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The Double-Edged 'Bio-Tech' Sword – Proposing Legal Solutions for Responsible Synthetic Biology Development in Kenya

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Abstract

As the race for Synthetic Biology research and governance heats up between global superpowers like the United States and China, developing countries risk being left behind. To prevent this from happening, it is crucial that such countries, like Kenya, embrace this cutting-edge biotechnology to promote their socio-economic growth. The interest in this area is important, especially for these countries, owing to the immense benefits the novel biotechnology promises. However, the pursuit of Synthetic Biology development must be undertaken with caution, as it poses catastrophic risks, such as engineered or accidental pandemics from pathogen release. This study explores the potential benefits of Synthetic Biology in Kenya, evaluates the risks requiring regulation, and proposes a structure of a potential legal solution that balances the pursuit of bio-innovation with the need to prevent pathogen risks. Through a rigorous analysis, this research seeks to demonstrate that developing countries can effectively manage the risks associated with Synthetic Biology development and protect their citizens by adopting a robust legal and institutional framework. This study's findings have global implications, as they provide a blueprint for other similarly situated developing countries. The propositions in this paper are a call to action for policymakers to prioritise responsible governance of Synthetic Biology and mitigate the potential catastrophic risks of this revolutionary biotechnology. Being a double-edged sword, this study offers a roadmap to ensure that Synthetic Biology is navigated safely and responsibly.

Keywords: *Emerging Technologies, Synthetic Biology, Pathogen Risks, Anticipatory Governance*

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I. Introduction

In a rapidly changing world, driven by the forces of emerging technologies, we now know that As, Cs, Ts and Gs[1] are not just letters in the field of biology, they are the deoxyribonucleic acid (DNA) gene codes that make up the substance of every living creature.[2] In recent years, scientists have made significant progress in learning how to read gene codes.[3] Over and above that, there have been developments in technology that allow them to edit as well as rewrite these gene codes.[4] The discovery of the DNA double helix in 1953 by Watson and Crick revolutionised biology, revealing the molecular code of life.[5] This breakthrough laid the groundwork for the Human Genome Project (1990–2003), a global scientific endeavour that successfully sequenced the entire human genome, unlocking new frontiers in genetic research.[6] By identifying the precise sequence of DNA base pairs, the project not only advanced the understanding of human biology but also enabled the development of powerful biotechnologies, including synthetic biology.

Synthetic Biology (SB) is a collection of technologies which allows the application of standardised engineering techniques to biology, thereby creating new organisms or biological systems with novel and/or specialised functions.[7] Simply put, these emerging bio-technologies not only enable the reading of the As, Cs, Ts and Gs, but also editing them and creating new organisms that are not

1 A, C, T, and G refer to the four nucleotide bases of DNA: **adenine (A), cytosine (C), thymine (T), and guanine (G)**. These bases form the fundamental building blocks of genetic code, pairing in specific ways where adenine always pairs with thymine, and cytosine always pairs with guanine. This pairing mechanism allows DNA to store and transmit genetic information, guiding the development, functioning, and reproduction of all living organisms. The unique sequence of these bases acts as a blueprint for protein synthesis and regulates biological functions, shaping everything from physical traits to cellular processes.

2 Vassilove M, 'BioError to BioTerror; promises of Synthetic Biology' YouTube, TEDTalk, 18 May 2022 —< https://www.youtube.com/watch?v=1YEbjpNX2hs >— on 2 January 2023.

3 Koonin E and Novozhilov A, 'Origin and Evolution of the genetic code: the Universal Enigma', 61(2) National Center for Biotechnology Information, 2009. 99-111.

4 Haynes K and Silver M, 'Eukaryotic systems broaden the scope of Synthetic Biology', 187 (5) *Journal of Cell Biology*, 2009, 589.

5 See: Crick F, 'The Discovery of the Double Helix, 1951-1953'— < https://profiles.nlm.nih.gov/spotlight/sc/feature/doublehelix> — on 28 March 2025.

6 Crick F, 'The Discovery of the Double Helix, 1951-1953'— < https://profiles.nlm.nih.gov/spotlight/sc/feature/doublehelix> — on 28 March 2025.

7 Trump B, 'Synthetic Biology regulation and governance: Lessons from TAPIC for US, EU and Singapore', 121 (11) *Health Policy*, 2017, 112.

naturally occurring.[8] This is primarily done by combining engineering and biology.[9] SB represents a transformative leap from traditional genetic engineering. Unlike genetic engineering, which modifies existing organisms, SB employs engineering principles to design and create novel biological systems, often from scratch.

When the organisms created through synthetic biological means are released into the environment, they can interact with the natural environment and replicate.[10]Although current SB techniques are yet to allow for the creation of entirely new life forms, there is a strong consensus within the field that this will likely be achievable in the near future.[11] Given the rapid pace of advancements, this potential development demands collective attention and concern.

The application of SB can lead to major benefits to society in terms of combating climate change, fighting disease, developing biofuels, and ensuring food security (later discussed in this paper).[12] There is evidence that demonstrates that SB will have a significant impact on fields such as human health, environmental crisis and biofuels.[13] Currently, developing countries such as Kenya are grappling with food security concerns, poor healthcare and are also severely affected by the climate crisis.[14] As such, the fruits of SB development are of special importance to these countries as they have an urgent need to combat these socio-economic problems.

As with most technological advancements, the development of SB poses a dual use research concern (DURC).[15] This is whereby research and development in a field can yield benefits to society, but at the same time, pose a considerable

8 The meaning of 'Synthetic Biology' is not agreed upon by everyone, but it first appeared in the early 2000s as a development of genetic engineering from the 1970s. The definition of this term should include two main things: (a) the creation and building of fresh biological parts and systems, and (b) the modification of present natural biological organisms and systems for practical purposes.

9 Trump B, 'Synthetic Biology regulation and governance', 112.

10 Trump B, 'Synthetic Biology regulation and governance', 112.

11 See: Cho R, 'Synthetic Biology: Creating New Forms of Life', Columbia Climate School, 8 July 2011—< https://news.climate.columbia.edu/2011/07/08/synthetic-biology-creating-new-forms-of-life/>— on 12 December 2024.

