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Governing Emerging Technologies: A Systematic Exploration of Kenya's Biotechnology and LMO-Specific Policy Documents for Adoption and Implementation of Synthetic Biology

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Abstract:- As an emerging yet disruptive technology, the most challenging questions surrounding synthetic biology (SynBio) are, arguably, those of regulatory nature. At the global scale, such questions have been framed within the Convention on Biological Diversity (CBD) and its protocols. Hence, SynBio regulatory debates have largely been framed as similar to Living Modified Organisms (LMOs). National policies on LMOs domesticated from the CBD frameworks (and other relevant instruments) have thus been perceived as applicable to the regulation of SynBio. Recent debates, however, within the CBD, at regional and national scales, have pointed to the 'complex' nature of SynBio leading to a call for policy-makers and regulators to 'update' LMO regulations or formulate SynBio-'specific regulations'. This is so, it is argued because certain products and components of SynBio contain unique potential risks and applications. Consequently, the present study is an excerpt from a Master Thesis Study, which exploited an exploratory qualitative design and the theory of adaptive anticipatory governance, to explore 16 biotechnology and LMO-specific policy documents for adoption of SynBio. The study was conducted between May November 2021. The results of the study show that although Kenya has domesticated several global regimes on biotechnology and LMOs, the policy environment is still inadequate to effectively regulate SynBio. The policy environment does not outline a clear platform for cooperation and coordination between potential key stakeholders, including academia, industry and the government, and the general public. Critically and more importantly, the biosafety, biosecurity, bioethical risk issues related to SynBio cannot be properly regulated using current biotechnology frameworks. The study concludes that Kenya should consider updating its biotechnology policies or define a Synthetic biology-specific policy in order to adapt and implement SynBio in a responsible research and innovation environment. In this regard, the study proposed an adaptive anticipatory governance model that can provide the needed tools to evaluate the regulatory gaps in the current LMOs regulatory frameworks; hence facilitating the formulation of the requisite regulatory environment for SynBio.

Keywords:- *SynBio, Kenya, Biotechnology-Related Policies, LMOs Regulatory Environment, Adaptive and Anticipatory Governance.*

I. INTRODUCTION

In 2014, the Institute for Agriculture and Trade Policy (the IATTP) asserted that 'products derived from SynBio are beginning to enter the marketplace without a regulatory framework in place that provides for pre-market safety assessment of its unique risks to health and the environment. In the very near future, a host of food and agricultural products could be on the marketplace without labeling and in natural ecosystems without biosafety controls or indeed, understanding about the effect of SynBio on biological diversity' (Suppan, 2014, p. 1).

Just two years after IATTP alarm, SynBio was named among top ten world's most significant technologies by the World Economic Forum (Bojar, 2016). While SynBio acquired global issue status in 2012 after a substantive discussion by CBD's Subsidiary Body on Science Technology and Technical Assistance (SBSTTA), regulatory deficiencies expressed by Suppan (2014) above have only become more pronounced. Kolodziejczyk & Kagansky (2017) have argued, with respect to the Group of 20 developed countries (G20) that while SynBio products are already in the market and more and more advanced products on their way to the market, G20 countries still employ regulations developed for genetically modified organisms (GMOs). In their view, LMOs regulations are 'outdated' since SynBio employs more 'superior' tools than its LMOS 'prototype' (p. 6). In essence, commercialized SynBio products are escaping proper regulations due to the assumption that SynBio products and components are similar to LMOs. The potential risks from this situation, they argue, would be the lack of containment of the health, environmental and societal risks associated with the technology's products and components. Such evidence spell more dangers

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particularly in a context where more countries, including from the developing world are entering into the SynBio playfield. Kenya for example has commissioned a research study to develop two pioneer SynBio innovations[4].This makes it crystal clear the need for a study to assess the applicability of biotechnology and LMOs-specific regulations to the regulation of SynBio, more particularly in those countries yet to adopt and implement SynBio like Kenya.

The debate whether LMOs regulations are applicable to SynBio is largely witnessed in those countries which have experienced the technology; particularly the USA (Suppan, 2016, Jayanti, 2020; Gronvall, 2015), Singapore (Trump, 2017), UK (Marris & Calvert, 2018; SynBio Leadership Council [SBLC], 2016) and selected countries in South East Asia (Ning, Poh, Aggrawal et al., 2020). Suppan (2014) and Jayanti (2020) highlight three avenues that make the current USA SynBio regulation inadequate; a) the Confidential Business Information (CBI) principle, the product not process approach, and the lack of SynBio-specific regulations. Through the CBI, products on the verge of commercialization are reviewed by government experts only. Any public expert review processes are thus blocked. The Product-not-process approach means that USA SynBio like LMOs law is based on the assumption that biotechnology and its techniques are good but some of its products may pose harmful impacts. Lastly, Suppan (20140 and Jayanti (2020) have argued, as have others (Gronvall, 2015) that SynBio have not been properly regulated under LMOs frameworks because some, particularly recent and more advanced SynBio products are produced through technologies that go beyond the 'traditional recombinant DNA techniques' (Jayanti, 2020). Moreover, '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. Switch grass engineered to be a more efficient feedstock for biopower, for example, is not regulated by the Animal and Plant Health Inspection Service (APHIS) because it is not a plant pest, nor was it made using a plant pest' (Jayanti, 2020, p. 10).

Studies on the USA and UK experiences have also pointed out that a lack of SynBio-specific regulation has facilitated Do-It-Yourself biology where senior and amateur SynBio researchers have had the leeway to conduct research out of controlled laboratory setups. While this has provided a sort of democratic environment for SynBio innovations, studies have expressed the fear that the DIY phenomenon is likely to lead to a scenario where SynBio products and components are weaponized and used against the 'public purpose' motive upon which SynBio should serve, something described as a dual-use threat (Jayanti, 2020; Marris & Calvert, 2018; Suppan, 2014, Gronvall, 2015; Pauwels & Stemerding, 2011).

At the global level, the inadequacy of current global and national SynBio regulations is debated under the platform CBD Technical Series on SynBio. The latest of such series is currently undergoing expert peer review to update the 2015 series. What has been pointed out very clearly is that not only should national governments update their biotechnology regulations to capture the full breadth of SynBio-enabling technologies, but also that the applicability of current global regulatory regimes to SynBio under the CBD needs to be reassessed (Secretary to the Convention of Biological Diversity [SCBD], 2021).

Against this backdrop, this study was conducted to generate the evidence needed for formulating a functional SynBio regulation in Kenya. Conducted under the National Research Fund on SynBio Project[5] (NRF SynBio) (under which the researchers' Master's Thesis from which this study is excerpted was conducted) the study utilized secondary data from 16 biotechnology and LMO-specific policy documents retrieved from the relevant Ministry websites of the Government of Kenya. The next part of the paper consist of five sections. The materials and methods section present the methodology, conceptual framework and empirical review of extant studies. The third section, results, presents the data analysis and interpretation. The four section attempts a discussion of the findings and the final section presents the conclusions and recommendations.

II. MATERIALS AND METHODS

A. The Methodology

Exploratory purposive sampling design guided the planning and collection of the data and guided the choice for policy documents to systematically explore. The exploratory design was adequate since SynBio is only a grey area of research in Kenya. Selected 16 biotechnology and LMO-specific policy documents formed the core of secondary data analyzed. To contextualize the data from these materials, the researcher also consulted international regimes on biotechnology, including CBD and its protocols; and other regimes relevant to the regulations of synthetic biology. Also important was empirical work published on regulatory issues concerning SynBio.

Data analysis was done through thematic content analysis. Validity and reliability of the study was achieved in three ways: the research proposal went through a due rigorous University review protocols, at the departmental level, School of Graduate Studies and Maseno University Ethics Review Committee; a further review and permit was done by the Kenya tertiary research regulatory, the National Commission on Science Technology and Innovation (NACOSTI).
Ethical issues adhered to in the study included: receipt of permits from the relevant bodies at the university: School of Graduate Studies and Ethics Committee, and out of

[4] The Government of Kenya through the National Research Fund has commissioned ISAAA to undertake a study that should produce SynBio-based biosensors and rapid diagnostic kits.

[5] The NRF SynBio Project, which this study is part, aims to produce SynBio –based biosensors and rapid diagnostic kits to be used in improve agriculture and health sectors in Kenya, respectively. The Project should end in 2021 during Kenya is expected to adopt these SB tools.

university, NACOSTI. The NACOSTI permit include the permit to retrieve and analyze the government authoritative works/documents used for this analysis appear.

B. Empirical Review

- *Global Perspectives on the Applicability of LMO Regulations to SynBio*

At the global scale, SynBio is discussed within the scope of the Convention of Biological Diversity together with its subsidiary protocols concerned directly with Living Modified Organisms (LMOs): the Cartagena Protocol or the Biosafety Protocol, Nagoya Protocol on Access and Benefits Sharing, and the Nagoya Kuala-Lumpur Supplementary Protocol on Liability and Redress (Keiper & Atanassova, 2020; SCBD, 2021). Due to the cross-cutting nature of SynBio, other non-CBD regimes have been considered as applicable to SynBio regulation. These include, for example, the Biological Weapon Convention (BWC) which for example is applied in the USA to deal with DIY biology issues (Jayanti, 2020). The SCBD (2021) which is the latest ongoing technical and expert revision of the CBD technical Series on SynBio 2015 has also advised states to consider applying BWC to the regulation of SynBio.

Convention of Biological Diversity in its 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" (SCBD, 2021). Under CBD therefore, States Parties which have adopted and implemented SynBio must ensure that there is, in place, a regulatory environment that will contain all the potential environmental risks that SynBio portends. The question as to whether SynBio can affect biological diversity thus falls under CBD has been answered in the affirmative by the CBD Technical Series on SynBio (CBDTSB) (SCBD, 2021).

The Biosafety Protocol lays the framework for biosafety regulation on transboundary, transit and handling of all forms of LMOs that have impact on biological diversity, and human health (Article 4). It defines the concepts living organisms, living modified organisms, and modern biotechnology. According to the SCBD (2021), SynBio to a given extent falls within the Protocol's conception of these three concepts and hence to a given extent can regulate SynBio. The excluded SYNBIOs include ''DNA and constituent parts' (Mackenzie et al., 2003), 'plasmids or DNA' (SCBD, 2021). The SCBD (2021) advices States Parties to the CBD to localize the Biosafety Protocol and contextualize it according to national environments. The challenge with Biosafety Protocol in regulating SynBio for countries that adopted and commercialized SynBio is that: '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' (SCBD, 2021, p. 85). This leads us to contend that current national regulations applicable to LMOs which is the focus of Biosafety Protocol should be assessed, and if necessary updated to capture the particularities of SynBio. This assertion has also been advised by Gronvall (2015), Jayanti (2020), Trump (2017) and other country or region-specific countries.

Nagoya– Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (the Supplementary Protocol) aims to ''…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 1). The Supplementary Protocol outlines avenues for redressing risks or damages from LMOs from three sources: any authorized use of the LMOs; resulting from unintentional transboundary movements and illegal transboundary movements as referred to in Article 25 of the Cartagena. The Protocol also defines technical concepts related to limitations and redress on LMOs risks such as the notifier, damage, importer, exporter, and operator. Like the CBD and other of its Protocols, the provisions of Supplementary Protocol applies to SYNBIOs which are considered part of LMOs. According to the 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, and intentionally released organisms may become invasive due to engineered fitness advantages (p. 92).

