revolutionalize the economy, attain sustainable livelihoods and assert herself as a regional biotechnology powerhouse. Proper regulation of SynBio will be critical to Kenya, as that will ensure the country can undertake production of SynBio products at the industrial level, and lay mechanisms for explorting high-end products into the international market. This way, many challenges of the country may be solved beginning with investible capital gaps that continue to force the country to be a loan-seeking country. Moreover, such approach with SynBio will see into it that Kenya do not join theleague of SynBio countries as yet another consumer and importer but as a producer and leader in SynBio products trade within African market and beyond.

The findings and interpretations from the specific objectives of this study leads the study to infer that despite SynBio portending enormous potentials to enhance Kenya's domestic productivity across a number of sectors: primarirly to the sectors of bioeconomy: health, agriculture, blueconomy, livestock among others, the current framework is deficient and must be amended in accordance with regulatory needs of the techniology. This will ensure optimal utlity of SynBio within an adapative anticpatroy governance framework which will mitigate potential risks as a result of its adption. The good news, however, is that like Reagan et al. (2022) contends, Kenya,

like South Africa, has a robust GMO framework which implies policy makers will not start from scratch but build on what is in place.

The study thus established that Kenya possesses a broad regulatory framework for biotechnology and GMO but these frameworks must be adapted to the regulatory issues concerning SynBio technologies for successful adoption and implementation of SynBio in the country. The policies, legislations, and NDPs concerned with bioeconomy must therefore be reevaluated to expand the mandates of the regulatory institutions they establish and establish and harmonize linkages between institutions, policies, legislations and NDPs within a TAPIC framework. This will see the establishment of an adaptive anticipatory governance framework and facilitate the achievement of her for a sub-regional, regional and global leader in ST&I achieve sustainable quality livelihoods for her citizens as spelt out in the Kenya Vision 2030. With a an adaptive anticipatory governance in place, the country will be ahead of the SynBio discourses in East Africa and only second to South Africa and Nigeria (See Reagan, 2022; ISAAA AfriCenter, 2022) where the technology has taken root, and GMO regulations are already being realigned to SynBio-specific issues. Kenya will therefore be able to produce locally, SynBio technologies on fields such as industry, medicine, agriculture, and all others, hence exert her self-dependence by reducing importation of the same (as witnessed with COVID-19) as well as begin exporting SynBio exportation within and without Africa. This will reduce reliance on loans and finally enable Kenya claim her rightful place in currently asymmetrical global political economy.

Based on each of the four objectives, the following deductions are made: As observed from first and second objectives, the Biotechnology Development Policy, 2006, is the policy regulating biotechnology in Kenya. Likewise, the Biosafety Act of 2009 is the key legislation that govern biotechnology in Kenya. However, these instruments need to be first, mainstream SynBio and explicitly lay out institutional and legal frameworks for its development in Kenya. Secondly, be expanded along the TAPIC concepts to cover SynBio regulatory issues such as biosecurity, socio-economic and ethical questions, and biological diversity and so on. Such adaption process should be replicated to other concerned policies and legislations like, with very clear provisions on how these institutions should operate as they regulate SynBio technologies in Kenya.

From the third objective, the study concludes that there is a strong support ST&I as an enabler in development planning in national blueprints such as Vision 2030 and Big Four Agenda, however,

biotechnology as an ST&I, is not properly mainstreamed in sectorial strategies/plans. This is very unfortunate owing to the immense potenatials SynBio has for example in climate change mitigation and adaptation in Kenya. A close look at the Kenya Climate Change Action Plans for example revealed a lack of appreciation of the technology with traditional approaches such as energy saving Jikos and such like being given prominence as opposed latest developments in ST&I that can have greater impact in climate change mitigation and adapatation in a vulnerable countr like Kenya. This is an opportunity for SynBio adoption because Vision 2030 is a long term development plan. It is also a weakness for SynBio because it could hinder application of SynBio as an ST&I in the various bioeconomy sectors.

From the findings from the fourth objective, the study infers that in terms of human resources capacity, institutional mandate, and expert support for investment of SynBio, Kenya is better placed to adopt and implement SynBio. However, there still need to revise and expand institutional mandates of GMOs institutions to capture new regulatory and development notions particular to SynBio technologies. Moreover, there is need for intensive sensitization and awareness creation for SynBio. The sensitization should target critical officers in key institutions such as NEMA, Ministry of Health, KEBS, IPR, and any others concerned with research, validation, or allowing commercialization of SynBio products. Thirdly, there is need to set an inter-organizational standard operating procedures that will ensure that unnecessary regulatory bottlenecks are avoided and a clear and facilitative functional framework is put into place to ensure to that SynBio R&D is not hampered like its precursor-the GMOs.

8.4. Recommendations

Based on the findings and conclusions from the study objectives and the theoretical analysis of the same. This study makes the following recommendations. The recommendations should help in informing the next debates of SynBio going forward of what remains to be done in the process of establishing an adaptive anticipatory governance. To make these recommendations informed by the theoretical framework that guided this study, it was imperative to fit all these findings and conclusions into the theoretical that guided the study. The study adopted the theory of adaptive and anticipatory governance. The recommendations that follow are based on the TAPIC questions framework of regulatory gaps analysis.