12 Trump B, 'Synthetic Biology regulation and governance', 1139.

13 McDaniel R, Weiss R, 'Advances in Synthetic Biology' 16 (4) *Curr Opin Biotechnol*, 2005, 476 and 483.

14 See evidence to all these claims respectively at: –<https://archive.unu.edu/env/govern/ElNIno/CountryReports/inside/Kenya/SOCIO-ECONOMIC/SOCIO-ECONOMIC_txt.html> and <https://www.mcgill.ca/globalfoodsecurity/files/globalfoodsecurity/JMBahemuka_FoodSecurityInKenya.pdf> on 15 February 2023.

15 Winter C, et al. 'Legal Priorities Research', 57-58. See also: Li J, Zhao H and Zheng L and An W, 'Advances in Synthetic Biology and Biosafety Governance' 9(1) *Frontiers in Bioengineering and Biotechnology*, 2021, 3.

threat.[16] SB research and development brings tons of benefits, but, among other risks, there is a likelihood of unintentional or intentional release of pathogens/ toxins into the environment.[17] Such pathogen releases can prove to be catastrophic since their reach is far beyond the geographical confines of their origin.[18] Given the examples of COVID-19, Ebola, Marburg, M-pox and similar viruses, it has become widely acknowledged that the release of dangerous pathogens into the environment can have catastrophic consequences.[19] The unknown origins of COVID-19 have also raised concerns about the bio-risks associated with SB, which enables rapid modification of organisms.[20] In a developing country like Kenya, where the healthcare infrastructure is poor, the release of pathogens resulting from SB could be devastating, as these pathogens are highly contagious and can spread rapidly. Moreover, the possibility of a release leading to a global catastrophic bio-risk (GCBR) remains a genuine concern.[21] Aside from the release of pathogens, which is one of the main risks when it comes to such biotechnology,[22] other risks associated with the development of SB include

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16 WHO, 'What is dual-use research of concern?', WHO, 13 December 2020—< https://www.who.int/news-room/questions-and-answers/item/what-is-dual-use-research-of-concern#:~:text=Dual%2Duse%20research%20of%20concern%20(DURC)%20describes%20research%20that,including%20engineering%20and%20information%20technology> on 15 February 2023.

17 Giese B and Von Gleich A, 'Hazards, risks, and low hazard development paths of syn- thetic biology' in French C, Horsfall L, Barnard D, Fletcher E, Joshi N (eds) in 2015th ed, *Synthetic Biology - Character and Impact* Springer International Publishing, 2015. p. 173–95.

18 Li J, Zhao H and Zheng L and An W, 'Advances in Synthetic Biology and Biosafety Governance' 2021, 1.

19 Trump B, Galatsi SE, Appleton E, Blejis D et al, 'Building biosecurity for Synthetic Biology' 16 (7) *Mol Syst. Bio,* 2020, 2-3.

20 Li J, 'Advances in Synthetic Biology and Biosafety Governance', 1.

21 Schoch-Spana M, Cicero A, Adalja A, Gronvall G, Kirk Sell T, Meyer D, Nuzzo JB, Ravi S, Shearer MP, Toner E, Watson C, Watson M, Inglesby T. Global Catastrophic Biological Risks: Toward a Working Definition. Health Secur. 2017 Jul/Aug;15(4):323-328

Global Catastrophic Risk refers to an event that could cause severe harm to human civilization on a global scale. Such risks could include natural disasters, pandemics, nuclear war, asteroid impacts, and other catastrophic events.

Global Catastrophic Bio-Risk (GCBR) specifically refers to the risks posed by naturally occurring or engineered biological agents, such as pandemics or bioterrorism, that have the potential to cause widespread, long-lasting harm to human populations and the global economy. GCBRs are of increasing concern due to the rapid advances in biotechnology and the potential for bioweapons development by state and non-state actors.

22 Flynn R, 'Synthetic Biology – A look into the controversy on creating new life' < https://web.mit.edu/demoscience/SynthBio/history.html>— accessed on 30 March 2025; and European Commission Scientific Committees Opinion, 'Final Opinion on Synthetic Biology III: Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology'27.

ethical challenges in relation to formation of new life forms,[23] data security threats from the potential misuse of data centric approaches to develop harmful biological agents,[24] and environmental risks from new organisms disrupting the natural ecosystem.[25]

At present, the United States, China and Singapore are at the forefront of leading SB research and governance.[26] On the African continent, the conversations about this topic have begun. Even though the pace of the development of this field is slower in Africa, compared to other developed countries in the game, several considerable developments have taken place.[27] With South Africa leading the continent in SB (with the only sizeable research and startups in SB placed in this country), it is notable that this emerging technology is relevant to the African continent too, owing to its promising benefits.[28] In Kenya, the year 2020 witnessed the first-ever government-funded SB research project that was to employ SV innovations in addressing food security and healthcare concerns in the country.[29] In addition, private companies on the continent are now venturing

23 Patrick S and Barton J, 'Mitigating Risks from Gene Editing and Synthetic Biology: Global Governance Priorities' < https://carnegieendowment.org/research/2024/10/mitigating-risks-from-gene-editing-and-synthetic-biology-global-governance-priorities?lang=en> — accessed on February 14 2025.

24 Zelenka R, Cara N, Sharma K, Sarvaharman S, Ghataora J, Parmeggiana F, Nivala J, Abdallah Z, Marucco L, Gorochowski T, 'Data Hazards in Synthetic Biology' 9(1), 2004, 7-8.

25 Donlan, 22 2014; Seddon et al., 2014 – EU Report (Citation TBC).

26 Trump B, 'Synthetic Biology regulation and governance', 112.

27 See: Otim G, Matinyi S, Baluku E, Chimwula I, Magoola K, Mukuze S, Kyabarongo A, Opiyo S, 'Syn-Bio Africa's story from the grassroots, the present and the future', Biotechnology Notes, 1-6 (2023) 4; and see also: ISAA, 'Kenyan Scientists Embark on Synthetic Biology Research', ISAA, 9 September 2020—<https://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=18323> on 15 February 2023.