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 (Access and Benefits Sharing Protocol (ABS)) covers: '… 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' (Article 3). According to the CBD Technical Series on SynBio, three aspects of the ABS protocol relate to SynBio regulation: '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 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 as defined in the Convention'. According to the SCBD (2021) '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 SB would be within the scope of the Nagoya Protocol' (p.93).

On the issue of benefit sharing and the degree of modification of synthetic genetic materials the SCBD (2021) cites Wang et al. (2009), who argues that SynBio comes with a variety of techniques that can manipulate naturally existing materials for more customized purposes, hence can fall under

the ABS protocol understanding of benefits sharing and modification of genetic materials. The SCBD (2021), however, argues that the extent and nature of implementation of the protocol will depend of agreements between the contracting parties, that is, importer and exporter but also will depend on whether in question have national frameworks defining such procedures. Lastly, on the concept of 'derivatives' what matters to SynBio is the question: whether or not biochemical compounds produced by synthesized organisms could be considered a "derivative" as defined by the Protocol (SCBD, 2021). SCBD (2021) concludes that ''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'' (p. 94).

- *Perspectives from SynBio Pioneer Nations: A Close Look at 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. Internationally, countries rely similarly on legislation for genetically modified organisms (LMOS)' (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 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 with particular issues related to the above three areas are:

''NIH Guidelines on Recombinant DNA: Establishes guidelines for NIH-funded research using recombinant or synthetic 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 synthetic 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 synthetic 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 Synthetic Double-Stranded DNA (HHS): This guidance prevents companies from synthesizing long stretches of DNA from select agents without applying strict "know your customer" rules. Additionally, it restricts certain pathogens from being synthesized, such as smallpox; National Science Advisory Board for Biosecurity: Though not a regulatory act, 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. Firstly, Jayanti (2020) argues that such an approach reduces focus on 'risk-focused regulation of SynBio R&D'; it overburdens already overburdened regulatory authorities which can make SynBio risk-assessment slow or ineffective; the framework cannot deal with the negative possibilities of the DIY approach ((Pauwels, Stemerding, 2011); Jayanti (2020) emphasizes that the approach oversees the fact that certain SynBio products completely fall out of the scope of current biotechnology regulations, such includes, "the 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" (p. 10).

Other issues are that the LMOs approach to SynBio blurs possibilities to explore systematic SynBio consumer and public education (Hart Research Associate, 2013: Jayanti, 2020); 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, adding that biological diversity issues are also overlooked under current regulations, but it is possible that certain Synthetically modified organisms could outcompete their naturally occurring counterparts.

➢ *Kenya's Experience with LMOs*

Mugo et al. (2017) outlines Kenya's journey with the regulation of *Bacillus thuringiensis* (*Bt* Maize); the first ever LMO plant to be authorized in Kenya, followed by Bt Cotton and recently Cassava (Kenya Agricultural and Livestock Research Organization, 2021). They argue that Kenya's LMO activities are regulated by the Biosafety Act, the Biotechnology Development Policy and what they call 'a biotechnology awareness strategy to enable research and development of GMO crops' (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 SynBio go beyond traditional biotechnology approaches used in the LMOs era, it remains unclear whether the biotechnology regulatory system in Kenya is applicable to SynBio. This warrants a study such as this with the intent of assessing the extent of applicability of the policies and legislations used for LMOs to SynBio.

Olembo, M'mboyi, Oyugi, Nyende & 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 are aimed at increasing agricultural crop production. They argue that there are three categories of countries in sub-Saharan Africa regarding biotechnology advancement, thus: 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 in Africa. 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, the country stands a chance not only to increase her productivity of the potato crop, which is one of the most commons foods, but also incomes of the majority smallholder poor farmers who are the most affected. The traditional regulatory system for LMOs may therefore be inadequate to capture this new generation of biotechnology. Indeed, some studies have already pointed out to the inadequacies of the LMOs regulatory system (Andanda, 2006). Therefore, to understand the current possibilities and impossibilities of the Kenya's LMOS regulatory system in regards their applicability to SynBio, this study endeavored to the analysis of policy documents and legislations, complimented with policymakers' perspectives.

Andanda (2006) analysed the legislative framework for LMOs regulation in South Africa and Kenya, 'the two leading producers and exporters of LMOs in Africa' (p. 1361). Citing UNCTAD (2000) Andanda argues that while modern biotechnology advances are riddled with both challenges and opportunities, the analysis of cutting-age innovations 'is almost always focused on the challenges rather the opportunities'. She contends 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 from within the biotechnology scholarship itself. She 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 while the funder on their side insisted that the techniques and the product had been tested elsewhere and that there was need for 'unnecessary regulations'.

The other problem facing biotechnology regulation is 'decentralised organisational framework with governmental and intergovernmental organisations having overlapping jurisdictions'. This implies, she argues, 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). This, according to Andanda complicates regulations of biotechnology, making it ineffective and inefficient.

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

Kivuva, Yegon & Ndue (2017) reviewed Kenya's biotechnology policy against the backdrop of the realities that have unfolded in the LMOs 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 argue that the due procedure was followed and the bollworm 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 Andanda (2006) reviewed above, was due to inadequacies in the biotechnology development policy that failed to foresee the economic and social impact scenarios of certain LMOS 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 LMOs development cycle and regulation are good lessons for policymakers and regulators 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. 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 SynBio regulation.

C. The theoretical Framework

As a student of International Relations, I found it difficult applying an IR theory as a guide to investigating my study problem. How exactly Realism[6] or Liberalism, or Constructivism or even so-called alternative approaches (see Baylis, Steve & Owens, 2011) could help as a theoretical guide to the phenomenon of governance of emerging technology like SynBio was a difficult question to answer. In the spirit of the multi-and-inter disciplinarity* of IR (Griffiths, 2007), and in the pursuit of a parsimonious theoretical framework to conceptualize the study and guide collection, analysis, interpretation, and drawing of inferences, the researcher exploited adaptive anticipatory technology governance as a theoretical framework. The arguments in this theory and how it applied to the research processes is presented as below.

- *Theory of Adaptive Anticipatory Governance*

The theory of adaptive anticipatory governance has been proposed not as a theory as such in the emerging technologies governance literature, including SynBio, but as an analytical framework for identifying the gaps which exists in biotechnology and LMOS-specific regulations (Greer & Figueras, 2016; Trump, 2017; Marris & Calvert, 2018) in countries in possession of such frameworks in order to adapt them to the regulation of SynBio. 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 among others) have explicitly argued that "anticipatory", "proactive" "sustainable" "responsible" and "adaptive" governance are the best approaches to governing emerging technologies. This study adopted the phrase adaptive anticipatory governance as an integrated nomenclature for all these concepts. Trump (2017) contends that the need to adopt an adaptive anticipatory governance model emerges from the very double-edged sword nature of SynBio. 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). The resulting SynBio modified organisms and products (referred in the literature as SynBio) may have tremendous positive impacts in fields such as drugs and medicine, climate change and environmental variability, energy, food security through control of pests and invasive species among may more (Harris, McKemey, Nimmo, Curtis, Black, Morgan et al., 2012). At the same time, "the release of various organisms with substantial genetic modification may potentially cause consequential and irreversible impact upon humans, animals, and the environment. Though highly uncertain, such impacts may include, among others, threats to biodiversity (where modified organisms unintentionally outcompete their native counterparts) and horizontal gene transfer (where artificial genetic information may be transferred from an engineered organism into an unintended native host). Further concerns include discussion of the dual use nature of SynBio, where nefarious actors could theoretically use the technology to produce deliberately harmful organisms" (Trump, 2017, p. 1).

The need for adaptive anticipatory governance has therefore emerged as a central approach to SynBio across the world because the magnitude of such risks it can cause to technologists, society, health systems and the environment are not only difficult to quantitatively model via existing risk assessment protocols, but are also exhibit "greater uncertainty, environmental permanence, and overall poor risk characterization" (*Ibid*, p. 1). While other scholars have based their arguments for adaptive anticipatory SynBio governance on the existing state practice for example in the USA, UK, Singapore and the larger EU where states are applying existing applicable regulatory rules and procedures as well as regulatory authorities to regulate SynBio, others have proposed that an adaptive anticipatory governance for SynBio would require sui-generis policy and legislative reforms where SynBio technology specific policies and legislations are defined to direct SynBio governance (Seager, Trump,

[6] I use capital r to distinguish the theory from the state of being realistic, etc.

Poinsatte-Jones, Linkov, 2017; Epstein & Vermeire, 2016; Kuiken, Dana, Oye, Rejeski, 2014; Giese, von Gleich, 2015). Overall, the adaptive anticipatory governance of SynBio provides a framework for collaboration between multiple sectors and actors in the process of laying the necessary policy and legislative reforms to adapt or develop new biotechnology policies and legislations that will ensure that there a balance between the anticipated benefits of SYNBIOs vis-à-vis the highly uncertain potential future risks of the technology to social fabric, environment, health and the processes of developing the technology itself.

This study employs adaptive anticipatory SynBio governance as a theoretical rather than an analytical framework. This is because of two main reasons, first is that nearly every literature on SynBio, and by extension other emerging technologies such as nanotechnology, artificial intelligence, etc., regulation refers to the notion of adaptive anticipatory governance (SCBD, 2021; Marris & Calvert, 2018; Trump, 2017; 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; Mandel & Marchant, 2014, among many others). Secondly, the notion of adaptive anticipatory governance (AAG) as an approach to regulating SynBio has been accorded to a great extent certain distinguishing features. This second reason for exploiting AAG as a theoretical framework is discussed in the following pages.

Three features of AAG emerge in the SynBio regulation literature. The first assumption is that the extent to which SynBio governance will be adaptive and anticipatory will depend on the existing risk culture characterizing the jurisdiction in question. The second tenet is that adaptive anticipatory governance is only possible when there mechanisms in place that foster and aim to continuously foster a multisectoral approach to governance. Lastly, that to assess the extent to which a governance system scores on the first two tenets will always depend on an assessment of a framework constituting five interrelated factors, namely, transparency, accountability, participation, integrity and capacity (TAPIC) (Douglas & Stemerding, 2014; Mandel & Marchant, 2014; Marris & Calvert, 2018; Trump, 2017; Greer & Figuera, 2016; Boven, 2007; Fatehi & Hall, 2015; Abbot, 2012).

Trump (2017) 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, he further asserts, include three integral issues "the availability of biotechnology or LMOS-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" (p. 2) or what he calls legalism. How risk culture varies for soft-authoritarian regimes like Singapore to culturally democratic regimes like the EU countries and USA, as well as how the variation plays out to influence policy reforms for SynBio has been well captured by the same author and is not the subject for this section. As regards the second tenet, the availability of multisectoral approaches to regulation, this matters in terms of the nature of participation which a country will adopt in regards to SynBio R&D, which AAG conceives as part and parcel of it since the aim to balance potential risks against potential benefits. Lastly, the TAPIC framework provides the regulatory/policy researcher with the opportunity to establish the gaps in a given jurisdiction's approach to SynBio governance as regards adaptive and anticipatory multi-stakeholder governance. Trump (2017) emphasizes that the TAPIC framework "can contribute to the development of either flexible, adaptive, and anticipatory governance to keep pace with the emerging knowledge of SynBio health risks, or inflexible and unresponsive governance that consistently lags behind existing practice and scientific capabilities" (p. 4).

The TAPIC environment in SynBio regulation applies as follows. The transparency element should cover four key issues: first issues is that a transparent SynBio governance should properly spell out the policies applicable to SynBio regulation with clearly stated scopes, also, there this should 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). Trump (2017), however, underscores that over-transparency could be a hindrance to development of emerging technologies like SynBio, at during their early stages. He nevertheless thinks that transparency should be considered to some extent as it sets out the framework for responsible behavior. 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).