Table 12: TAPIC Framework and Study Recommendations

TAPIC QUESTIONS (Q)	STUDY RECOMMENDATIONS
Q1	Explore best avenues for having an overarching framework for Bioeconomy Strategy would suffice, learning from existing practice in UK, USA, & Singapore.
Q2	The works of KALRO, NEMA, Institute of Primate Research (IPR), NBA, KEBs, KEPHIS and other concerned institutions should be realigned accordingly to capture SynBio regulation and R&D in a manner that will solve the unnecessary regulatory bottlenecks and attendant bureaucratic politics.
Q3	A Bioeconomy Strategy should spell out how concerned institutions will be engaged in the life cycle of the development of SynBio products and make clear the-who, what, when to curtail unnecessary inter-institutional conflicts.
Q4	A biosecurity policy needs to be implemented either as single-standing policy or as part of a SynBio policy. This should prioritize SynBio biosecurity and other issues not covered in current biotechnology law.
Q5	Adopt a Bioeconomy Strategy and enact a legislation charging all concerned legislations to incorporate issues particular to SynBio that they should cover.
Q6	There is a need to establish a SynBio Consortium in Kenya that will bring stakeholders from industry, academia and government with inclusion of key stakeholders from the general public such as leaders of inter-religious associations. Such a consortium will play a critical role in harmonizing the different views and hence different framings of SynBio (and of cause biotech/GMO) and solve cases of opposition as the consortium will constitute the different members of the Kenyan publics who can then feedback to their members.
Q7	Engage stakeholders and explore which form of participation is appropriate; explore examples of Singapore, UK, and USA to choose what's most applicable to local context; design a SynBio communication strategy which among others should spell out these issues.
Q8	Formulate a SynBio legislation and SynBio Guidelines on the specific regulatory issues it concerns.
Q9	Define an overarching framework for SynBio such as a Bioeconomy Strategy that will make clear which organizations should do what and how, in coordination and collaboration with whom and at what stage.
Q10	Explore all possible IPR conflicts relevant to SynBio and embed them in to the revised IPR policy and legislations or a SynBio policy.
Q11	Make provisions in policy and law that will ensure regular and formalized government investment in SynBio for sustained R&D. A biofoundry is one of the most critical investments for a sustained R&D of SynBio in Kenya. Its viability should be explored.
Q12	Government should explore possible collaborations with the Singapore, USA and UK scientists and governments on areas of mutual benefits in SynBio R&D; emphasis should be laid on capacity building of the local expertise and on funding of projects relevant to acute local challenges.

Q13	Government should nurture and support local scientists; create framework to reduce political interference and promote political support; establish, furnish and make operational a bio-foundry to promote biotechnology and related research

Table 8: Study Recommendations
Source: Researcher (2021).

These recommendations can be summarized into four as follows:

To begin with, the study recommends, based on the findings from the first objectives, that the Government of Kenya needs formulate a SynBio policy. The process of coming up with such a framework should be informed by a TAPIC model, especially the TA(P)IC where key actors in SynBio policy processes as revealed by this study, including the religious establishments, industry, business community, and the research community play a key role.

Secondly, there is need to enact a SynBio legislation. Existing legislations are deficient and are incapable of ensuring SynBio R&D within a TAPIC framework. Actors and their roles are not clear, instutions have no legal manadates, and most importantly, regulatory issues that require the law to make clear when, how, by whom, why, and so on, are currently not present. The particpants in the process of coming up with legislagisaltion should take into consideration the major actors as research community, industry and business among others.

Thirdly, for a concerted and sustainable regulation and development of SynBio, an overarching development plan will be required. Such a plan should be in the form of a Bioeconomy Strategy to mainstream SynBio into national development plans. This should be akin to the UK's Synthetic Biology Roadmap, spelling out the intensions the country has, the different sectors where SynBio applications will be applied, and the interrelationships between different sectors and actors in ensuring the technology is used optimally for the common good, to increase chances for attaining sustainable livelihoods, and for utlity of the technology for external/foreign aspirations of Kenya such as through export of SynBio products to the global market. A national development plan for SynBio is one of the critical items that will facilitate successful adoption and implementation of SynBio.

Fourthly, based on the fourth objective which explored expert perspectives, the following can be recommended: Construct a national Synthetic Biology Forum. Such a forum should bring multidisciplinary and multi-sectorial stakeholders' together, to chart a course for the technology to the nation and given constant independent feedback to governmental MDAs concerned, as well

as clear the air for any misundertandings from the publics concerning the technology. The A*STAR model discussed in the literatre review is one way to go about this. Prioritize public-private partnership platforms and promote industry academia engagements. Additionally, there is need for the government of Kenya, through expert advice to explore possibilities for establishing Synthetic Biology Biofoundry to facilitate a one-stop shop for SynBio R&D in the country. This should consider questions such as: where will this be hosted? What equipmemts are needed and is their economic justification for their acquisition (how can the needed equipment be attained locally?)? What equipment already exist in biotechnology institutions like Nairobi University, KALRO, KEMRI, etc? What are the potential for collaborative frameworks with internal and external donors and actors in a manner that will not render Kenya a consumer rather than a key producer for export of high-end SynBio products?

8.5. Suggestions for Further Research

Based on the findings, conclusions, and recommendations made out of this study, the following areas still remain unexplored to continue informing SynBio regulation:

8.5.1. Explore the political economy perspectives of globalizing biotechnology in Kenya

The current study established that almost all research projects on biotechnology have emerged as a result donor funding. In this process, political economy issues have become enormous asking such questions as: what interests do donors have in Kenya's biotechnology development? What impacts have these donors – who come in in the form of transnational actors – had on Kenya's biotechnology development and? How can Kenya take up the challenge and fund her own biotechnology? The questions have not been explored in this study but as objective four revealed, a donor-funded biotechnology raises many political economy questions which affects societal and experts' perspectives on whether biotechnology can have any serious impact in Kenya. In deed it is revealed by the study that a donor-oriented approach accounts for the meagre change in biotechnology development two decades later since Kenya allowed Bt Cotton.

8.5.1. Need for a survey of the non-expert public's views

The findings and conclusions made out of this study were based on a survey of respondents who had diploma education and above and were largely experts involved in biotechnology-related activities. There is need for further studies to explore perspectives of the unemployed and

biotechnologically uninformed general public, such as farmers, who are also the majority of the would-be consumers of SynBio products.