Syn-Bio Africa, Open Plant, BioMarker Africa, Amino Labs and several other organisations have started open source registries and are providing grants for Synthetic Biology start ups. One of the major Synthetic Biology project is currently being undertaken by Syn-Bio Africa which is a Ugandan company. The project is regarding Polyethylene terephthalate (PET) is a widely used thermoplastic polymer found in clothing fibers, food packaging, and plastic containers, but its poor biodegradability contributes to environmental pollution. Scientists are exploring alternative methods for PET degradation, such as using microorganisms like *Ideonella sakaiensis*, which breaks down PET into reusable monomers, ethylene glycol, and terephthalic acid, through PETase and MHETase enzymes. Engineered organisms like *E. coli* can also express these enzymes. Syn-Bio Africa is working to utilise these enzymes for efficient PET degradation and repurpose the by-products for biofuel production.

28 Agaba J, 'Synthetic Biology in Africa: 'Golden opportunity' once regulations are in place' Alliance for Science, 16 November 2021 —<https://allianceforscience.cornell.edu/blog/2021/11/synthetic-biology-in-africa-golden-opportunity-once-regulations-are-in-place/> on 15 February 2023.

29 ISAA, 'Kenyan Scientists Embark on Synthetic Biology Research', ISAA, 9 September 2020—<https://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=18323> on 15 February 2023

into research on this novel biotechnology.[30] The speedy development of biotech on the continent warrants a detailed discussion on the regulation and governance of SB in Sub-Saharan African countries such as Kenya. Therefore, it is important to establish effective governance systems to minimise the risk of such incidents.

Whenever a new technology is introduced, there is often a gap in the pace of regulation known as the 'pacing problem.'[31] This means that the current rules and regulations are not sufficient to address the complexities and unique features of the new technology. This is also the case with SB, where there is a pacing gap.[32] As a result, the potential risks associated with SB may require special regulation or reforms that are specific to this technology. Some argue that the existing regulatory frameworks can be adapted to accommodate the unique nature of Synthetic Biology.[33] Special attention needs to be drawn to the bio-risks posed by SB, and how they can be minimised, while allowing maximum benefit from the novel biotechnology. Bearing this in mind, this study assesses what legal solutions a developing country like Kenya should adopt, specifically to guard against the risk of pathogen release, while enjoying the benefits of this new biotechnology's development.

The discourse in this paper will take the following trajectory: Section I lays out the introductory notes of the paper by defining Synthetic Biology and its relevance, as well as the core thesis of the paper. Section II will be a detailed explanation of the conceptual lens through which this paper should be read, that is, anticipatory governance. Section III provides a historical trajectory of Synthetic Biology development in the world, Africa and in Kenya by highlighting key events for the reader. Sections IV and V discuss the benefits and risks of Synthetic Biology, respectively. Section VI provides holistic legal solutions that can be used for Synthetic Biology regulation on the African continent. The solutions range from legislative interpretation to using different fields of law to govern the development of this promising yet dangerous biotechnology. The paper ends with some concluding remarks and questions for future researchers.

30 Smith J, 'The 5 hottest private `Bio-techs in South Africa' Labiotech.eu, 28 September 2022 —<https://www.labiotech.eu/best-biotech/biotech-companies-south-africa/> on 15 February 2022. Also: companies such as: Open Plant, Joint BioEnergy Institute, Biomaker Africa, Amino Labs and African Institute of Open Science and Hardware.

31 Wallach W, Saner M, Marchant G, 'Beyond Cost-Benefit Analysis in the Governance of Synthetic Biology' 48 *Supplement: Governance of Emerging Technologies* 1*: Aligning Policy Analysis with the Public's Valuesat*, 2018, 70.

32 Wallach W et al. 'Beyond Cost-Benefit Analysis in the Governance of Synthetic Biology', 70-71.

33 Trump B et al. 'Building biosecurity for Synthetic Biology', 5.

II. Conceptual Framework – Anticipatory Governance

The conceptual framework adopted for this study is anticipatory governance. Anticipatory governance is a proactive approach to decision making and policy formation that considers the potential impacts and consequences of future events, trends, and technologies.[34] It is an approach that aims to anticipate the future and prepare for potential challenges and opportunities, rather than simply reacting to them once they have already arisen.[35] Given the rapidly changing world we live in today, characterised by technological advances and global interconnectedness, anticipatory governance is particularly relevant as it helps decision makers and policymakers anticipate and plan for changes, and make informed decisions that will shape the future in positive ways.[36] As noted by Professor Richard Susskind, in his upcoming book 'How to Think Like an A.I',

Anticipatory governance is a 'system of systems' that allows one to make assumptions about an emerging technology and draw conclusions based on those assumptions.[37] This approach is interdisciplinary, involving experts from various fields such as science and technology, sociology, economics and politics.[38] Additionally, a critical feature of anticipatory governance is its focus on collaboration and participation.[39] This means that all relevant stakeholders, including government agencies, businesses, civil society organisations and the public, are involved in the decision-making process and that decisions are made in an inclusive, equitable and sustainable manner.[40]

The application of this conceptual framework in this study is justified due to the potential risks and benefits associated with SB and the lack of evidence-based research in this area. The risks and uncertainties are exacerbated by the rapid pace of technological change, the complexity of biological systems, and the novelty of the technology.[41] This type of governance is particularly important

34 Moe-Behrens G, Davis R and Haynes K, 'Preparing Synthetic Biology for the world' 4(1) *Front Microbiol*, 2013.

35 Sarewitz D, 'Anticipatory Governance of Emerging Technologies' in Marchant G, Allenby B and Herkert J (eds) *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*, Springer Publishing, 2011.

36 Sarewitz D, 'Anticipatory Governance of Emerging Technologies.'

37 Heo K and Seo y, 'Anticipatory governance for newcomers: lessons learned from the UK, the Netherlands, Finland, and Korea' 9(1) *European Journal of Futures Research,* 2021, 1.