Still, several studies have pointed out that sui-generis regulatory tools may need to be adopted to ensure that SynBio is regulated with relevant rules or to ensure that it is assessed the extent to which existing biotechnology or LMOS-specific regulations can be applied to SynBio (SCBD, 2021; Marris & Calvert, 2018; Akpoviri, 2018; Trump, 2017). This means that accountability is still important, albeit to some extent owing to the emergingness of SynBio. On the participation element, emphasis is laid on the notion that the creation of constructive, flexible, and anticipatory soft law for SynBio requires the engagement of key stakeholders outside of government bodies (Mandel & Marchant, 2014; 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). Thus, Trump (2017) discerns two approaches of participation, bottom-up, where the government emphasizes on non-state participation and where government regulators only play a minimal role as in EU or a top-down, state-experts driven governance approach where government policy makers and regulators play a critical role in framing the direction of SynBio regulation and development as in Singapore. Either the approach adopted, there are merits and demerits. This is important for particularly new comers like Kenya to learn.

Concerning integrity, Trump (2017) reiterates the reality that ensuring integrity in SynBio governance is still an illusory issue largely because states still apply what they have as regulatory pieces relevant to the technology to regulate it, for example the application of chemical regulations in the USA or biotechnology regulations in EU and Singapore. As such he 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" (p. 5). At the same time, two integrity issues are being discussed in the literature as regards 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 (P. 6)

Finally, capacity issues in the governance of SynBio are also at their initial stages. 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. Generally, the theory of adaptive anticipatory governance presents a framework for assessing the efficacy of biotechnology governance to regulate SynBio. For this case, scholars propose that it is important to understand the risk culture of the country in question as this will impact the TAPIC framework which aids in the identification of regulatory gaps that may hinder an adaptive, effective, flexible anticipatory governance for SynBio. In the final analysis therefore, the risk culture and the TAPIC framework affects each other to give rise to either an adaptive anticipatory regulatory environment or vice versa.

III. RESULTS

This section presents the findings from the analysis of policy documents regulating biotechnology in Kenya. The policy documents explored are 16 in number and are analyzed one after another in a bid to identify regulatory gaps. The gaps approach will inform further analysis discussions in section VI.

A. The Biotechnology Development Policy, 2006

Kenya's Biotechnology Development policy was drawn with the regulation of LMOs 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, 2006, p. 9). Through the policy, Kenya aims 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' (p.10). The scope of the policy is to 'seeks 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 under which the government undertakes to promote biotechnology education through of curriculum 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.

Under bioresources, 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

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ex-situ (Gene banks) conservation centres; focused exploitation of fauna, flora and microbes in marine and extreme habitats for novel genes for development of SynBio-tolerant crops, enzymes, biopolymers, marine pollution biosensors (p. 13-14).

The environmental biotechnology priorities deal with risks perspectives of biotechnology. 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 LMOs. 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 LMOs. 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 undertakes to put into place an inter-sectoral 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 LMOs 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 and the Kenya Biosafety Act.

Medical Biotechnology is the fifth issue area and through which the Government hopes 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, such as the novel COVID 19, 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 LMOs which are health and nutrition-related, listed as vaccines, vitamins, hormones, diagnostic kits, and naked DNA (*Ibid*, p. 18).

Sixth priority area is the Industry and Trade when 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 do value addition to primary commodities (p. 18). Four actions 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 (SMSBEs); 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 set goal 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 takes 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 LMOs 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" (*Ibid*, 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. 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 sectoral 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 established the National Biotechnology Council (NBC) to solve problems associated with the sectoral 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 NBEC.

➢ *Gaps in the Biotechnology Development Policy, 2006*

The Biotechnology Development policy is central policy regulating biotechnology in Kenya. Ideally, the larger visions of policy covers the so called 'promises' of SynBio to a larger extent; across fields such as health, food security, and livestock development. At the same time, the policy in inherently deficient to regulate SynBio as it stands by the time of writing this paper. This is in the following ways.

The policy limits its recommendations and action plans to traditional and modern biotechnology. According to Tonui (2019) and SCBD (2021) a large part of SMOs are perceived going beyond what is conceived in the CBD, and its Nagoya, Cartagena, Nagoya-Lumpur protocols, as 'modern biotechnology'. The risks and biosafety issues it aims to mitigate are thus confined to GMO processes such as research, field tests/field trials, commercialization, including labelling. As SynBio is more advanced technology (SCBD, 2021; Keiper & Atanassova, 2020) the policy fails to capture issues relating to SynBio potential risks.

Secondly, alternative international regulatory frameworks applicable to SynBio are not referred to. Other than the precautionary principle and article 15 of the Cartagena Protocol on scientifically provable potential risks and Principle 15 of the UNCED the policy does not consider that alternative regimes such as the Convention on Biological Diversity can be applied to deal with issues relating to dual-use or DIY biology. This is the approach in the USA (Jayanti, 2020) and can be learnt and adopted according to local contexts. Thirdly, due to the LMOs-orientation of the policy it does not recognize the dual nature of biotechnology, which is a central issue for the governance of SynBio (Suppan, 2014; Jayanti, 2020; SCBD, 2021). By looking beyond CBD, and beyond LMOs the country could begin to see the full range of the 'enabling technologies' of SynBio and make necessary adjustments to the biotechnology framework.

Fourthly, the policy does not lay out a structured approach to stakeholders' engagement in the research, development and commercialization of biotechnology of an advanced level as SynBio. The NBEP, NBC and NBA are not closer to a SynBio coordinating institution bringing academia, industry and government together in the sense that such approaches are practiced in the European Union, USA and Singapore (Trump, 2017). Moreover, the Public-Private Partnerships (PPP) framework envisaged in the policy is not pro-cooperation for innovation as it emphasizes 'acquisition of consumables and equipment' (p. 22). It fails to foresee an emerging technology consortium capable of bringing together not just government institutions and the private sector to "research and develop" but critically to provide a balanced information that should inform activities of policy makers, regulators, industrialists, and the non-technologically informed members of the public.

Lastly, the relationship between disruptive biotechnologies such as SynBio and biological diversity, indigenous knowledge and cultural expressions (IKCE), among others, is not outlined. For example, the policy has no prouncements on biotechniques which may lead to products such as the 'designer babies' (Keiper & Atanassova, 2020) and the mechanisms for mitigating such risks. The policy should be revised to care for the extent of the impact of SynBio innovations on biological diversity as well as on IKCE.

B. National Food and Nutrition Security Policy

This policy document identifies food and nutrition security issues and lays out the intended measures the Government of Kenya (GoK) needs to take in ensuring that the country is food and nutrition secure. The policy development process encompassed a review of the Sessional Paper No. 2 of 1994 on National Food Policy. The policy sets up the National Food Safety Agency (NFSA). It incorporates food traceability elements and international Sanitary or Phytosanitary (SPS) standards. It commits the Government of Kenya (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 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*

SynBio has immense potential contributions to Kenya's vision for a sustainable food and nutrition secure country. The SynBio toolkits such as diagnostic kits and biosensors 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. Because SynBio has both human and national development potentials within the sphere of food and nutrition security, it is important to identify the gaps that the National Food and Nutrition

Security Policy (NFNSP) have to mainstream SynBio into food and nutrition policies. The following gaps exist in the policy.

Firstly, the policy was drawn before the dawn of SynBio and has no reference to the technology. The lack of focus on SynBio is understandable owing to the 'newness' of the concept as well as part of its tools and products. However, it is important that as Kenya officially adopts SynBio, the concept is systematically synchronized in her next/revised food and nutrition security policy.

Secondly, 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 may pose the successful implementation of the NFNSP. By including such potential risks that applications of SynBio to food and nutrition processes in Kenya and laying out frameworks for their management, the technology's promises to an economy resilient to food insecurity could be achieved more cost-effectively and efficiently.

Secondly, the stakeholders' engagement envisioned in the policy and its latest implementing framework (NFNSPF) is both limited in scope and does not provide explicitly the involvement of biotechnology players as an important component. 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 programmes. There is no provision, however, on the component of STC-FN. Because the country has accepted the critical role SynBio (ISAAA, 2020) can play in achieving its food and nutrition goals, it is important that overall leadership platform constitutes as its part actors in the biotechnology/SynBio field; at least from policy and technical aspects of the field.

Thirdly, the legal provision reiterated in the NFNSPF is based on the UN Universal Declaration on Human Rights (UDHR) (1948) that food and nutrition is a fundamental 'human right'. Kenya accepts to be bound by all international regimes on food and security including soft regimes such UN World Food Summit, 1996 and Sustainable Development Goals. The implementation framework advises the relevant stakeholders to review legislation and develop as necessary needed but lacking legislation and programmes to implement policy provisions. As the country adopts and implements SynBio, this exercise should incorporate not just SynBio stakeholders but also issues specific or more pronounced in the technology such as the possibility of SynBio food and security applications dual-use for unintended use such as advanced food poisoning or BWMD based on foodstuffs.

C. The Sessional Paper No. 1 of 2017 on National Land Use Policy and the National Land Use Policy, 2018

The national land Use Policy (2018) aims to achieve optimal and sustainable use of land. The policy objects "to provide legal, administrative, institutional and technological frameworks for optimal utilization and productivity of land and land-related resources sustainably and desirably at National, County and Sub-county and other local levels" *(*Ministry of Lands and Physical Planning., 2017). As envisaged in the Foreword of the Sessional Paper No. 1 of 2017 on National Land Use Policy (SPLUP), the policy aims to create mechanisms for seeking a critical balance between *satisfying the human livelihood needs and sustainable use of resources for posterity* (p. iv). This is a valid point as 75% of the country's population lives in areas characterized as medium to high potential agricultural lands (accounting for a mere 20% of the land area). This critical population, at the same time, comprises largely smallholder farmers who practice non-commercialized, low-income agriculture (Ministry of Lands and Physical Planning, 2017; ISAAA, 2020). From an International Relations vantage point, the policy is part of Kenya's policy domestication processes of the 1992 United Nations Convention on Environment and Development (UNCED) principles of sustainable development, including the fact that 'land is a finite resource that should be utilized sustainably' (Ministry of Lands and Physical Planning, 2017).

The specific problems that informed the formulation of the KLUP were to fill the gap of "absence of a clearly defined land-use policy in Kenya after years of independence has resulted in a haphazard approach to managing the different land-use practices and policy responses" (p. v) which has continued to give rise to 'uncoordinated' legal and policy approaches to managing issues of land use in Kenya. These problems have been identified in the Constitution of Kenya--*which* records in Article 60 that *land in Kenya has to be managed and used in a manner that is equitable, efficient, productive and sustainable*--the Kenya Vision 2030 and the Sessional Paper No. 3 of 2009 on the National Land Policy. Twelve guiding principles are identified in the policy document as follows: Efficient and sustainable land use management; Ecological sustainability; Integrity and adherence to the rule of law; Food security; Access to land use information; Amicable resolution of land-use conflicts; Equity, inclusivity and transparency in decision-making; Effective public participation; Elimination of discrimination and respect for human rights in land use; Public benefit and interest; Order and harmony in land use; Adoption of technology in land use management (Ministry of Lands and Physical Planning, 2017, p. 6).

The policy document identifies 9 themes/issue areas upon which land use management would serve a critical purpose: agricultural development-the policy takes cognizance of the critical role that agriculture plays in the economy; providing livelihoods to over 80% of the population and contributing over 25% directly to the national GDP. This theme aims to find solutions to the varied problems associated with agricultural development in Kenya, including climate change, underutilization of land, stringent

land tenure systems, among others. Other themes include; pastoralism and livestock development; industrial development; mining and energy; tourism; transport and infrastructure; national resources and environment including biodiversity conservation and transboundary issues; human settlement and housing and urban land use.