8.5.2. The dynamics of political interference on biotechnology development in Kenya

Secondly as it emerged, that political will has been a hindrance of biotechnology research, there is thus a need for exploratory study that will help establish the cause-effect of such a scenario.

8.5.3. Need to explore the limitations of bureaucratic decision Models on biotechniology governance in Kenya

Thirdly, there is need for a study to explore the various causes and nature of inter-organization conflicts and hindrances between the biotechnology regulatory agencies which were reportedly responsible for the slow pace of biotechnology development in Kenya.

8.5.4. Cost-benefit analysis of the exact type/form of synthetic biology regulation benefitting Kenya

Fourthly, this study recommended that the Government of Kenya establishes an overarching policy framework that will serve as are reference document for all the issues pertaining to SynBio. However, a further study needs to be commissioned by the government of Kenya to explore what type of overarching framework should be adopted in Kenya; whether a Bioeconomy Strategy, or SynBio Policy, or Biosecurity Policy is most appropriate.

8.5.5. A comparative study of Kenya's and UK's (or any other developed country whose SynBio system is already thriving) Biotechnology Systems for practical learning and context-informed adaptation

There is a need for a cross-country comparative study of Kenya and countries which have gone far in terms of SynBio, to establish the approaches, issues, and other important lessons that can be learnt, and adapted to the local context.

8.5.6. A systematic study into the feasibility of a bio-foundry as a booster to Kenya's Synbio Visions

A systematic analysis of the bio-innovation system in Kenya is needed aimed at establishing the needs and possibilities for utilizing a biofoundry and key approach to spearheading an industry-oriented SynBio development.

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APPENDIX 1: PARTICIPANT CONSENT AND STUDY INFORMATION FORM

1.0.Introduction and Project Description

You are being requested to take part in a Masters Research project titled Exploring Kenya's Biotechnology Regulatory Environment for Adoption and Implementation of Synthetic Biology. Your expert opinion on the suitability of selected existing biotechnology and bio-innovations regulatory mechanisms to the regulation of Synthetic biology (herein after SynBio) will help the researcher understand, in-depth, the gaps that exist in selected regulatory mechanisms applicable to SynBio and make necessary recommendations to relevant stakeholders. The findings of this study should lead to the generation of evidence necessary for formulating a regulatory environment to facilitate smooth adoption and implementation of SynBio. This study will proceed in two stages, all of which we request you to participate. This first stage of the study will involve answering a 45 minutes-1hour descriptive questions derived from the study's three objectives. In the second stage, we will also contact you to answer a 45 minutes-1.30 hour Google-enabled survey. This project is being conducted by the researcher: Odhiambo Alphonce Kasera, Adm. MA/DS/00019/19 of School of Development and Strategic Studies (SDSS) Maseno University under the facilitation of the Kenya National Research Fund on SynBio Project through the International Service for Agri-Biotech Acquisition and Application Africa Chapter (ISAAA AfriCentre) based in Nairobi.

By taking part, you are agreeing that you have read and understood the information about the study below. Please ensure you have read and understood this information before continuing to answering the study guide questions.

2.0.What is this project about, and do I have to take part?

This study aims to explore the Kenya's regulatory environment applicable to SynBio to generate evidence that can be used to better such an environment to facilitate the adoption and implementation of SynBio in Kenya. The regulatory environment under exploration will include: existing necessary policies and legislations; existing necessary national strategies; and finally the current perspectives of key stakeholders on the SynBio and issues pertaining to its regulation. The target population are adults (18 and above) selected experts in biotechnology; either as technical experts or social scientists who may have a predisposed to research (or any kind of work) on biotechnology regulation. Although we encourage and highly expectant of your participation, taking part in this study is entirely your voluntary decision.

3.0.What will taking part involve?

You will be asked to give provide your expert opinions on the descriptive questions under the research themes/objectives during a one-on-one in-depth interview or online. We may also email to you the interview guide which you can then fill and return as soon as you finish. In the second phase, we will invite you to participate in a Google-enabled survey lasting about 30-50 minutes. We will, finally, invite you to a policy round-table facilitated by National Commission on Science Technology and Innovation's (NACOSTI) and ISAAA where we will collect expert group opinions on the SynBio regulation issues.

What will you ask and what will happen to the information you give us?

You will be asked questions about yourself, and your background, including your organizational affiliation, years of service in the field, whether you are biotechnologist in the technical sense or a social science/biotechnologist in the policy segment of the field. We will also ask you for an email

address so that we can contact you for the next stages of the research. If your participation is by e-mail, prior to analysis of the data, your email addresses will be de-linked from the responses you provide so that your data are anonymous and your participation in this study confidential. Your anonymous data will then be analyzed by researcher and the findings will be published in research materials (e.g., policy briefings, scientific articles). Your participation in this study will not be identifiable from the publications produced.

4.0.How long will my data be stored for?

Your data will only be used for this study and not shared. Your background data will be destroyed after the analysis of the findings but your expert opinions will be anonymized and published in research materials which can stay as long as possible. However any audio, images, and/or videos data ciollected using interviews will be destroyed effectively at the end of analysis and writing of this thesis.

5.0. Potential benefits

There will be no any immediate economic, political and cultural benefits as a result of your participation. However, in the long run, I hope that the benefits from your participation will be immense and macro in scale if and when the government and other concerned actors to the subject of uptake of SynBio use the insights of the study to ensure an adaptive anticipatory governance framework is put into place to facilitate smooth adoption and implementation of SynBio in Kenya.

6.0.Local Data Protection Privacy Notice Concerns

If you have any concerns about the study, you can contact Dr. Benson Mburu, Senior Scientist at benson.kinyagia@nacosti.go.ke. If you feel your concerns have not been handled satisfactorily, you can contact Margaret Karembu, PI, National Research Fund on SynBio and Director, ISAAA, at mkarembu@isaaa.org.