38 Heo K and Seo y, 'Anticipatory governance for newcomers', 1-2.

39 Trump B, 'Synthetic Biology regulation and governance', 112.

40 Heo K and Seo y, 'Anticipatory Governance for new commers', **X;** and Trump B, 'Synthetic Biology regulation and governance', 112.

41 Trump B, 'Synthetic Biology regulation and governance', 112.

in the context of SB because it enables decision-makers and policymakers to anticipate and plan for the potential risks and opportunities associated with the technology. By applying an anticipatory governance framework to SB, this study can draw from the experiences and best practices of other emerging technologies and adapt them to the unique context of SB in Kenya.[42] This approach will enable the research to make informed conclusions and recommendations on the appropriate governance of SB in Kenya.

Overall, the application of anticipatory governance as a conceptual framework in this study is justified because it provides a forward-thinking and interdisciplinary approach to decision-making and policy formation that is designed to help leaders and organisations anticipate and prepare for the future and to make informed decisions that will shape the development of SB in positive ways.

III. Historical Trajectory and Development of SB – Global, Continental and National Trends

i. Global trajectory of growth and landmark achievements

The term Synthetic Biology first appeared in the academic space in the year 1912 in a book written by Stephane Leduc, a French biologist.[43] He proposed the possibility of modern biology being able to use the synthetic engineering method to reproduce phenomena.[44] Following the major scientific breakthrough in the mid-1900s, on the discovery of the DNA double helix, SB was reintroduced into the biological spaces. In 1974, Waclaw Szybalski wrote in terms that sound almost prophetic from today's perspective: 'Up to now, we are working on the descriptive phase of molecular biology. But the real challenge will start when we enter the SB phase of research in our field. We will then devise new control elements and add these new modules to the existing genomes or build wholly new genomes. This would be a field with unlimited expansion potential and hardly any limitations.'[45]

Following the development of molecular cloning in the 1970s and 1980s, genetic manipulation became widespread in microbiology research, seemingly

42 This has been done before in other jurisdictions.

43 Boldt J, 'Synthetic Biology: Origin, Scope and Ethics', Humans Nature, 28 February 2016 —https://humansandnature.org/synthetic-biology-origin-scope-and-ethics/ on 15 February 2023.

44 S. Leduc, *La Biologie Synthétique*. A Poinat, Paris, 1912.

45 W. Szybalski, 'In Vivo and In Vitro Initiation of Transcription,', 44(1), *Adv Exp Med Biol* 1974, 23-24.

offering a technical means to engineer artificial gene regulation.[46] By the end of the 1990s, a small group of engineers, physicists and computer scientists recognised the opportunity and began to delve deeper into this field and conduct research. By the start of the millennium in 2000, SB made its very first breakthrough with the invention of a toggle switch and repressilator, the first synthetic circuits which allowed gene manipulation.[47]

Since then, several other achievements have been bagged by scientists in this revolutionary area of biology. Especially between the past two decades (2000-2020), this field has grown notably, making landmark research achievements.[48] The biggest SB story of the year 2010 was the complete synthesis of a working bacterial genome by a team at the J. Craig Venter Institute (JCVI), in the United States. This achievement showed that DNA synthesis and DNA assembly could be scaled to a larger scale.[49] JCVI effectively created the first self-replicating synthetic cell. With increased research into this area, scholars, scientists, and other relevant stakeholders are discovering the true potential of SB.

While it is not yet possible to synthesise an entirely new life form using current synthetic biology techniques, the rapid growth of the field warrants a discussion on the potential for such a breakthrough.[50] This novel biotechnology has the potential to bring great societal benefits to society, cutting across combating climate change, fighting disease, developing biofuels, and ensuring food security, just to name a few.[51] In recent times, in the face of a global pandemic, SB ensured the breakthrough of a vaccine that could be distributed to countries all around the world, thus showcasing its prowess.[52] SB has played a critical role in the rapid development of COVID-19 vaccines by enabling fast genome sequencing, digital vaccine design, and scalable manufacturing. In January 2020, scientists sequenced the SARS-CoV-2 genome within days, allowing researchers to digitally design mRNA vaccines (Pfizer-BioNTech & Moderna) without needing physical virus samples.[53]

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46 Cameron D, Bashor C and Collins J, 'A brief history of Synthetic Biology', 12 *Nature Reviews Microbiology,* 2014, 381-383.

47 Haynes K and Silver M, 'Eukaryotic systems broaden the scope of Synthetic Biology', 187(5) *Journal of Cell Biology*, 2009, 589.

48 Meng F and Ellis T, 'The second decade of Synthetic Biology: 2010-2020', 11(1) *Nature Communications*, 2020, 2. View the timeline drawn.

49 Meng F and Ellis T, 'The second decade of Synthetic Biology', 2-3.

50 Winter C, et al. 'Legal Priorities Research', 59. See also: Li J et al., 'Advances in Synthetic Biology and Biosafety Governance', 3.

51 Li J, 'Advances in Synthetic Biology and Biosafety Governance', 1.

52 Kasera C, et al. 'Synthetic Biology Regulatory Opportunities and Gaps in Kenya', 195.

53 Park W, Kwon NJ, Choi SJ, Kany C, Choe P, Kim J, Yun J, Lee G, Seong MW, Kim N, Seo JS, Oh M, 'Virus Isolation from the First Patient with SARS-CoV-2 in Korea' 35(7) J Korean Med Sci, 2020.

ii. African developments in Syn-Bio

South Africa is leading the continent in SB research.[54] Stellenbosch Biomass Technologies and Inqaba BiotecTM are respectively engaged in biofuel production and gene sequencing services.[55] Biomass Technologies engaging in biofuel production have been received by the African researchers very well, as they hold great promise for the country to move to a non-oil-based industry of energy production.[56] While the truth remains that we are far from achieving this, it still holds merit to invest energy and time to critically think about the time when such inventions do become possible on a large scale.