The policy sets principles and strategies to find solutions to 24 issue-specific areas. The issues range from land use to climate change, biodiversity. Specific strategies to be undertaken by the government are specified per issue area. To implement the policy, the NLUP sets up the institutional framework to oversight the sustainable, coordinated and optimal land use in Kenya. These include the National Council for Land Use Policy; the National Technical Implementation Committee; the County Technical Implementation Committees; restructuring the Ministry of Lands and Physical Planning, the National Department of Physical planning such as through *increase budgetary allocation to the National Department of Physical Planning to facilitate the effective performance of the enhanced functions assigned to that office* (*Ibid*); finally, the National Land Commission is charged 'to Conduct research on matters related to land and the use of natural resources and make recommendations to the relevant authorities; Prepare reports to bring out challenges in the implementation of National Land Use Policy by the different sectors' (Ministry of Lands and Physical Planning, 2017, p, 61).

- *Gaps in the National Land Use Policy, 2018*

As Kenya prepares to adopt SynBio, land use regulations can be made more explicit in land use policy pronouncements that explicitly recognize the value of the technology. This should include considering SB explicitly as an important avenue for, for example, providing solutions to the problems affecting land as an asset for agriculture, particularly in regards to the majority of small-holder farmers who constantly face the problem of decreasing agricultural land and experience inability to access information about and technologies to detect and manage crop pests and diseases in good time for informed decisions and actions.

SynBio can thus be key to unlocking solutions to the problems of land use; land and environmental degradation, urban environment management, among others. By providing cheap, easy to use biosensors, alternatives such as animals with edited DNA with improved traits for production, and many more promises, the technology can facilitate sustainable land use by improving yields and incomes of the majority of smallholder farmers. This can ensure that these farmers utilize their lands properly, reap good yields, avoid losses, earn good incomes and consequently contribute to the household, communal as well as national food and nutrition security.

Additionally, SynBio can contribute to disaster risks aversion to environmental accidents which can disrupt the operation of ecosystems such as those in the wetlands, and dry lands. For example, SynBio biosensors that can detect environmental pollutants long before their outbreaks can help in averting such challenges before they occur hence facilitating continued, for example, farming, wildlife or aquaculture life. Bio-sensing can also efficiently meet the goals aimed at being achieved by remote sensing as a way of increasing knowledge on natural resources which, according to the policy is a current gap. It is important therefore to appreciate the value of the technology in a land policy. The policy gaps in the NLUP, 2018 are:

The policy has no provisions on the applicability of SynBio in the management and resolution of problems related to land use in Kenya. It is imperative that as the policy's provision that the government undertakes a review of existing policies and legislation, such an exercise be done with SynBio in mind. The review should include, among others, explicit consideration of SB as an approach to a cost-effective innovation in the promotion of sustainable land use in Kenya. Secondly, the policy does not envisage biotechnology/SynBio stakeholders' engagement. The institutional framework it envisages for its implementation; the National Council for Land Use Policy, National Technical Implementation Committee, County Technical Implementation Committees (CTIC), Ministry of Lands and Physical Planning, The National Land Commission do not involve those with expertise in SynBio. To appreciate the promises of SynBio on sustainable land use and management, SynBio stakeholders should be involved in the decision processes of land use; right from policy formulations up to the implementation. This should be reflected in both national councils and steering committees as well as at the CTIC.

D. The National Agricultural Sector Extension Policy, 2012

The Agricultural Sector Development Strategy (ASDS) is implemented through the National Agricultural Sector Extension Policy (NASEP), albeit, it was never presented to Parliament for debate and ratification. Its goal is to empower extension clients by sharing information, teaching knowledge and skills, and behavioral change so that they can utilize their resources more efficiently and improve their quality of life (ASCU, 2012). It aims to achieve this goal through fostering heterogeneous extension service supply and administration, as well as guiding extended service providers' activities through the establishment of a separate regulating organization to ensure the provision of quality extension services.

The Policy directs extension services providers, in particular those who promote demand-led and beneficiary-led strategies for the selection of technologies and extension messages, to apply environmentally sound, evolving, ingenious and effective extension approaches and techniques. It promotes democratization of extension by utilizing clientele groups (e.g., popular interest groups, small farmers associations, and primary cooperatives) and wider public outreach for cost-effectiveness, while taking indigenous knowledge and technologies into account. In addition to providing flexibility for gradual privatization and change, this policy aims to maintain extension services for smallholder farmers inside the government. It also provides for an information system based on stakeholders and the technical assistance of agricultural extension service providers.

➢ *Gaps in the NASEP*

Firstly, the role of modern biotechnology is not appreciated in the policy yet modern biotechnology such as SynBio can play a cost-effective role in crop disease control and management through such applications as biosensors hence cutting costs associated with traditional extension service provider visits, while at the same time enabling smallholder and commercial farmers to experience a sustained production and high yields. Secondly, although the policy envisages a pluralistic approach to agricultural extension; the stakeholders it lists neither covers special interest groups (SIGs) in modern biotechnology nor government and private sector actors in the field of modern biotechnology/SynBio. Finally, the policy does not envisage a regulatory framework for modern biotechnology potential risks to agricultural extension services such as the side-effects of using biosensors by farmers or the potential dual-use risks of SynBio applications to which could be authorized in future to further agricultural extension services.

E. National Forest Policy, 2014

In appreciation of the 3.6% forest resources contribution to national GDP, and other non-economical contributions to the local communities; and the need to sustain and increased this contribution of forest resources, the National Forest Policy, 2014 sets out the principles, programmes, the legal and institutional frameworks for sustainable management and development of forest resources in Kenya. The policy appreciates the role of technology in this endeavor and devolves forest management and development asserts for example, under the problems related to forest research and education: *need therefore for research and development to refocus on basic forestry disciplines such as productivity, health, crop diversification, processing, value addition, intellectual property rights and indigenous knowledge* (Ministry of Environment, Water and Natural Resources, 2014, p. 3). The role of technology is also implied in other problems the policy aims to find systematic solutions to, these include climate change has caused among other things, droughts that affect food supply and biomass fuels; high levels of land degradation due to forest overuse and misuse; and decreasing low-quality water flows.

The objectives include: increasing tree and forest cover to at least 10%; promoting investment in commercial tree growing and trade; promote public-private partnership (PPPs) and community participation in forest process; support research, training and education in the forestry sub-sector and finally establish a functional legislative and policy environments for development and management of forests. The principles espoused in the policy include an emphasis on public good; an ecosystem approach; sustainable forest management (SFM); livelihood enhancement; research education and knowledge; and application of regional and international law which Kenya is a State Party, among others (*Ibid*, p. 6-7).

The programmes set in the policy for implementation of the goals within the bounds of the guiding principles include a commitment to review the Forest Act, 2005 to be in line with the Constitution of Kenya 2010 (CoK, 2010) the emerging issues forest management and development; mainstream forest cross-cutting issues across other sub-sectors; ensure partnership and stakeholder involvement through, '*…professional societies established to advance the science, technology, education and practice of professional forestry will enhance the professionalism and the formulation and implementation of forestry policies and practices (*Ministry of Environment, Water and Natural Resources, 2014, *p. 16);* and to localize multilateral environmental agreements (MEAs) on forest issues in Kenya as part of the forest regulating law.

➢ *Gaps in the National Forest Policy, 2014*

The policy does not envisage the application of either modern biotechnology or SynBio in the management and development of forest resources in Kenya. Secondly, the public-private partnership and stakeholders' envisaged does not particularly mention the role that modern biotechnology private sector actors can play. SynBio applications scientists, researchers and industrialists in the private sector could thus lack policy provision to join in this sort of PPPs for management and development of forest resources. Thirdly, there is no policy statement on the application of modern biotechnology within a devolved system of forest resources management and development. The policy statements on county and community based-sustainable forest management thus are deficient in regards to SynBio applications at these levels.

Fourthly, without an explicit consideration of the application of modern biotechnology, and particularly advanced biotechnologies such as SynBio in the above three areas, applying the technology to forest management without a reconsideration of the National Forest Policy, 2014, will consequently mean that ethical, legal social, biosafety and biosecurity issues relevant to SynBio may be overlooked or if such risks are managed, could only be done through chances. Such risks may span from potential risks that could emerge from the utility of the use of SynBio-based sensing systems to monitory forest environments, such as bio-sensors, to risks that may accompany applications of SynBio to biological diversity preservation of forest biological systems.

F. The National Environment Policy, 2013

Environmental Conversation and Management has been a key issue in Kenya since particularly 1999. 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 a coverall 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) – including tourism, land reforms, energy, human settlements, fisheries, livestock and others. The policy mainstreams previously unconsidered issues in environmental planning and management such as health, gender, community-based environmental management, HIV/AIDS, and climate change.

The guiding principles to attaining these 7 specific 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*

SynBio has immense potential contributions to the management, and sustainable use of the different sub-sectors of the Kenyan environment identified in the policy. Despite this, the policy is a pre-SynBio document and has several gaps which must be filled to enable systematic targeting of SynBio applications development and utility for delivering a safe, clean and healthy environment to the Kenyan citizens. The following gaps flow from the policy.

The policy has no special mention of the role of biotechnology in the realization of a safe, healthy environment. The concept of technology is only mentioned 3 times in the entire policy document concerning the issues of; i) biodiversity concerning benefit-sharing of technology (and other benefits) with communities where the genetic materials are obtained; ii) Industrialization, but again, only 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 under this issue commits the country to target and promote biotechnologies as a tool for environmental management and conservation. Since SynBio is only an advanced technology from biotechnology techniques part of which have been used in Kenya, these gaps are key to consider as Kenya forges ahead in adopting and implementing SynBio innovations.

Secondly, the lack of mention of biotechnology throughout the policy document, and a lack of appreciation of its role in environmental management implies that the bio-innovations sector was not properly targeted and engaged as key stakeholders in the decisions leading to the formulation of the policy. Subsequently, it is not clear the extent to which the bio-innovations of the private sector were engaged in the drawing of the policy as well as how they should be engaged as key stakeholders in processes intended to ensure production and consumption of the environment and natural resources sustainably. Lastly, the role of industry, particularly the bio-industry and modern technologies, in the management and conservation of the environment is not appreciated. In successful countries like the UK where SynBio has taken a lead role in knowledge biobased economy transformation, the industry has been a central player, even the overall sector guiding critical SynBio processes such as the drawing of the UK SynBio strategic plan 2016.