Consent

I understand that:

- My participation is completely voluntary.
- I will need to provide an email address so that I can be involved in the future stages of the research.
- For accuracy in documentation of the research findings, my voice will be recorded and the record shall be used entirely for the stated objectives of the study.
- The data gathered in this study will be stored securely and it will not be possible to identify me in any outputs from this research.
- For purposes of accuracy in recording my responses the researcher may use an audio recorder to capture my voice records which shall be used strictly for the stated objectives of this study.
- The researcher will collect and analyze special category personal data, especially my line of work but that this information will not be used to identify me in any direct ways.
- I might be consulted in the post-survey or post-interview if the researcher feels there is the need to get more clarifications.

Name of Participant……. Signature……..

Date……..

APPENDIX 2: IN-DEPTH AND FOCUSED GROUP DISCUSSIONS INTERVIEWS GUIDE

i) Profile of Interviewee/Institution

QUESTION	RESPONSE
What is your email address?	
What is your age?	
What is your gender?	
What is your education level?	
Name of Interviewee	
Organizational Affiliation:	
Core Work of the Organization/Department (Vision, Mission & current priorities)	

ii) What 'promises has SynBio to the following sectors of Kenya economy?

a) Health
b) Environmental Conservation and Management
c) Food and Nutrition Security
d) National Security (in military sense of the word)
e) Coastal zones management
f) Animal productivity
g) Employment and economic growth

PART ONE (KI GUIDE): TAPIC ASSESSMENT OF THE REGULATORY FRAMEWORK

Guide Question 1: To what EXTENT can the following Kenya's biotechnology-related policies facilitate the adoption and implementation of SynBio technologies through effective regulation?

a) The Biotechnology Development Policy, 2006
b) National Food and Nutrition Security Policy (NFNP)
c) The National Environment Policy, 2013
d) National Policy on Culture and Heritage, 2009
e) National Policy Framework on Science Technology and Innovation, 2012
f) The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009

Guide Question 2: To what extent can the following Kenya's biotechnology related legislations facilitate the adoption and implementation of SynBio technologies through effective regulation?

a) The Constitution of Kenya (COK 2010):
b) The Science Technology and Innovation Act 2013
c) Environmental Management and Coordination Act (EMCA 1999)

d) Biosafety Act, 2009
e) Kenya Agriculture and Livestock Research Act, 2013
f) Agriculture Act, 2012
g) Food and Nutrition Security Regulations

Guide Question 3: To what EXTENT are current Kenya National Development Plans (NDPs) favorable to the Research & Development of SynBio?

I. What is the position of ST&I in Kenya's development planning"
II. How far is biotechnology mainstreamed in ST&I and Kenya's development generally?
III. Is the country making necessary investments in knowledge bio-based economy/bioeconomy?
IV. What opportunities has the devolved system of governance to the utility of emerging and disruptive technologies? How can those opportunities be harnessed for adoption, implementation & development of SynBio?
V. How adequate are the provisions of these legislations to the development of SyBio?

NATIONAL DEVELOPMENT PLANS

a) The Kenya Vision 2030
b) ''The Big Four Agenda''
c) Kenya Biodiversity Reports to the CBD Secretariat
d) National Climate Change Response Strategy (NCCRS), 2010
e) Kenya National Climate Change Action Plan (NCCAP) 2013-2017
f) NCCAP for the period 2018-22
g) Agricultural Sector Development Strategy (ASDS) 2010–2020;

PART TWO: THEMATICALLY-FOCUSSED DISCUSSIONS (FGD GUIDE QUESTIONS)

National R&D Strategy

a. As a latecomer country, how can Kenya adopt and implement SynBio?
b. Should the public sector play a role in the promotion of market development? If so, how should this role be defined within the larger landscape of private sector investment and development?
c. How does the development of the bio-economy play a role in the large Kenyan innovation landscape, especially as policymakers consider modern national competitiveness strategies?
d. What measures can be put into place to ensure Kenya stays competitive in the research and development of SynBio?

Workforce Training

a. Does Kenya have the life science education and training capacity to facilitate the development of the bio-economy? How will Kenya expand its current workforce pipeline in order to support growth in the SynBio field?
b. As alternative, bio-based forms of production are pursued across all industries, what plans are in place for dealing with job loss in the traditional industries (for example, traditional meat production being replaced by plant- and cell-based meat alternatives)?

Regulatory Approach

a. How can regulation act as a promoter for foreseeable opportunities? What is the balance between oversight and encouragement, to ensure there is domestic progress of SynBio technology?
b. How can regulation support the growth of necessary infrastructure, resources, and tools for to capture the opportunities of SynBio?
c. What are current and foreseeable governance gaps of SynBio if it would be regulated under the GMOs framework?
d. Do regulators have sufficient capacity to meet the increased need for oversight of products produced with SynBio?
e. Will an increase in personalized therapeutics and treatments dramatically increase the burden on health regulators to appropriately govern consumer products? If so, how should this be addressed?

Cost & Accessibility

a. How can new SynBio technologies impact the developing world?
b. What specific role can Kenya play as a proactive developing country in SynBio R&D?
c. What role should various domestic and international actors play in ensuring the low-cost and accessible nature of these technologies?

Dual-Use Research

a. Does dual use research suggest that there should be greater regulation of the scientific process, as opposed to specific products?
b. What steps can be taken to prevent scientists from engaging in high-risk dual use research, especially if they do not rely on NRF or other Government-based funding?

Democratization

a. What opportunities are presented through the democratization of SynBio biological production and application? How can a regulatory framework acknowledge and support these opportunities?
b. What are the governance needs around DIY biologists, if any?
c. How can governance structures, if needed, be built to support the positive aspects of democratized biological innovation, while addressing potential risks?
d. Will DIY biologists be liable for any damage that they cause (to health, the environment, etc.) as a result of accidental release or inappropriate use of their products?