Uganda is also making developments on the continent with its Open Philanthropy-supported organisation, SynBio Africa.[57] Syn-Bio Africa is an organisation that was founded in 2018 by Geoffrey Otim, with the aim of promoting Synthetic Biology initiatives in Africa.[58] The organisation collaborates with government and non-governmental organisations, educational institutions, the public and private sectors, and other stakeholders across Africa. Syn-Bio Africa's main interest lies in providing sustainable and low-cost technologies to address various challenges in agriculture, energy, environmental conservation, biomanufacturing, pharmaceuticals, and crop improvement.[59] In fact, the organisation conducted its annual conference and invited all stakeholders, policymakers, biologists and students in a collaborative effort.[60]

Apart from Syn-Bio Africa, other organisations in Africa's Synthetic Biology ecosystem include Open Plant, Joint Bio-Energy Institute, Biomarker Africa, Amino Labs, and the African Institute of Open Science and Hardware.[61] As

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54 Akpoviri F, 'Responsible and Sustainable Synthetic Biology in Africa' —<https://www.synbiobeta.com/read/responsible-and-sustainable-synthetic-biology-in-africa> on 15 February 2023.

55 Akpoviri F, 'Responsible and Sustainable Synthetic Biology in Africa' —<https://www.synbiobeta.com/read/responsible-and-sustainable-synthetic-biology-in-africa> on 15 February 2023.

56 Akpoviri F, 'Responsible and Sustainable Synthetic Biology in Africa' —<https://www.synbiobeta.com/read/responsible-and-sustainable-synthetic-biology-in-africa> on 15 February 2023.

57 Inference drawn from: –< https://www.openphilanthropy.org/grants/early-career-funding-for-global-catastrophic-biological-risks-scholarship-support-2022/ >- accessed on 1st February 2023.

58 Otim G et al. SynBio Africa's story from the grassroots, the present, and the future', 1.

59 See: Otim G et al. SynBio Africa's story from the grassroots, the present, and the future', 1. Also note that, the organisation has faced challenges such as public concerns over genetically modified organisms, lack of policies and regulations, and limited funding and project equipment. Despite these challenges, the organisation has made significant achievements, including hosting the inaugural Synthetic Biology and biosecurity conference in Africa, the Africa iGEM showcase, and launching the SynBio Africa Global Catastrophic Biological Risks Initiative.

60 LinkedIn post about the Syn Bio Africa conference 2023:-< https://www.linkedin.com/company/synbio-africa/posts/?feedView=all >- accessed on 1st February 2023.

61 Otim G et al. SynBio Africa's story from the grassroots, the present, and the future', 2.

noted by Otim et al, 'these organisations provide various services, such as open-source registries for plants, grants for startup Synthetic Biology labs, lab training, and affordable Syn-Bio toolkits.'[62] In the author's view, these organisations also provide a forum for key SB players to collaborate. While most African countries are yet to develop regulatory policies for SB, some nations, such as Kenya, are already making use of certain provisions in genetically modified organism (GMO) regulations.[63]

It is vital to note at this juncture that all these developments in SB in Africa also pose risks and disadvantages, including the accidental release/intentional release of engineered microorganisms into the environment. This remains the focus of this study.

iii. Kenyan developments in Syn-Bio

The Government of Kenya officially made a financial commitment to joining the SB League, currently spearheaded by the United States of America, China, Singapore and the United Kingdom.[64] The National Research Fund was commissioned in 2020, to carry out the country's debut project in the novel biotech field. This project is two-fold, including producing biosensors to detect Cholera-causing viruses and detecting Potato Brown Streak Diseases that ruin crop yields every year.[65] Evidently, food security and health are the two areas that these projects are geared to tackle. Additionally, the efforts of Richard Smith-Unna, a Cambridge University student, to teach Synthetic Biology as a module in the bioinformatics course offered to some 20 students in Nairobi, Kenya are also an attempt at meaningful contribution, starting up the conversation and building community in this area.[66] Such efforts are useful since they can pique the interest of people in the country and could potentially lead to more opportunities for research and development.

While the current efforts are commendable, it has been suggested that developing countries need to create enabling frameworks, and for countries such

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62 Otim G et al. SynBio Africa's story from the grassroots, the present, and the future', 2.

63 In Kenya the *Biosafety Act* (Act No. 2 of 2009) defines GMO, and in 2022 Kenya established the *National Biosafety Authority (NBA***)** to regulate activities involving GMOs. In 2022, the NBA published *Genome Editing Guidelines*, providing clarity on which genome-edited organisms and products fall under the Biosafety Act's jurisdiction.

64 Kasera C, et al. 'Synthetic Biology Regulatory Opportunities and Gaps in Kenya', 195**.**

65 Kasera C, et al. 'Synthetic Biology Regulatory Opportunities and Gaps in Kenya', 197**.**

66 Unn S, Strengthening Synthetic Biology capacity in Kenya through bioinformatics training' —<https://static1.squarespace.com/static/584d41b3f5e2310b396cd953/t/59636490b3db2b7eda40a784/1499686032748/Strengthening+synthetic+biology+capacity+in+Kenya+through+bioinformatics+training.pdf> on 15 February 2023.

as Kenya that already have an enabling framework, assess the capacity of the frameworks to tackle any issues that may arise.[67] The focus of this study is to do the latter in light of pathogen release that can cause catastrophic risks to society.

The above is an attempt to show the trends in this area thus far. The author has demonstrated that there is good reason to think that Syn-Bio will likely emerge in Africa, and perhaps in Kenya, too. This has been demonstrated by listing all significant events to date, which illustrate the present growth trajectory. This study assumes that this field will soon be making more leaps based on all the developments in the world, Africa, and Kenya. As this field is expected to continue growing, there is a good rationale to control it. Such anticipatory governance would be quintessential in ensuring more funding, research and innovation in this area of Syn Bio, as well as to secure the country from potential bio-risks.