G. National Livestock Policy, 2008

The livestock sector accounts for nearly 95% of the source of livelihood for households in the ASAL regions, (Ministry of Agriculture, 2008), where it employs over 90% and 60% of total livestock is concentrated. To the national GDP, the sector contributes about 10% directly and 42% considered as agricultural sub-sector as well as employing 50% of the total agricultural labour force (Ministry of Livestock Development, 2008). The sector also contributes a substantive share of the total value added to Kenya's economy (Engida, Guthiga, Nyota et al. n.d.). Moreover, the sector's development has multiplier effects on several other sectors such as food and nutrition security, biological diversity, health, poverty, and industrial biotech technology among others. In recognition of the critical role of the livestock sector and the need for its development for maximal sustainable economic benefits, the government of Kenya put a livestock policy in place that considered the issues and challenges facing the sector and how these can be resolved through a planned approach. The policy replaced the 1980 Livestock Development Policy (Ministry of Livestock Development, 2008, p. 13-14)

The policy considers nine livestock-related challenges and makes policy commitments for each issue. These challenges include among others; food security and safety, animal diseases and pests, and animal genetic resources. Policy recommendations per issue area include the following: conduct a demographic survey of species, types and breeds distribution of animal genetic resources; conduct research to line-breed indigenous chicken; strengthen livestock and recording schemes; improve breeding programmes through stakeholders collaborations; put into place regulations to manage genetic resources; put into place breeding programmes that produce breeds with locally adaptive traits especially in the ASAL areas; establish a central organization charged with the responsibility of developing and coordinating self-sustaining breeding programmes which should also serve a local point (p. 17); revise the animal diseases Act (Cap 364) to facilitate interventions such as animal disease zones; establish livestock emergency fund to meet livestock-related emergencies; promote government, communities, farmers and private sector interactions in the containment of animal disease emergencies;

➢ *Gaps in the National Livestock Development Policy, 2008*

SynBio has an immense potential contribution to livestock development in Kenya. For example, the health-related techniques used by the technology can produce more effective livestock vaccines that lead to efficient livestock disease management. Secondly, the biosensors systems can enhance livestock disease surveillance and improve management of dangerous re-emerging, emerging or emergency livestock diseases. Thirdly, genome editing techniques of SynBio, now already in the field as well as being developed further, can edit whole genomes or DNA of targeted livestock to improve their traits by replacing unproductive DNA or even by replacing non-adaptive with adaptive DNAs particularly in the ASAL livestock where the country targets most with the livestock policy. Many other potential contributions of SynBio can be listed. Despite this potential, there are gaps in the current livestock development policy being used by the government which must be bridged to enjoy in these SynBio promises. These gaps include:

Firstly, the policy is a pre-2010 document and as such does not provide an environment upon national and county governments can both commit to applying SynBio in the development of livestock in Kenya. Secondly, the policy document has no direct reference to the concept of biotechnology and thus does not envisage a scenario for the application of biotechnology or SynBio in the development of livestock in the county. The concept of technology is, however, mentioned 6 times, and technology innovation is mentioned only once throughout the document. These are about challenges related to livestock marketing, lack of appropriate research and extension and required human expertise, the gender-technology use nexus in the development of livestock (p. 35). The lack of focus on biotechnology points to the lack of a favourable policy environment for the adoption and implementation of SynBio in the livestock development sector in Kenya.

Thirdly, it follows automatically that does not make policy recommendations on how to mitigate the potential risks of modern biotechnology products organisms and systems to the livestock or environments where livestock and livestock resources are found. Lastly, the policy has no guiding principles which could be said to be favourable for the adoption and implementation of new promising technologies like SynBio. The philosophical basis of the policy is thus unclear. While the concept of sustainability implied and the word sustainable is mentioned 11 times throughout the policy, sustainable livestock development is not explicitly stated as a guiding principle.

H. The National Wildlife Conservation and Management Policy, 2012

The National Wildlife Conservation and Management Policy, 2012 (NWCMP) aims to ensure continued gain from wildlife and wildlife resources while managing the pertinent issues affecting the wildlife sector. this is captured in the policy overall goal which states: to *create an enabling environment for the conservation in perpetuity, Kenya's rich diversity of species, habitats and ecosystems for the wellbeing of its people and the global community following the Constitution* (p. 5). Kenya is categorized by the CBD as a mega biological diverse country (Ministry of Forestry and Wildlife, 2012) and hosts about 35, 000 known specifies of animals, plants and microorganisms (CBD, 2005). The economic value of wildlife and its resources to the Kenyan economy cannot be undermined. For example, in the 2010-2011 financial year wildlife contributed 70% to the total earnings from tourism, 25% of the GDP and about 10% of the formal sector employment (Ministry of Forestry and Wildlife, 2012). The importance of wildlife to Kenya is also necessitated by the fact that Kenya's major water towers are found in wildlife-protected zones, though wildlife facing threats are those out of protected areas and lands owned by the community or private entities.

The NWCMP is was launched in 2012 to replace the older policies and legislations guiding wildlife conservation and management while filling the gaps therein which had made wildlife conservation and management difficult to achieve. The two important policy and legislative documents replaced by the NWCMP are Sessional Paper No. 3 of 1975 entitled "A Statement on Future Wildlife Management Policy in Kenya" and Wildlife (Conservation and Management) Act of 1976) (amended in 1989). The policy aims to align the Act within the provisions of the Environmental Management and Co-ordination Act, 1999 and the CoK, 2010. The policy discusses the challenges and impediments to wildlife (Ministry of Forestry and Wildlife, 2012, p. 4-5 and p. 7-10). The challenges include, among others: loss of biological diversity, land use challenges, invasive alien species, climate change, biopiracy, human-wildlife conflict and compensation, Illegal and unsustainable off-take of wildlife and bushmeat trade, and pollution.

The objectives and guiding principles of the policy are tailored to find solutions to these wildlife-related challenges. The principles include for example devolution of wildlife management, effective public participation, wildlife conservation and management as a form of public, community or private land use, the precautionary principle, equitable benefits sharing, integrated ecosystem approach, and obedience to the constitutional principles.

The NWCMP has eight stated objectives and the government commits to undertake stated strategies to implement each objective. The institutional reforms advised by the policy include**:** Put in place needed institutional, legal & regulatory structure in line with a devolved system of governance; Establish the Wildlife Regulatory Council as the overall for licensing and regulation of the sector; establish the Wildlife Directorate as the policy oversight; Establish County Wildlife Conservation Committees; restructure and strengthen KWS as the lead agency; develop Wildlife Disease Management Strategy and to develop capacity through education and training.

➢ *Gaps in the NWCMP*

The policy enumerates risks that may result from SynBio such as bioprospecting (objective 5) and allows for the application of concerned national, regional and global law: CBD, Cartagena Protocol and Bonn Guidelines.

However, these guidelines have been said to be inadequate in regulating SynBio applications and that national governments must assess the extent to which they are applicable. The policy is deficient, therefore, because it does not make any provisions to further probe national, regional, and global regimes concerning how they may apply to regulate advanced biotechnology techniques and methods such as those used in SynBio.

Secondly, the policy does not appreciate the role of private sector stakeholders in the conservation and management of wildlife resources within the purview of bio-innovations and bio-driven industrial development of wildlife conservation and management tools such as synthetic vaccines, SynBio-based wildlife monitoring systems, and SynBio-based diagnostic kits which can be a cheap, efficient tool for wildlife pests disease surveillance and early warning signs enabler of wildlife pests and diseases. Thirdly, there is no commitment for the development of the necessary biotechnology human resource. Fourthly, there is no commitment to the need to commit resources for public education and awareness creation on the biotechnology applications in the conservation and management of wildlife and wildlife resources.

I. Sessional Paper No. 1 of 2010 on Enhancing Sustainable Tourism in Kenya

Tourism-related activities comprise a critical share of the world economic sector, providing over 200 million jobs (Ivany, n.d.). The industry is also among the fastest-growing industries worldwide at 4.2% between 1990 and 2004 and it was forecasted that the number of international arrivals would reach 1.56 billion by 2020 (www.biodiv.org). Until the 1960s, and early 1970s, the tourism industry was largely perceived as a 'white industry' without negative effects and national governments made enormous investments in efforts to promote foreign arrivals to boost the sector's share to national GDP and other economic measurements like employment (Ivany, n.d.). By the mid-1970s, critical voices emerged and a negative analysis on the impact of tourism began to take place. This resulted in governments laying out policies that did not just want to boost the sector but also to make it sustainable.

The basis for the Sessional Paper No. 1 of 2010 on Enhancing Sustainable Tourism in Kenya is not different from the above situation. In the 2007/2008 financial year, the industry contributed 10% of the national GDP and employed around 9% of the total workforce in the country (Ministry of Tourism, 2010). At the same time, it is recognized that tourism could have negative impacts on the social, economic, cultural and ecological spheres of the country not less because it has become an excessively competitive industry (*Ibid*). The policy document thus aims to *achieve sustainable tourism that contributes to a better quality of life for all people* (p. 14). It takes cognizance of the achievements and weaknesses of Sessional Paper No. 8 of 1969 and Economic Recovery Strategy for Wealth and Employment Creation (ERSWEC) provisions on tourism development. The stated objectives of the policy are to (p. 14):

Provide a framework for integration of tourism sector considerations into the various sectoral policies and national development planning as well as decision making processes;

Strengthen the legal and institutional framework for effective coordination and management of the tourism sector; Ensure adoption of sustainable tourism that enhances economic development, environmental sustainability and social justice; Promote and support the provision of incentives and other economic instruments that enhance investment in the sector; Promote and enhance collaboration, cooperation, synergy, partnerships and participation in the tourism sector by all the stakeholders.

The principles that should guide the pursuit of these objectives include: the polluter/user pays principle, the precautionary principle, sharing of accruing benefits with the host community, devotion of tourism management, public participation, conservation and sustainable use among others. The policy recognizes the need for the establishment of a legal and institutional framework for the sustainable development of the tourism industry. It recognizes the legal framework is dispersed into various pieces of law and commits the government to:

Put in place a comprehensive tourism law that will consolidate all the existing tourism-related legislation for the regulation of the sector and; Ensure that the Policy and enabling legislation are reviewed regularly to be in tandem with emerging tourism issues (p. 28).

The policy also considers that the tourism institutional framework is outdated and that there are *overlapping, duplication and conflicting mandates and responsibilities (p. 28).* To deal with this, the policy commits the government to*:*

Restructure, reorganize and strengthen the capacity of the Directorate of Tourism at the Ministry; Establish a national tourism regulatory agency with overall responsibility of regulating the tourism sector; Establish a Tourism Tribunal to arbitrate on all disputes relating to the tourism sector (p. 28).

The institutions to be established include the national tourism regulatory agency (NTRA), the national tourism training agency (NTTA), the national tourism protection service (NTPS), Tourism Tribunal, the national tourism research institution (NTRI) and a Tourism Fund.

The policy also recognizes the multi-sectoral nature of the tourism sector and commits the government to institute an inter-sectoral approach to the management of tourism of issues. The policy advised the government to; establish an inter-ministerial committee on tourism; encourage roundtable meetings, encourage appropriate use of sector-wise approach (SWAP) and ensure tourism policies are subjected to strategic environmental assessment (SEA) and to develop, working with National Environment Management Authority (NEMA), environmental sector impact assessment guidelines (EIA).

- *Gaps in the Sessional Paper No. 1 of 2010 on Enhancing Sustainable Tourism in Kenya*

The policy does not maintain the concepts of technology nor biotechnology throughout its 36 pages. This could mean the lack of a vision for a tourism industry driven by biotechnology techniques and methods. For example, in the EU, a knowledge bio-based economy is seen as a key driver for sustainable tourism and where modern biotechnology innovations such as SynBio have immense potential in the sustainable use of tourist resources including wildlife.

Secondly, the linkages between the industry and biotechnology/knowledge-based economy are not considered or envisioned. This, however, have the potential of making the thought of a 'paradigm shift' in the use and management of tourist resources not just achievable, but also efficiently and sustainably. As WEF (2012) has shown, SynBio can make a great contribution to the conservation of biological diversity. This way, the technology can be an important tool in the preservation of those tourist resources which are currently under threat of extinction yet are a national heritage prestige and tourist attraction instruments.