Consumer Knowledge

a. Should all SynBio products made available to consumers be required to be labelled as being produced via SynBio?
b. Is labelling necessary if there is no demonstrated risk to the consumer from any given product?

Biosecurity

a. How can we prevent individuals from making pathogens more dangerous?
b. And how can we detect and prevent against engineered pathogen release?
c. Are current sequence-based methods (SELF_REGULATION) of identifying dangerous SynBio DNA sequences sufficient for preventing the Synthesis of the most high-risk pathogens?

Biodiversity

a. Should there be any requirements for community outreach and approval before introducing an engineered species to a community?
b. Should we bring back species simply for the sake of biodiversity or should they serve a “useful purpose”?

c. How could the introduction new, and reintroduction of old, species impact and/or disrupt present ecosystems and biodiversity?
d. Are there ways to mitigate undesirable disruptions? How can we account for uncertainty of outcome?

Containment

a. What technologies are being put into place to ensure that organisms that are accidentally released can be contained? How do we test the efficacy and readiness of these technologies?
b. Does containment need to be considered after a product is used for its intended purpose, for example a biological or food product that is excreted?
c. Is there a need for environmental monitoring to survey for the presence of SynBio products that may be accidentally released?

APPENDIX 3: EXPERT SURVEY QUESTIONNAIRE

Questionnaire on knowledge, attitude, and practices & regulatory issues and gaps on Synthetic Biology (SynBio)

Respondent No_____

SOCIO-DEMOGRAPHIC VARIABLES
(Please tick where applicable)

1.Gender	Male	
	Female	

2.Education level	Informal	
	Primary	
	Vocational	
	Secondary	
	Diploma	
	Bachelors	
	Masters	
	Doctorate	

3. How old are you	18-45	
	45-70	
	70-100	

4. Affiliated Institution	
Academia	
Research	

Policy , governance & Regulation	
Media & Communication	
Medical	
Industry	

EXPERT STAKEHOLDERS PERCEPTIONS ON R&D ISSUES THAT WOULD INFLUENCE ADOPTION OF SYNBIO

(Strongly agree-SA; agree=A; neutral=N; disagree=D; strongly disagree-SD)

No.	Statement	SA=5	A=4	N=3	D=2	SD=1
5	I believe in the capacity of Kenyan scientists and innovators to produce products through SynBio that can be applied locally and internationally					
6	I care about the safety of SynBio products					
7	It is very important for me to know the implication of SynBio on my religious belief					
8	I am confident that SynBio can lead to economic development in Kenya					
9	I believe the government needs to invest in another technology (maybe bioinformatics, nanotechnology, artificial intelligence) because the cost of adopting SynBio is high for Kenyans					

PERSPEXCTIVES ON OVERALL SUFFICIENCY OF BIOTECXHNOLOGY LEGISLATIONS

(Strongly agree-SA; agree=A; neutral=N; disagree=D; strongly disagree-SD)

No.	Statement	SA=5	A=4	N=3	D=2	SD=1
10	I think existing legislations are sufficient to govern use of SynBio and its applications in Kenya					

EXPERT STAKEHOLDERS PERCEPTIONS ON SELECTED APPLICATIONS OF SYNBIO PRODUCTS AND ITS ADOPTION IN KENYA

(Strongly agree-SA; agree=A; neutral=N; disagree=D; strongly disagree-SD)

No.	Statement	SA=5	A=4	N=3	D=2	SD=1
11	I have heard about diagnostic tools developed using SynBio technology					
12	I think biosensor technology can be used for Human medical/ health diagnostics					

13	I think biosensor technology can be used for plant health diagnostics					
14	I think biosensor technology can be used for animal health diagnostics					
15	I am comfortable using food products (synthetic food) developed through SynBio					
16	I can use pharmaceutical and medical products developed through SynBio					
17	I am in support of manufacturing of various goods through SynBio technologies					
18	I am comfortable with products manufactured using SynBio, being used in my environment					
19	I prefer the use of fuels generated through SynBio than those generated through traditional methods such as coal burning					

PERSPECTIVES ON THE NATURE OF RISKS AND SAFETY CONCERNS ON SYNBIO

No	Statement	SA -5	A-4	N=3	D-2	SD=1
20	What comes to my mind are the health related risks resulting from its use?					
21	What comes to my mind are the health related opportunities resulting from its use?					
22	What comes to my mind are the environmental related risks resulting from its use?					
23	What comes to my mind are the environmental related opportunities resulting from its use					
24	What comes to my mind are the ethical related issues resulting from its use?					
25	What comes to my mind are the moral/religious related issues resulting from its use?					

PUBLIC POLICY PROCESSES AND SYNBIO REGULATORY OPPORTUNITIES AND GAPS

26 What do you understand by the term public policy? (Choose the most applicable statement to you)

No.	Designating behavior of some actor or set of actors, such as an official, or government agency, or legislator	
A	Public policy also may be seen as whatever a government chooses to do or not to do	

B	It is used mainly in reference to what government does in order to meet the needs of the citizenry	
C	Mere declaration of intentions, wishes, principles, or expression of desires	
D	Should mean actual resource allocation presented by projects and programmes designed to respond to perceived public problems and challenges requiring government action for their solution	

ACTORS AND THEIR LEVELS OF SIGNIFICANCE IN SYNBIO POLICY PROCESSES

No.	Statement	SA=5	A=4	N=3	D=2	SD=1
27	I believe Public policy making in Kenya is a domain for experts only					
28	Public policy is a domain for politicians					
29	Public policy is a domain for government sponsored experts only					
30	Public policy is a domain for government sponsored experts only					
31	The business community plays a lead role in policy					
32	I believe that the research community will play a critical role in identifying policy loopholes and providing governments with needed evidence for new or enhanced policies					