IV. Benefits of Synthetic Biology: The Special Interest Case

Syn-Bio researchers now have evidence to believe that this field can lead to major impacts in several fields such as human health, the environment, biofuels and chemical production.[68] Recent studies have provided evidence to support the impact of Syn-Bio in these fields. This sub-section will focus on exploring some of the benefits that Syn-Bio offers and will later discuss how these benefits could potentially apply in developing countries, such as Kenya. The aim of this Section is to provide a comprehensive overview of the potential benefits of Syn-Bio and to evaluate its relevance in the context of developing countries, considering the unique challenges and opportunities that these countries face.[69]

67 Mudziwapasi R, Mufandaedza J, Jomane F, Songwe F, Ndudzo A, Nyamusamba R, Takombwa R, Mahla M, Pullen J, Mlambo S, Mahuni C, Mufandaedza C, and Ryman Shoko, 'Unlocking the potential of Synthetic Biology for improving livelihoods in sub-Saharan Africa', 15(1) *All Life*, 10 February 2021, 1-2. Also see: Agaba J, 'Synthetic Biology in Africa: 'Golden opportunity' once regulations are in place' Alliance for Science, 16 November 2021 —<https://allianceforscience.cornell.edu/blog/2021/11/synthetic-biology-in-africa-golden-opportunity-once-regulations-are-in-place/> on 15 February 2023.

68 McDaniel R and Weiss R, 'Advances in synthetic biology: on the path from prototypes to applications' 16(4) *Current Opinion in Biotechnology,* 2005, 476; Serrano P, Casas J, Llebaria A, Zucco M, Emeric G, Delgado A, 'Parallel synthesis and yeast growth inhibition screening of succinamic acid libraries' 9(4) *Journal of Combinatorial Chemistry,* 2007, 635-643; Khalil S and Collins J, 'Synthetic biology: applications come of age', 11(1) *Nature Reviews Genetics,* 2010, 367; and Schmidt J, Enhancing the relevance of palaeoclimate model/data comparisons for assessments of future climate change, 25 *Journal of Quaternary Science,* 2010, 80.

69 However, the author would like to emphasise that the benefits discussed herein are not an exhaustive list, since there are numerous possible benefits. The discussion however focuses on some the key benefits that must be focused on owing to their relevance, especially to developing countries.

Synthetic biology has the power to completely change the way that *healthcare* is provided. Biologists can alter the genetic code of living things to build brand-new remedies and cures for illnesses.[70] This is done by developing fresh genetic tools. Drug production could become simpler, less expensive, and more effective as a result, opening the door to the creation of tailored medications. For instance, a cancer treatment has recently been developed using synthetic biology.[71] Salmonella was used to sense a tumour and release medications in a time-dependent manner to limit the growth of tumours. Researchers have found that Salmonella carries genes for synthetic anticancer pharmaceuticals.[72]

Another recent gift that Syn-Bio has given to modern medicine was its assistance in developing a vaccine for the SARS-CoV-2 virus.[73] Much has been achieved already by this novel biotechnology, which allows this study to assume that as the field grows, more promising benefits can be expected in medicine (and other arenas). Obviously, the increased interest in this field also raises concern that the research could pose a harm, as these medical scientists can intentionally or unintentionally release pathogens that can multiply and wreak havoc.

The novel biotechnology also promises benefits to the *agricultural sector*.[74] This includes the creation of genetically engineered crops that are more productive, resistant to pests and diseases, and better suited to environmental circumstances. For instance, by altering the DNA of cotton plants, researchers were able to make the plants immune to bollworm, a prevalent insect that causes large output losses in cotton crops.[75] To manage pests like the European corn borer, genetically modified maize types have been developed to produce their own insecticide.[76]

By using synthetic biology techniques, researchers can also introduce desirable traits into crops, such as drought tolerance, salinity tolerance, and

70 Danino T, Prindle A, Kwong Skalak A, Li H, Allen K, Hasty J and Bhatia S, Programmable probiotics for detection of cancer in urine' 7(289) *Science Translational Medicine,* 2015; Xie S, Garcia-Prat L, Voisin V, Ferrari R, Gan O, Wagenblast E, Kaufmann K, Zeng A, Takayanagi S, Patel I, Lee E, Jargstorf J, Holmes G, Romm G, Pan K, Shoong M, Vedi A, Luberto C, Minden M, Bader G, Laurenti G and Dick J, 'Sphingolipid modulation activates proteostasis programs to govern human hematopoietic stem cell self-renewal' 25(5), 2019, 640.

71 Din M, Danino T, Prindle A, Skalak M, Selimkhanov J, Allen K, Julio E, Atolia E, Tsimring L, Bhatia S and Hasty J, 'Synchronized cycles of bacterial lysis for in vivo delivery', 536 *Nature*, 2016, 81-85.

72 Li J, et al. 'Advances in synthetic biology and biosafety governance', 3.

73 Kasera O et al. 'Synthetic Biology Regulatory Opportunities and Gaps in Kenya', 195.

74 Li J, et al. 'Advances in synthetic biology and biosafety governance', 4.

75 Gatehouse A, Ferry N and Edwards G, 'Insect-resistant biotech crops and their impacts on beneficial arthropods', 366(1569) *Philosophical Transactions of the Royal Society: Biological Sciences*, 12 May 2011.

76 Bessin R, 'BT-Corn: What is it and how it works', University of Kentucky: College of Agriculture, November 2019, 1-2.

improved nutritional content.[77] In addition to genetically modified crops, synthetic biology is also being used to develop biological control agents, such as bacteria and viruses, to protect crops from pests and diseases. For example, a company called Insect Allies, based in the United States, is developing genetically modified viruses that can infect plants and introduce beneficial genes that provide resistance to diseases or pests.[78]

Climate change is one of the most consequential challenges of our time, and Synthetic Biology is a promising tool to help mitigate its impact. One of the ways in which Synthetic Biology can contribute to combating climate change is by enabling the production of renewable energy.[79] Biofuels are an alternative to fossil fuels and can be produced from biomass such as plant material, algae, or waste.[80] Researchers have developed Syn-Bio techniques to produce biofuels from algae more efficiently.[81] These techniques involve engineering the algae to produce higher amounts of lipids, which are then converted into fuel. Therefore, SB can help in optimising the production of biofuels by engineering the microbes involved in the process, which eventually helps in combating climate change.