J. Wetlands Conservation and Management Policy, 2015

Kenya is a party to the Ramsar Convention on Wetlands of International Importance which it ratified in 1990. State Parties to the Convention are obliged to put into place national policies which ensure systematic approaches to planning, conservation and management of wetlands. Wetlands in Kenya include:

swamps, marshes, bogs, shallow lakes, ox-bow lakes, dams, riverbanks, floodplains, water catchment areas, fishponds, rice paddies, lakeshores, mangroves, seagrass beds, deltas, estuaries, coral reefs and seashores. In Kenya, wetlands occupy about 3% to 4% of the land surface, which is approximately 14,000 km2 and fluctuates up to 6% during the rainy seasons (Ministry of Environment, Water and National Resources, 2015, p. 2).

As a way to implement her international commitments under the Ramsar Convention and other related global regimes, as well as to manage the challenges associated with wetlands use, conservation and management, the government of Kenya put into place a Wetlands Conservation and Management Policy. The policy appreciates that wetlands importance to the country range from ecological and as the prevention of floods and soil erosion to socio-economic such as energy production to research and education. The economic value-driving Kenya's quest for systematic planning and management of the sector is best captured by this excerpt from the document:

Wetlands constitute part of the critical natural capital for the country's economy. For instance, from horticulture alone, Lake Naivasha contributes over 5.3 billion Kenya shillings (63 million US dollars) per year while over thirty thousand (30,000) people derive their livelihoods from this important wetland ecosystem. Lake Nakuru on the other hand, tourism contributes an estimated 2.1 billion Kenya shillings (24 million US dollars) per year while the Nyando Wetland provides an aggregated economic value estimated at 204.1 billion Kenya shillings (US 2.1 Billion) per year (Ibid, p. 2).

The stated objectives of the policy include (Ministry of Environment, Water and National Resources, 2015, p. 14):

Enhance and maintain functions and values derived from wetlands to maintain ecosystem goods and services, protect biological diversity and improve the livelihood of Kenyans; Promote innovative planning and integrated ecosystem management approaches towards wetlands conservation and management in Kenya; Strengthen institutional capacity on conservation and management of wetlands; Promote communication, education and public awareness among stakeholders; Improve scientific information and knowledge base on Kenyan wetland ecosystems;

Establish an effective and efficient legal and institutional framework for the integrated management and wise use of wetlands; Promote partnership and cooperation at the county, national, regional and international levels for the management of transboundary wetlands and migratory species.

The policy analyses wetlands-related challenges and pronounce policy statements on how to find sustainable solutions to such challenges. Three broad challenges considered in the policy include wetland degradation, conservation and management of wetlands and research, education and awareness. With the consideration that there is a lack of a comprehensive legal and institutional framework to guide conservation and management of wetlands, the government commits to among other things, harmonize all laws and policies regulating wetlands in Kenya, identify and strengthen a supervisory agency in national and county levels, and adopt and implement an ecosystem approach to the management of Kenyan wetlands. The policy also commits the government to undertake necessary actions to find and establish linkages in wetlands conservation and management at the county, national, regional and international scales. Lastly, policy statements are also made with a view to mainstream emerging issues to development and management such as youths, community participation, HIV/AIDS, gender, special groups.

- *Gaps in the Wetlands Conservation and Management Policy, 2015*

To begin with, although the policy identifies that there is *a general lack of infrastructure and technology to support sustainable wetland management (p. 22),* the policy statement in this regard does not envisage the role of biotechnology, hence SynBio innovations in this endeavour. Secondly, the policy document mentions the concept of technology only twice and does not mention the concept of innovation. This reflects the lack of a vision for the application of technology innovations, particularly those emerging and highly promising such as SynBio.

Finally, there is a lack of an explicit policy statement on the applicability of the precautionary principle in putting

restraint/caution when applying emerging technologies such as SynBio in the conservation and management of wetland and wetlands biological resources. Policy statement 6 under the legal and institutional framework section (4.1) calls for the establishment of legal mechanisms *for regulating access to wetland genetic resources benefit sharing and technology transfer* (p. 24) but is not clear enough on the extent of technology implied.

K. Sessional Paper No. 5 of 2016 on National Climate Change Framework Policy

Kenya's economy is highly dependent on the natural resource base and thus is highly vulnerable to climate variability and change. Rising temperatures and changing rainfall patterns, resulting in increased frequency and intensity of extreme weather events such as droughts and flooding, threaten the sustainability of the country's development. To safeguard sustainable development, the Government of Kenya has developed this National Climate Change Framework Policy to provide a clear and concise articulation of overall response priorities to climate variability and change (Ministry of Environment and National Resources, 2016, Preamble).

Worldwide, climate change is being discussed as a top policy priority issue and is currently being linked very directly to hitherto domains of national strategic security issues. For example, the issue of climate change has occupied a centre stage in the UNSC debates since 2007. To take a most recent debate, the United Nations Secretary-General, Antonio Guterres told a high-level panel of the UNSC that ''the last decade was the hottest in human history'' adding that extreme weather and climate ''shocks not only damage the environment on which we depend; they also weaken our political social and economic systems'' (World Meteorological Organization, 2021). Climate change and variability discussions have been discussed since the Stockholm Conference, under the United Nations Framework Convention on Climate Change (UNFCCC) and which sets the rules of the game for countries a bid to cut carbon emissions, adopt green technologies and reduce global atmospheric temperatures.

As Party of the UNFCCC, the UNEP Constitution, and several other global MEAs including regional and sub-regional, Kenya has tried to play its part in global climate goals and regularly submits her National Communications to UNFCCC on Climate Change (GoK, 2015). The National Climate Change Framework Policy, 2016 is the overall guide to the country's climate change mitigation processes. The policy recounts the multi-sectoral impacts of climate in such sectors as; health, coast and marine ecosystems, tourism, energy, extractive industries, physical infrastructure, trade, agriculture and fisheries, and environment, water and forestry. These impacts hit more intensely on the ASALs which comprise about 83% of the total landmass in Kenya.

To realize these objectives the policy pronounces itself on 10 areas: putting into place measures to realise low carbon climate-resilient development. Policy statements for this aim include mainstreaming climate resilience into national and county government development plans, processes and implementation (p. 18); Identify and implement fiscal, taxation and other policy options in priority areas with high GHG emission abatement potential that enhance sustainable development (p. 19). The second area relates to mainstreaming climate change through actions such as Mainstream climate change into national and county planning processes, including national development policies and plans, County Integrated Development Plans, Performance; Develop a framework and tools for mainstreaming climate change responses into national and county government planning and budget procedures (p. 20-21). The third area is research and technology. Here, the government commits to ensure that the low carbon development pathway in Kenya is informed by scientific evidence and enhanced research and development (R&D). Policy statements in this light include actions such as Identify research and technology needs; and promote strategic and systematic climate change-related research, impact and vulnerability assessments, and technology development and diffusion; Enhance linkages between government, academia, private sector, civil society and global climate change innovation institutions (p. 23). The fifth area is education and public awareness where the government commits to for example place a strategy for identifying, refining and disseminating climate change knowledge to the public and other stakeholders in user-friendly formats (p. 23). Another issue identified in the policy is climate change governance. To restructure relevant governance frameworks, create new frameworks and mainstream climate change into governance structures, the government commits, among others, to:

Place a strategy for identifying, refining and disseminating climate change knowledge to the public and other stakeholders in user-friendly formats; Regularly review and amend relevant sectoral laws and policies to integrate climate change policy considerations and implement priority actions in respective sectors (p. 27).

- *`Gaps in the Sessional Paper No. 5 of 2016 on National Climate Change Framework Policy*

The policy documents mention the concept of *technological innovation* three (3) times and the concept of *innovation* 5-times both concerning research and technology. This appears favourable to the adoption and implementation of new and emerging technologies to the climate change and variability processes. However, there is a need to directly acknowledge SynBio, the latest of the modern bio-innovations, to systematically account for how the technology can be used, but also developed locally and applied within the scope of the required risks management framework. Moreover, there is no mention in the entire policy document, of the concepts such as bio-innovation and biotechnology which can imply that the policy does not account for the possibility of the utility of bio-innovations to meet the low carbon development pathway goal.

Secondly, the policy does not take into consideration the potential risks which may accompany the use of modern biotechnologies in the search for low carbon development pathways, such as bio-photosynthesis, production of bio-

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energy such as by use of E.coli bacteria (SCBD, 2021). Finally, following from the above, the industrial and non-industrial bio-innovations stakeholders, public and private are not explicitly appreciated as key stakeholders in the management of climate change in the country. If biotechnology has the potentials to meeting climate change management goals in Kenya, the stakeholders in the sector must be properly identified and engaged in the development or review of a climate change policy and other regulatory instruments.

- *National Fisheries Policy, 2006*

The need to regulate fisheries in Kenya is informed above all other things with vast aquatic resources in the country and the promising economic value of fisheries and aquatic sector and the declining fish production and consumption due to challenges such as overfishing. Fisheries and aquaculture contributed about 5% to the GDP in 2013 (Ministry of Livestock and Fisheries Development, 2005). Fish consumption has been declined from 6.0 kg/caput in 2000 to 4.5 kg/caput in 2011 (FAO, 2016). The average producer value of the sector was Kenya Shillings (Kshs.) 8 billion and approximately 500, 000 ake a living from fishing-related activities. Freshwater fish contributes the highest share of fish production at 96% (Ministry of Livestock and Fisheries Development, 2005) and Kenya's freshwater aquaculture is the fastest in Sub-Saharan Africa especially in 2009¬2010, making Kenya one of the fast-growing major producers in Sub-Saharan Africa. From the annual production of about 1 000 tones in 2001–2006, the harvest of farmed fish leapt to over 4 000 tones in 2007–2009 (FAO, 2016, p. 2).

To realize a fisheries development within an outlined policy framework that can facilitate this promising evidence of the value of the fisheries sector and to manage its associated challenges, the Fisheries Policy was designed to "create an enabling environment for a vibrant fishing industry based on sustainable resource exploitation providing optimal and sustainable benefits, alleviating poverty, and creating wealth, taking into consideration gender equity" (p. 10). The policy outlines 10 strategic actions to actualize its nine stated objectives. These actions include others; Strengthening of institutional framework and sustainable funding through actions such establishment of Kenya Fisheries Development Authority as the lead agency for fisheries development; Sustainable utilization of fishery resources through actions such as KFDA shall, in consultation with other fisheries stakeholders and other arms of government, specify access rights to all fisheries, determine the optimal harvest, and encourage sustainable utilization of under-exploited stocks; Achievement of efficient and effective fisheries management through for example, development master plan to facilitate effectiveness and efficiency in management; Promotion of sustainable and efficient aquaculture development ; Promotion of sustainable and efficient recreational and ornamental fisheries; Promotion of fish quality, consumption, trade and investment; Improvement of infrastructure and human resource development; Support and coordination of fisheries research; Enhancement of fisheries information and extension service through for example, KFDA shall take measures to ensure that fisheries research is well funded, coordinated, multi-disciplinary and demand-driven, KMFRI in liaison with the Department of Fisheries shall create a data bank for all fisheries research; among other policy statements (p. 10-24).

- *Gaps in the Kenya Fisheries Policy, 2006*

The policy is pre-devolved government and pre-Kenya Vision 2030. It needs to be updated to take cognizance of the new administrative characteristics of fisheries management and development. Secondly, the policy lacks stated guiding principles and it's unclear whether the philosophical grounding of the policy can be favourable for the adoption and implementation of new and emerging technologies in the development of the fisheries sector.