PERSPECTIVES ON REGULATORS AND EXISTING FRAMEWORKS

No.	Statement	SA=5	A=4	N=3	D=2	SD=1
33	I strongly believe that SynBio can best be regulated by private institutions and actors in the SynBio industry					
34	I strongly believe that SynBio can best be regulated by government institutions and actors					
35	Do you think SynBio is a new (or post-modern) biotechnology area requiring its specially designed policy and regulatory framework?					
36	Because of existing policy and regulatory frameworks, Kenya is ready to adopt and implement SynBio innovations					

PERSPECTIVES ON ROBUSTNESS OF THE MANDATES OF KEY REGULATORY AND RESEARCH INSTITUTIONS

37. What is the level of your confidence on the following institutions in regards to regulation of SynBio in Kenya? (very cable=VC; capable=C; Neutral=N; incapable=I; very incapable=VI)

		VC=5	C=4	N=3	I=2	VI=1
37.1	National Council for Science Technology and Innovation (NACOSTI)					
37.2	Kenya Medical Research Institute (KEMRI)					
37.3	National Biosafety Authority (NBA)					
37.4	Kenya Agricultural Livestock Research Organization (KALRO)					
37.5	National Environmental Management Agency (NEMA)					

38. IMPRESSIONS ON RISKS VERSUS BENEFITS OF SYNBIO

Benefits outweigh =3 ◯	*Risks equal benefits=2* ◯	*Risks outweigh benefits=1* ◯

SUFFICIENCY OF SELECTED POLICY FRAMEWORKS

39. Do you think the following policies can properly regulate, cannot regulate at all, or can regulate but needs modifications in order effectively regulate synthetic biology in Kenya?

(Can properly regulate=CR; Can regulate but needs amendments=CA; cannot regulate at all=CAT)

No.	Policy	CR=3	CA=2	CAT=1
39.1	Biotechnology Policy, 2006			
39.2	National Land Use Policy, 2018			
39.5	National Tourism Policy, 2006			
39.6	Environmental Policy, 2013			
39.8	Climate Change Policy, 2016			
39.9	Aquaculture Policy, 2006			
39.10	Science Technology & Innovation Act of 2013			
39.12	Agricultural Policy, 2015			
39.15	Food and Nutrition Policy, 2011			
39.17	The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions			
39.18	National Policy on Culture and Heritage, 2009			

SUFFICIENCY OF THE BIOSAFETY LEGISLATION ACT, 2009

40. Rate the sufficiency of the following legislative frameworks to the regulation of SynBio.

No.	Statement	SA=5	A=4	N=3	D=2	SD=1

40.1	I am aware about the Biosafety Act of 2009 that was also amended in 2012					
40.2	I am confident about capacity of the Biosafety Act to facilitate responsible research and minimize risks that may be posed during use of SynBio products					
40.3	I am confident about the capacity of the Biosafety Act to establish a transparent, science based and predictable process for reviewing and making decisions on the development, transfer, handling and use of SynBio products and related activities.					
40.4	I am confident about capacity of the Biosafety Act to ensure adequate level of protection in the development, transfer, handling and use of SynBio products that may have an adverse effect on the health of the people and the environment;					
40.5	I am confident that the Biosafety (Environmental Release) Regulations, 2011 constitute the needed protocols for releasing SynBio products in Kenyan environment					