Another way in which Synthetic Biology can contribute to combating climate change is by reducing greenhouse gas emissions.[82] Methane, a potent greenhouse gas, is produced by ruminant livestock such as cows, sheep, and goats, as well as in rice paddies and landfills.[83] Synthetic Biology can be used to engineer microbes that can break down methane and convert it into useful products such as biofuels. Biologists have begun engineering bacteria that can produce biofuels from methane, which can significantly reduce greenhouse gas emissions.[84] Overall, these examples demonstrate the potential of Synthetic Biology to contribute to

77 Sargent D, Conaty W, Tissue D, and Sharwood E, 'Synthetic biology and opportunities within agricultural crops', 1(2) *Journal of Sustainable Agriculture and Environment,* 16 May 2022, 89-90.

78 Pfifer K, Freiß J, and Giese B, 'Insect allies—Assessment of a viral approach to plant genome editing', 18(6) *Integrated Environmental Assessment and Management,* 12 January 2022, 1488.

79 Jatain I, Dubey K, Sharma M, Usmani Z, Sharma M, and Gupta V, 'Synthetic biology potential for carbon sequestration into biocommodities', 323(1) *Journal of Cleaner Production,* 10 November 2021.

80 Jatain I, et al. 'Synthetic biology potential for carbon sequestration into biocommodities.'

81 DeLisi C, 'The role of synthetic biology in climate change mitigation', 14(1) *Biology Direct,* 20 August 2019, 1-3.

82 DeLisi C, 'The role of synthetic biology in climate change mitigation', 1-3.

83 Tom K, 'How bacteria could help turn a potent greenhouse gas into renewable fuel', University of Alberta, April 19 2018 — <https://www.ualberta.ca/folio/2018/04/how-bacteria-could-help-turn-a-potent-greenhouse-gas-into-renewable-fuel.html> on 15 february 2023.

84 Tom K, 'How bacteria could help turn a potent greenhouse gas into renewable fuel', University of Alberta, April 19 2018 — <https://www.ualberta.ca/folio/2018/04/how-bacteria-could-help-turn-a-potent-greenhouse-gas-into-renewable-fuel.html> on 15 february 2023.

a more sustainable future, and as the technology continues to advance, its impact in mitigating climate change is likely to grow even more significant.

Lastly, *de novo synthesis* of living organisms refers to the creation of entirely new organisms from scratch using synthetic biology techniques.[85] This is a potential benefit of the novel biotechnology because it can enable scientists to create organisms with specific functions and properties that do not exist in nature. For example, researchers have successfully synthesised the genome of the bacterium *Mycoplasma genitalium* and transplanted it into another bacterium, creating a new organism.[86] This demonstrated the possibility of creating entirely synthetic organisms with tailored properties and functions. This shows that there is hope for non-naturally occurring organisms to be created. While this may raise certain ethical and religious concerns, the promise of such bio-innovation is also an avenue to help humanity reach greater heights of technology and development.

Developing countries have been given the short end of the stick for generations on end. For most Sub-Saharan African countries, Synthetic Biology promises benefits that can potentially improve the livelihoods of the population by tackling the most fundamental problems of starvation, poverty and diseases.[87] Experts have noted that if Africa were to join the Synthetic Biology race and realise its potential, it could not only reduce the continent's dependency on oil-bringing foreign exchange savings and much needed political stability, but also improve food and energy security, support the industrial sector, alleviate poverty in rural areas, boosting local agriculture production, giving farmers access to additional markets and revenues and generating jobs.[88]

The author of this study claims that developing countries need to have a 'special interest' in actively engaging in Syn-Bio research and development as opposed to entirely relying on the West to develop the bio-tech. 'Special interest' is the general shared interest that a certain group has in advancing an area of technology.[89] While ordinarily used in an organisation context, the author seeks

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85 Li J, 'Advances in Synthetic Biology and Biosafety Governance', 1.

86 J. Craig Venter Institute, 'Scientists Create First Synthetic Bacterial Genome: Largest Chemically Defined Structure Synthesized In The Lab' ScienceDaily, 24 January 2008 — www.sciencedaily.com/releases/2008/01/080124175924.htm on 15 February 2023.

87 Akpoviri F, 'Responsible and Sustainable Synthetic Biology in Africa' —<https://www.synbiobeta.com/read/responsible-and-sustainable-synthetic-biology-in-africa> on 15 February 2023.

88 Garang B and Onkware A, 'Redirecting the Wheels of Natural Progression: Review of Synthetic Biology and the African Biotechnology Revolution', 4(2) *Bioengeneering and Bioscience,* 2016, 15.

89 See: https://aisnet.org/page/SpecialInterestGroup and Wikipedia.org, 'Special interest Group' — <https://en.wikipedia.org/wiki/Special_interest_group#cite_note-1> on 15 February 2023.

to extend this term to 'members in developing countries', as the group that needs to have a vested interest in Syn-Bio.

It would be prudent to admit at this point that Syn-Bio also has negative implications for these countries. Two studies conducted by Path in 2013 and Mitchell in 2018 demonstrate that Syn-Bio can replace conventional agriculture, thereby depriving African farmers of income from small-scale subsistence farming using traditional methods.[90] However, the weight of the benefits of this field is much stronger than the harms, even in these countries (as noted in this Section). The development of the field has a better chance at improving the present and future lives in developing countries, such as Kenya.

Africa, especially Sub-Saharan Africa, is among the most food-insecure regions in the world.[91] Syn-Bio has several applications, as noted in the onset of this Section, that can potentially revolutionise the agriculture sector. Also, Syn-Bio can contribute to the development of nutrient-enriched plants. Such plants are ideal for people in developing countries living in poverty, as one plant would be able to address several nutritional needs. Synthetic biology can also help address challenges in agriculture by developing crops that are more resistant to pests and diseases, have higher yields, and are better suited to environmental conditions. Additionally, it can provide more sustainable solutions that can reduce the use of harmful chemicals in agriculture and improve soil quality. All these benefits are especially attractive to the developing countries that are currently facing more than one problem in trying to achieve food security.