Thirdly, the policy does not make any reference to the concept of *technological innovation or innovation.* The concept of technology is, however, only mentioned once concerning regional cooperation and international favourable to technology advancement and technical assistance. The policy thus does not envision the utility of new and emerging technologies such as SynBio in the development of the fisheries sector. Fourthly, and consequently, there are no considerations for a mechanism for risks and disaster management that could result from the use of SynBio in the fisheries development processes, for example, the potential impacts that may result if SynBio was used to create fish with better productive traits than the naturally existing ones through modification of the genomes of certain naturally occurring fish breeds or species.

Lastly, the stakeholder framework envisaged in the policy includes the private sector. However, if new and emergent advanced bio-innovative technologies such as SynBio are adopted and implemented to catapult fisheries development, there is a need to explicitly recognize biotechnology/SynBio potential key stakeholders in the processes of fisheries development.

- *National Policy Framework on Science Technology and Innovation, 2012*

The National Policy Framework on Science Technology and Innovation, 2012 aims to provide an impetus to the Kenya Vision 2030 by elaborating further on the research and development (R&D) basis of the Vision. It recognizes that science technology and innovation (ST&I) in Kenya is underdeveloped due to a lack of a systematic approach owing largely to the fact that ST&I is a highly fragmented developmental area; all these accounting for its lack of relative global competitiveness which is both a cause and effect of underdeveloped ST&I in Kenya.

The policy priority areas are identified as: biotechnology; space science; telecommunications, electronics and computers; and automobile and nuclear electricity (p. vi). The policy aims to re-innovate the Kenya National Innovation System (KNIS) with the recognition that the current linkage between academia, industry and research are unclear and unfavourable for the advancement of ST&I. Three institutions are proposed, including; the national commission on STI (NCST&I) to set priorities and coordinate

ST&I issues, the National Research Fund (NRF) to mobilize resources of 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 would be 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. 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, recognise 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 regulation, in the phases or generations which it has since merged worldwide; first-generation so-called GMO 1.0 and now second generation, now called in biotechnology and the bioengineering parlances, GMO 2.0 SynBio. The ST&I policy 2012 should thus be expected to set out a clear structure upon which the country can adopt, implement, domestically develop and progressive innovate new and emerging technologies in an environment where potential biosafety, biosecurity, and other ELSIs are properly taken care of and mechanisms necessary for their mitigation put in place. In light of biotechnology, or SynBio more particularly, the policy poses the following gaps.

Firstly, the policy has no special focus on biotechnology and the value it adds to both the R&D 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. Of the 5 policies and 53 strategies presented in the document, none makes direct reference to bio-innovations. Although strategies that aim to develop the food and nutrition sectors, health sector, nuclear energy and green and renewable energy are listed and may implicitly insinuate commitments to biotechnology, the framers of policy may have had different approaches to achieving these in their minds at the time of the policy documentation. This is a gap that could stand on the way to the successful adoption and implementation of SynBio innovations in a risk-managed environment.

Secondly, and following the first point, there is a lack of focus on the potential risks of highly advanced new and emerging biotechnologies. The ST&I policy should commit the government to put into place mechanisms for managing both current and future risks of current and future/new and emerging technologies, respectively. Thirdly, the stakeholders' engagement envisioned in the policy is robust enough but must be realigned to the actors in the biotechnology field, that is both the experts in biology and related fields applied in SynBio such as data science and the social scientists working in the field of Science and Technology Studies (STS), but also the society at large and their socio-ethical considerations about such emerging, highly promising but also highly catastrophic technologies as SynBio.

L. Integrated Coastal Zones and Management (ICZM) Policy 2013

Kenya's coastal zones constitute a great opportunity but also a threat if not properly targeted in national development planning and management. It constitutes 60%% of the total earning from tourism. The threats emerge most significantly from the fact that the area serves nearly all sectors; tourism, water, agriculture. To mention a few, yet

Past sectorally based governance systems failed to recognize the interconnectedness of ecosystems in resource management. Consequently, the sectoral approach to development planning and management, combined with population pressure and the intensity and complexity of human activities in the coastal area have spawned resource use conflicts and adverse socio-economic and environmental effects (Ministry of Environment, Water and Natural Resources, 2013, p. 1).

To ensure the continued flow of benefits from the coastal zones while ensuring an integrated approach to ecosystems management and as a way of undertaking her obligations under the under international treaty law by obeying her obligations such as under the UNCLOS III, Kenya dreams for "*A coastal zone with healthy ecosystems and resources that sustain the socio-economic development and well-being of the current and future generations*". This is to be achieved through the following objectives (Ibid, p. 1):

Promote integrated planning and coordination of coastal developments across the various sectors; Promote sustainable economic development to secure livelihoods of coastal communities; Conserve the coastal and marine resources and environment for sustainable development; Manage environmental risks associated with changes in shoreline and climate; Develop capacity in research and education and enhance stakeholder awareness and participation in sustainable resource management; Establish effective institutional and legal frameworks for the implementation of the ICZM policy.

The policy builds on the existing sectoral and regional policies and legislations such as the Environment and

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Management and Coordination Act, 1999 (EMCA), the CoK, 2010, The Physical Planning Act of 1996, Merchant Fishing Act 2009, Inter-Governmental Relations Act, 2012 and Treaty for the Establishment of the East African Community Act, among others.

- *Gaps in the ICZM Policy, 2013*

The policy does not acknowledge bio-based emerging technologies (such as SynBio) as neither an opportunity nor a potential risk factor for coastal environmental risk and risk management. Secondly, the potential contribution of the biotechnology/emerging biotechnology innovations in the management of coastal zones is not considered in the policy strategies outlined.

Thirdly, R&D programmes the policy aims to promote for the management of coastal zones are therefore limited in that they do not make any proposals for R&D in the biotechnology fields that have a high potential for making coastal zones management not only efficient but also sustainable. For example, if a policy such as the ICZM policy focuses on the development of 'white biotechnology' of SynBio, which *takes advantage of enzymatic processes to produce high-value chemicals from sustainable sources with less energy consumption as well as waste production* (Bojar, 2018), the problems of oil spoilage into the coastal zones which can be catastrophic as witnessed in the Great Pacific Garbage Pack, could be very cheaply and efficiently managed.

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

Kenya is a State Party to the CBD and its three key protocols. Under the CBD, Article 15, Kenya obliges 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."

Nagoya Protocol 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 LMO and related GR. Kenya's attempt to put into place the National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009 is due to two broad rationales: as a way to finding solutions to national problems related to the convergence between Intellectual Property Rights (IPR), GR resources management traditional knowledge and traditional cultural expressions or so-called folklore (GoK, 2009; Otswong'o, 2011). 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.

The objectives and policy statements/strategies set for their achievement revolve around seven principles. These include: a) respect which calls on actors and stakeholders to respect traditional knowledge and associated GR and folklore, b) full disclosure which calls on stakeholders to disclose all relevant information relevant to TK, GR and folklores to the communities who are their natural custodians, c) prior informed consent (PIC) which implies that any activity aimed at an access or any form of the utility of community-based GR must only proceed when their consent, as the custodians of the GR materials, have been sought for, d) confidentiality which gives the communities a right to keep away from the public TK and GR information by way of, for example, publication in a journal. e) Access, which emphasizes the need to research the issues surrounding the convergence between TK, GR and folklore (traditional cultural expressions [TCEs]); f) Equitable benefit sharing (EBS) which gives the communities the right to share equitably in the accruing benefits of TK and GR derived from their communities. It also gives the utilizers (researchers, corporates, etc.,) the duty to ensure that the communities get

their fair share from such activities. g) Finally, the principle of sustainable development emphasizes that the utility of TK, GR should be done on basis of inter-generational equity.

- *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 domestically SynBio innovations. Secondly, the policy does not preempt utilization of genetic materials[7] or genetic resources[8] 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. 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—the most important concept in the regulation of SynBio—is not mentioned at all.

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. 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[9] with closed set-ups that can reduce the risks related to DITYB.

Lastly, community approaches to the protection TK and associated GR are not elaborated. Although the policy document mentions that part of possible community approaches, that is, the utility models[10]can be derived from existing law such as the Industrial Property Act, 2001, no policy statement elaborates or aims at building communities 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[11]

N. National Policy on Culture and National Heritage, 2009

The turn to inclusivism[12] as a panacea to sustainable development as witnessed the consideration that global and national progress must proceed only upon the fact that humankind exists in a myriad of cultural settings, each with its unique characteristics. Global Development Blueprints (GDB) such as Millennium Development Goals (MDGs) and Sustainable Development Goals (SDGs) (United Nations, 2015). Have therefore underscored the transformative value of cultural inclusion by setting global targets for cultural development. 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 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; culture and information

[7] 'Any material of plant, animal, microbial or other origin containing functional units o heredity' (GoK, 2009).
[8] 'Genetic material of actual or potential value' (Ibid).
[9] According to the GoK (2009) this means ''any generation of new or improvement methods of using traditional knowledge''
[10] '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 detailed inventive step' (Otswong'o, 2011).
[11] 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 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.
[12] 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.

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 is pre-CoK, 2010 hence lacks the administrative opportunities of a devolved system of governance that can promote a devolved approach to SynBio regulation in light of Kenya's cultural values. Secondly, the policy does not preempt the impacts of emerging technologies on cultural development. although 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 project the culture of Kenyan culture and heritage against adverse potential effects upon adoption and implementation of emerging technologies such as SynBio.

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

IV. DISCUSSIONS

This section attempts a discussion of the documentary analysis which formed the basis of this paper. The foregoing analysis of the Kenya's biotechnology and LMOs-specific policies in lieu of empirical literature reveal the regulatory gaps that the country must fill in order to put into place the needed requisites for an adaptive anticipatory governance for SynBio. These gaps are discussed within the theoretical and conceptual frameworks adopted in the study as follows.

A. Kenya's Biotechnology risk culture and biotechnology policy environment is democratic in nature and which has both opportunities and disincentives

Kenya is a democratic presidential system and adheres to a constitutional doctrines of separation of powers and checks and balances (The Constitution of Kenya, 2010). The parliament has the duty to make new policies, and amend old ones. The process of policy making is expected to adhere to principles of participation and where the citizens have a right to participate in policy making by giving their views on contested issues. Moreover, the citizenry which include researchers, have the right to challenge Government processes. Any of the three arms of the Government of Kenya also exercises veto on any perceived excesses of the other arms. What this implies to biotechnology regulatory tools, including policies, is that by defector, the policies must be subject to public approval, usually through their respect Members of Parliament (MPs) representatives. In need, a number of the policies reviewed including the Biotechnology Development Policy provides for public participation.

As Trump (2017) has extensively discussed with respect to EU and USA, such a democratic system of Governance may pose both opportunities and challenges in regards to the quest to foster an adaptive anticipatory governance for SynBio. The opportunities may include clearly stated platforms for engaging researchers, industry, academia, and the technologically-uninformed members of the public. Such platforms may provide, as need be, bottom up (non-governmental experts driven) or top-down (government experts-driven) participatory frameworks of the sort of Synthetic Biology Consortium of Singapore, or the European Scientific Committees of the EU all of which bring academia, industry and government in to a dialogue discourse. Such a discourse may serve an important "public purpose" (see Jayanti, 2020) by providing the requisite reference data for SynBio decision makers; including policymakers, regulators and even industry (manufacturers and traders) and consumers (the general public).

At the same time, a democratic approach to regulating emerging technologies may lead to an "adversarial legalism" where the multiple actors with veto powers can serve as stumbling blocks to policy reforms which may lead to negative stalemates in SynBio development life cycle or situations where technologists take advantage of policy makers and regulators confusion to conduct SynBio research non-regulated environments.