INSTITUTIONAL MANDATES AND RELRVANCE OF CURRENT WORK

No.	Statement	SA=5	A=4	N=3	D=2	SD=1

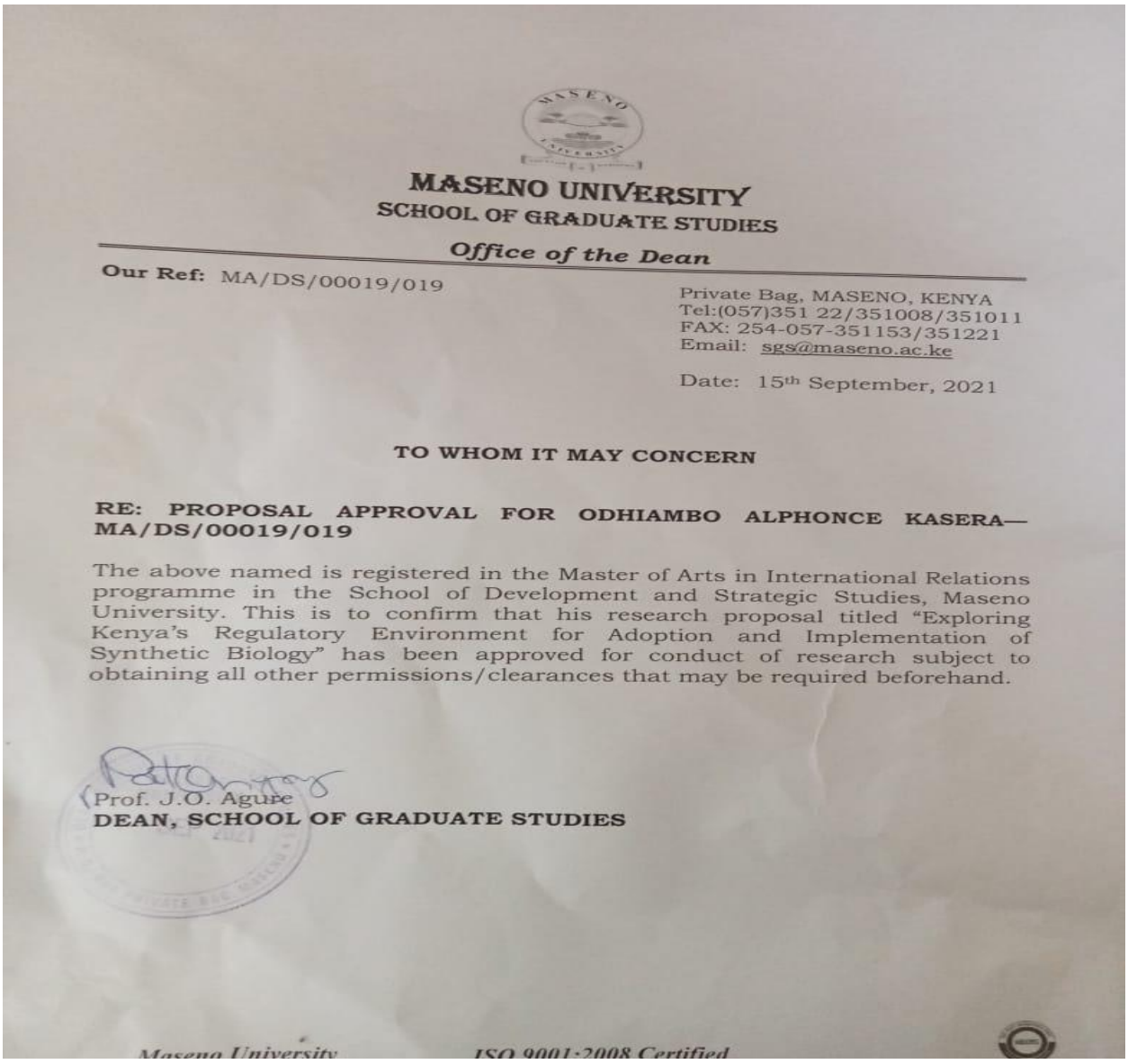
THE LEVEL OF EMBEDDING ST&I (BIOTECHNOLOGY) OF NATIONAL DEVELOPMENT PLANS

41. What is your overall assessment of the current national development strategies in regards to their SCIENCE, TECHNOLOGY & INNOVATIONS (ST&I) provisions which are relevant for adoption and implementation of SynBio in the country?

Very well placed		well placed		Moderately		Not placed		Not at all placed	

42. Please help me assess these specific National Development Plans in regards to favorable adoption and implementation of SynBio innovations that can solve national problems such as health and food and nutrition security

APPENDIX 4: SGS APPROVAL



MASENO UNIVERSITY
SCHOOL OF GRADUATE STUDIES
Office of the Dean

Our Ref: MA/DS/00019/019

Private Bag, MASENO, KENYA
Tel:(057)351 22/351008/351011
FAX: 254-057-351153/351221
Email: sgs@maseno.ac.ke

Date: 15th September, 2021

TO WHOM IT MAY CONCERN

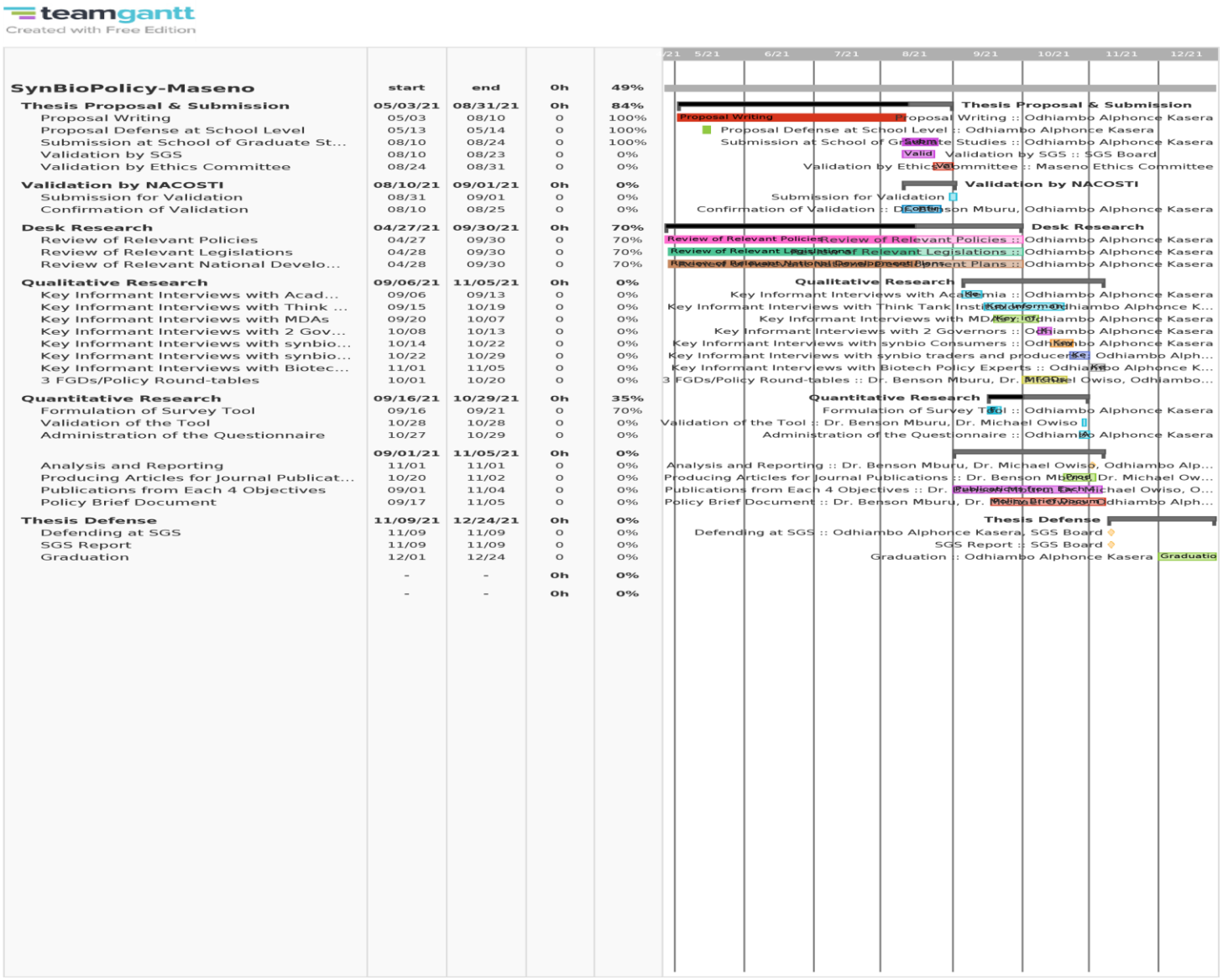
RE: PROPOSAL APPROVAL FOR ODHIAMBO ALPHONCE KASERA— MA/DS/00019/019

The above named is registered in the Master of Arts in International Relations programme in the School of Development and Strategic Studies, Maseno University. This is to confirm that his research proposal titled "Exploring Kenya's Regulatory Environment for Adoption and Implementation of Synthetic Biology" has been approved for conduct of research subject to obtaining all other permissions/clearances that may be required beforehand.

Prof. J.O. Agure
DEAN, SCHOOL OF GRADUATE STUDIES

Maseno University *ISO 9001:2008 Certified*

APPENDIX 5: STUDY PLAN



	start	end	0h	49%
SynBioPolicy-Maseno				
Thesis Proposal & Submission	05/03/21	08/31/21	0h	84%
Proposal Writing	05/03	08/10	0	100%
Proposal Defense at School Level	05/13	05/14	0	100%
Submission at School of Graduate St...	08/10	08/24	0	100%
Validation by SGS	08/10	08/23	0	0%
Validation by Ethics Committee	08/24	08/31	0	0%
Validation by NACOSTI	08/10/21	09/01/21	0h	0%
Submission for Validation	08/31	09/01	0	0%
Confirmation of Validation	08/10	08/25	0	0%
Desk Research	04/27/21	09/30/21	0h	70%
Review of Relevant Policies	04/27	09/30	0	70%
Review of Relevant Legislations	04/28	09/30	0	70%
Review of Relevant National Develo...	04/28	09/30	0	70%
Qualitative Research	09/06/21	11/05/21	0h	0%
Key Informant Interviews with Acad...	09/06	09/13	0	0%
Key Informant Interviews with Think ...	09/15	10/19	0	0%
Key Informant Interviews with MDAs	09/20	10/07	0	0%
Key Informant Interviews with 2 Gov...	10/08	10/13	0	0%
Key Informant Interviews with synbio...	10/14	10/22	0	0%
Key Informant Interviews with synbio...	10/22	10/29	0	0%
Key Informant Interviews with Biotec...	11/01	11/05	0	0%
3 FGDs/Policy Round-tables	10/01	10/20	0	0%
Quantitative Research	09/16/21	10/29/21	0h	35%
Formulation of Survey Tool	09/16	09/21	0	70%
Validation of the Tool	10/28	10/28	0	0%
Administration of the Questionnaire	10/27	10/29	0	0%
	09/01/21	11/05/21	0h	0%
Analysis and Reporting	11/01	11/01	0	0%
Producing Articles for Journal Publicat...	10/20	11/02	0	0%
Publications from Each 4 Objectives	09/01	11/04	0	0%
Policy Brief Document	09/17	11/05	0	0%
Thesis Defense	11/09/21	12/24/21	0h	0%
Defending at SGS	11/09	11/09	0	0%
SGS Report	11/09	11/09	0	0%
Graduation	12/01	12/24	0	0%
	-	-	0h	0%
	-	-	0h	0%

APPENDIX 5: MUSERC APPROVAL

MASENO UNIVERSITY SCIENTIFIC AND ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
Fax: +254 057 351 221

Private Bag – 40105, Maseno, Kenya
Email: muerc-secretariate@maseno.ac.ke

REF: **REF**: MSU/DRPI/MUERC/01062/22 **Date**: 29th August, 2022

TO: Odhiambo Alphonce Kasera
PG/MA/DS/00019/2019
Department of International Relations and Diplomacy
School of Development and Strategic Studies
Maseno University, P.O. Box Private Bag, Maseno, Kenya

Dear Sir,

RE: Exploring Kenya's Biotechnology Regulatory Environment for Adoption and Implementation of Synthetic Biology Technologies

This is to inform you that **Maseno University Scientific and Ethics Review Committee (MUSERC)** has reviewed and approved your above research proposal. Your application approval number is MUERC/01062/22.The approval period is 29th August, 2022 – 28th August, 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by Maseno University Scientific and Ethics Review Committee (MUSERC).
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to Maseno University Scientific and Ethics Review Committee (MUSERC).

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely

MASENO UNIVERSITY ETHICS REVIEW COMMITTEE 29 AUG 2022 P.O. BOX PRIVATE BAG MASENO

Prof. Philip O. Owuor, PhD, FAAS, FKNAS
Chairman, MUSERC

APPENDIX 6: NACOSTI APPROVAL

REPUBLIC OF KENYA

NATIONAL COMMISSION
SCIENCE, TECHNOLOGY & INNOVATION

Date of Issue: **19/October/2021**

Ref No:**613027**

RESEARCH LICENSE

This is to Certify that Mr.. Odhiambo Alphonce Kasera of Maseno University, has been licensed to conduct research in Kakamega, Kiambu, Kilifi, Kisumu, Nairobi, Nakuru, Siaya, Uasin-Gishu on the topic: EXPLORING KENYA'S REGULATORY ENVIRONMENT FOR ADOPTION AND IMPLEMENTATION OF SYNTHETIC BIOLOGY for the period ending : 19/October/2022.

License No:**NACOSTI/P/21/13392**

613027
Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE.TECHNOLOGY & INNOVATION

Verification QR Code

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