Other than the political and institutional factors and he manner in which regulatory questions are adjudicated, another aspect of the risk culture is the availability of biotechnology and LMOs-specific regulatory tools (Trump, 2017). Particularly the extent to which they can be adapted to regulate SynBio. Kenya is State Party the Convention of Biological Diversity and one of the earliest ratifiers of the same. She is a bonafide member to all the platforms upon which the CBD discourses have been framed, including the AHTEG, and is proactive participating in COPs debates including the 14th conducted in 2021. The country has ratified the Nagoya Protocol to the CBD, the Cartagena Protocol to the CBD as well the Nagoya Lumpur Protocol to the CBD. As a consequence, all these pieces of biological diversity governance are part of Kenya's law by constitutional provision (Constitution of Kenya, 2010, Article 1 para. 5 & 6). The biotechnology policy environment is Kenya is thus informed by these global developments and the analysis which is presented above reveals how detailed the policy environment is. The Biotechnology Development Policy, the National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, the National Fisheries Policy, the National Livestock Policy, and the National Water Policy and the varies institutions established under these policies, are among the country's policy instruments which are directly concerned with biotechnology regulation. As is already presented in the analysis these policies and all the others analyzed which will obviously regulate an aspect or two of SynBio, have gaps which the country must fill in order to ensure that these policies are adapted to SynBio regulation, "sui-generis" (entire new

policy (ies)) to regulate SynBio. More of this discussion below.

B. A TAPIC model as an Analytical Framework for Kenya's Biotechnology Governance may reveal several gaps that adaptive governance can fill

The discussion that follow in this subsection borrows from the TAPIC framework as argued by Trump (2017). A transparency, accountability, participation, integrity, and capacity (TAPIC) framework can aid in identifying the regulatory gaps that exists in the whole biotechnology governance landscape in Kenya. This can help point to the grounds requiring specific actions by the relevant stakeholders in order to foster an adaptive anticipatory governance for synthetic biology.

Trump (2017) articulates how transparency can help us identify regulatory gaps in the regulation of emerging technologies by arguing that the governance of emerging technologies is

Improved when the scope and operation of policy decisions are clearly articulated to the general public. For synthetic biology 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 essences sets the rules that gatekeepers and decision makers operate within relative to technology governance (p. 4).

As at now, SynBio is an alien to the country (ISAAA, 2020) and by consequence, such a framework for ensuring transparent governance of the technology is absent. In need, none of the policies, legislations and national development plans analyzed by the researcher mentions the term SynBio. While there are disagreements as to whether SynBio is an entirely new technology (SCBD, 2021), with some experts feeling that a large part of LMOs regulations can be applied to SynBio, literature on adaptive governance points to the need to either review and adapt existing biotechnology regulatory frameworks to SynBio or create sui-generis instruments (Greer & Figueras, 2016; Trump, 2017; Marris & Calvert, 2018) in countries in possession of such frameworks in order to adapt them to the regulation of synthetic biology. Several studies (Joyce et al., 2013; Bar-Yam et al., 2012; Pei et al.,2012; Kuiken et al., 2014; Giese & vo 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 among others). What this means for Kenya is to decide as to whether the key policy and legislative documents, for example the Biotechnology Development Policy and the Biosafety Acts are to be revised accordingly, or all new policy and legislation are to be drawn for SynBio. Such an exercise should aim to meet the transparency issues asserted by Trump (2017) above. The experts interviewed expressed this necessity thus:

I think we may be moving so fast. Am saying this because we have had a lot of problems with LMOs. Institutions were struggling and fighting because there is a lot of gaps as to who should regulate what. For SynBio, the problem could be worse. Maybe the Government should consider domiciling an independent department of SynBio in the National Biosafety Authority, or if there are resources, a new policy, legislation and authority be established (In-depth Interview with Former Research Scientist, International Maize and Wheat Improvement Center (CIMMYT)).

Another important component of the TAPIC framework is 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 synthetic biology, where instead such standards and practices must be borrowed from pre-existing hard and soft law". For this reason, a latecomer country like Kenya must ask herself two questions: are there all the would-be needed biotechnology instruments (policies, legislations and experts)? How would the tools apply to SynBio regulation and to what extent? How can these be modified, and adapted in a manner anticipatory of the potential risks of SynBio. The policy and legislations documentary analysis, and the expert surveys answered the three questions in the following manner. It is not clear whether Kenya has all the would-be needed policies and legislations to regulate SynBio even if they were to be applied directly without processing. There is no clear framework of how they would be applied in SynBio governance and to what extent they can achieve the ideals of adaptive anticipatory governance. Finally, that there is need for further assessment of how exactly existing biotechnology governance tools should adapted or completely re-drawn for proper SynBio governance.

Thirdly, a participatory framework for SynBio is not conceived in the existing biotechnology policies, legislations and NDPs. Such frameworks should be conceptualized based on practices across the world of those countries which have adopted, implemented, and even commercialized SynBio like UK, USA, Singapore and a number of countries in the EU. Kenyan Government must foster a platform for participation that ensures that the shortcomings of either a bottom-up, or top-top participatory models are reduced and the opportunities enhanced.

Fourthly, integrity in SynBio regulation, though a difficult consideration for a technology only at its emerging stages (Guston, 2014) may still play an important role in identifying regulatory gaps. For adaptive anticipatory governance, integrity asks the question: are their SynBio specific regulations and are the rules therein able to capture the entire technology development life cycle properly? This is a difficult question for researchers, regulators and policy makers, at least up to now since across the world, there is

specific regulatory framework which has been instituted for SynBio. Hence in the USA, chemical regulations are applied, in the UK and larger EU and Singapore biotechnology regulations have been adapted to SynBio (Trump, 2017). The concern expressed in the literature on adaptive governance as applied in SynBio is that Government should be able to specify for purposes of accountability what aspects of the biotechnology regulations apply to what aspects and stages of SynBio (Guston, 2014; Carter et al. 2017; Kuiken et al., 2014).

Finally, capacity building as conceived in current biotechnology governance in Kenya is inadequate owing to the magnitude of R&D of SynBio. The policy and legislative instruments analyzed by the researcher revealed a lack of explicit policy statements on how the government aims to build capacity domestically or through international cooperation. As such, a lot remains to be done to explore the possible ways to design and sustain an adaptive governance which is formed by a capable regulatory authority, a capable developers club, a capable industry, and an informed public capable to participate in the discourses pertaining to SynBio.

V. CONCLUSIONS: FRAMING AN ADAPTIVE ANTICIPATORY GOVERNANCE FOR SYNBIO IN KENYA

To conclude, "as an emerging and uncertain science, synthetic biology requires a proactive, flexible, and adaptive approach for technology governance in order to keep up with the state of the science and address emerging risk concerns to human and environmental health. Attempts to foster this 'good' governance framework are still in their earliest stages, yet several themes are beginning to emerge relative to both the strengths of governments like the United States, European Union, and Singapore to develop this technology responsibly, as well as potential gaps or areas of concern that could foster regulatory pacing problems and outdated governance for synthetic biology moving forward" (Trump, 2017, p. 8). These regulatory needs must be considered very seriously, particularly in countries which are yet to adopt the technology like Kenya. Drawing from the evidence of SynBio governance in practice in pioneer countries, Kenya can emphasize three elements of the TAPIC framework to foster a risk culture that will not discourage technology development at the risk of "over regulation" (see SCBD, 2021) or risk health, community and socio-cultural values and the environment at the risk of deregulation due to pursuit of unclear duplicate policies.

Firstly, the country can adopt a transparency framework that takes cognizance of the emergingness* of SynBio. With this, the policy makers can design a SynBio policy that sets clearly all the aspects of potential risks to health, socio-cultural and environment with clear policy statements on how to eliminate or mitigate risks related to biosafety, biosecurity, dual-use, and bioethics. At the same time, the policy can set the limitations to the transparency in governance to prevent governance from relapsing into "adversarial legalism" by setting the scope and limitations of public and political scrutiny. This can be done through modifying and adopting such approaches as CBI as is the case in the USA, adopting a soft-authoritarian technology governance approach as in Singapore where accountability is emphasized than transparency through ensuring the effectiveness and answerability of developers and regulators while at the same time positively limiting the extent of public scrutiny in order to cut the cycle of public acceptance of policy reforms and adopted approaches.

Secondly, the government should lay emphasis on a top-down participatory/stakeholder engagement approach. Such as approach should be forged through a rectangular stakeholder engagement model which brings into play, the government (regulators and policymakers but also politicians), industry (SynBio manufacturers, and traders), academia (SynBiologists and social scientists engaged in social aspects for the technology) and finally the non-technologically informed members of the public (this should include groups such as religious institutions, cultural groups among others). Such an approach will ensure that technology governance discourse reflects the different visions which the various components of the Kenyan society may possess.

Finally, the country should emphasize capacity building as a critical component of building an adaptive anticipatory governance. While capacity is not very much an issue due to the fact that SynBio is only a new technology, elsewhere (UK, USA, China and others) targeted capacity-building has been the sole reason for the type and magnitude of successes achieved in those spaces. Kenya must design a SynBio policy which spells out how it aims to work with pioneer nations and other would-be donors that would support Kenya's priorities for SynBio projects. Such arrangements should not be overtaken by blind technology transfers that will discourage domestic creativity and innovations. Other than such donor-oriented capacity building, the country should forge, by way of policy and law, how to harness the domestic capabilities. This should come in through funding national and county SynBio symposiums, through promoting tertiary education in bioinformatics, genomics, big data science and other related platforms. Harnessing domestic capacity should also aim at tapping the capabilities of existing industrialists, academicians, and researchers in the fields related to biotechnology.

VI. RECOMMENDATIONS

Following from the above conclusions the following recommendations emerged from based on the potential regulatory challenges that would characterize SynBio governance in Kenya.

A. Government Policymakers and Regulators

- Learn from the experiences of countries that have already commercialized SynBio products and use those lessons as a mirror in attempts to forge an adaptive anticipatory governance.
- Explore the pros and cons of adaptive and sui-generis approach and ensure that whatever approach is adopted is based on evidence.

- Formulate a clear national SynBio communication strategy to educate and make aware the citizenry to whom SynBio is an alien concept that whom will be affected directly and indirectly with the potential risks of the technology. A communication strategy should not only be perceived from the angle to education and awareness creation; it should also be designed as a tool to strategically deal with possible public anti-SynBio movements.
- Explore and fill areas of cooperation with donors. These may include areas such as: technology transfers, capacity building (through such platforms as the Inaugural International Synthetic Biology Conference in Africa convened in Uganda, 14th-17th October 2021). May include trainings and fellowships aimed at governance capacity building.

B. Social Scientists

- Social scientists should not perceive the field of SynBio as for only the hard core biologists. There are several potential research areas in the field spanning ethics, legal, policy, social, cultural etc. issues which can be studied from a myriad of theoretical cleavages disciplinary outfits.

C. Kenyan Potential Synthetic biologist

- Begin to explore SynBio innovations and deploy them through asking the government to facilitate their commercialization.
- Form a National Association of synthetic biologists and use the platform to ask for domestic and international funding and push for SynBio-development friendly policies and legislations. This should provide technologists with a big voice with which to argue against overregulation which may discourage commercialization of lucrative technologies.

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AUTHOR CONTRIBUTION STATEMENT

Odhiambo Alphonce Kasera conceived, proposed, researched, analysed and interpreted, and compiled the findings of the study. Dr. Michael Owiso and Dr. Benson Mburu supervised the research process in the capacities of university assigned supervisor and external supervisor, respectively. Dr. Mburu linked the researcher with funders and played a critical role in conceiving the study.

DECLARATION OF CONFLICT OF INTEREST

The researcher declares no conflict of interest.

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