Diseases such as malaria, tuberculosis, influenza, Ebola and Zika are also plaguing the population in Sub-Saharan Africa and other developing countries.[92] Syn-Bio, the new ray of hope, has helped scientists make breakthroughs in aiding to solve some of these diseases. For example, scientists at the Berkeley University used Syn-Bio to develop an antimalarial drug that can be mass-produced at low costs, with minimal side effects.[93] This next-generation antimalarial drug has proven to be effective against strains of the malaria parasite that are resistant to current front-line drugs. Admittedly, it is far too expensive right now for the countries in Africa and South America where it is needed most. Nonetheless,

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90 Mitchell P, 'Symptom science – a uniquely nursing arena', 65(3) *International Nursing Review,* 2018, 466.

91 Hung-en L, Caoimhe C, Loren C, Simon M, Danchenko M, Kuiken T, Sekeyova Z, Freemont P, 'Synthetic biology and the United Nations' 37(11) *Trends Biotechnology,* November 2019, 1146.

92 Nyaruaba R, Okoye C, Akan O, Mwaliko C, Ebdo C, and Ayoola A, 'Socio-economic impacts of emerging infectious diseases in Africa', 54(5) *Infectious Diseases,* 22 September 2021, 1-2.

93 Yarris L, 'Synthetic Biology Offers New Hope For Malaria Victims', Science Beat Berkley, 24 March 2004 — https://www2.lbl.gov/Science-Articles/Archive/sb-PBD-anti-malarial.html on 15 February 2023.

scientists agree that once the gene synthesis can be finalised, it will be cheaper and more accessible.[94]

V. Risk posed by SB development – Pathogen Release

The development of SB has many facets to it. As a result of the dual-use nature of this novel bio-tech, there are several potential risks that arise, such as accidental/intentional release of toxins and pathogens, artificial products that may have some health side effects, potential ethical violations and other socio-political concerns.[95] While there are a variety of concerns in this area, the scope of this study is limited to assessing how accidental (biosafety) and intentional (biosecurity) pathogen release can be addressed in the Kenyan legal context, while allowing continued bio-innovation in the field.[96] The reason for the specific focus on pathogen release is for two reasons: 1) It has been identified as a general threat when it comes to SB development,[97] and 2) researchers have often recommended the study of this question in relation to pathogen release, which shows the interest and necessity of the same.[98] Therefore, this Section will analyse the two main bio-risks that need to be governed in terms of pathogen release – to ensure biosafety and biosecurity.

Biosafety describes the containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.[99] Biosafety equally captures the protection, control

94 Martin V, Pitera D, Withers S, Newman J, Keasling J, 'Engineering a mevalonate pathway in Escherichia coli for production of terpenoidsVictims', 21(7) *Nature Biotechnology,* 2003, 796.

95 Keiper F and Atanassova A, 'Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols', 8(1) *Frontiers in Bioengineering and Biotechnology*, 2020, 1-3.

96 Keiper F and Atanassova A, 'Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols', 1-3.
Winter C, et al. 'Legal Priorities Research', 57; See also: Board on Life Sciences; Division on Earth and Life Studies; Committee on Science, Technology, and Law; Policy and Global Affairs; Board on Health Sciences Policy; National Research Council; Institute of Medicine. Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop. Washington (DC): National Academies Press (US); 2015 Apr 13. 5, Potential Risks: Biosafety and Biosecurity. Available from: https://www.ncbi.nlm.nih.gov/books/NBK285575/

97 European Commission Scientific Committees Report, 'Final Opinion on Synthetic Biology III: Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology' 2015, 27.

98 European Commission Scientific Committees Report, 'Final Opinion on Synthetic Biology III: Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology' 2015, 45; and Winter C, et al. 'Legal Priorities Research', 58.

99 World Health Organization (WHO) (2006). *WHO Biorisk Management Laboratory Biosecurity Guidance WHO/CDS/EPR/2006.6*. Available online at: https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

and accountability of biological agents and toxins within facilities to prevent their loss, theft, misuse, diversion, unauthorised access or intentional release.[100]

In the field of biotechnology, scholars have always suggested that experimentation using biological organisms poses the threat of intentional or unintentional pathogen or toxin releases that can cause catastrophic damage to society.[101] In fact, existing traditional biotechnologies have been known for intentional misuse or unintentional accidents causing serious damage in the past.[102] Therefore, in order to guard the country from pathogen releases, this sub-section argues that the two main bio-risks that need to be governed are the unintentional release and intentional release.

a. Unintentional Release of Pathogens

Unintentional release implies a lack of intent from the term itself. Therefore, it is regarded as a bio-safety concern whereby the actor(s) accidentally allow a dangerous pathogen to escape from its controlled confinement.[103] This can be an escape of a microorganism from a laboratory into the external environment. Such exposure could then lead to disease outbreaks in humans and non-humans.

The concern of such accidents is not based on assumptions or myths, as some critics of SB argue.[104] Emerging evidence shows that the unintentional release of pathogens has occurred in the past in traditional biotechnology. In 2014, a vial containing a relatively harmless strain of bird flu was inadvertently mixed with a much more virulent strain by a researcher. The vial was then transported to a laboratory that was not authorised to handle such a dangerous virus, where it was used in research involving chickens. That went undetected until its discovery by the Centre for Disease Control and Prevention (CDC), which found that 75 federal employees may have been exposed to live pathogens,

100 World Health Organization (WHO) (2006). *WHO Biorisk Management Laboratory Biosecurity Guidance WHO/CDS/EPR/2006.6*. Available online at: https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

101 Winter C, et al. 'Legal Priorities Research', 57.

102 Carus S, *Biocrimes and Bioterrorism the Illicit Use of Biological Agents Since 1900*, Fredonia Publishing, 2002, 3. See also, Li J et al., 'Advances in Synthetic Biology and Biosafety Governance', 6.

103 World Health Organisation, 'Enhancement of Laboratory Safety', UN Doc 74/18, 27 April 2021, 6.

104 Jefferson C, Lentzos F and Marris C conducted a study, in which they were challenging the 'myths' on biosecurity concerns arising from Syn-Bio development. In their article, these scholars challenge the position that Syn-Bio will become easily available and/or that it will be used for any intentional harmful purposes. They argue that most scholars and stakeholders are making some leaping conclusions and assumptions regarding the biotechnology, and that it is not going to be that simple for bioterrorism or intentional misuse of Syn-Bio. See: efferson C, Lentzos F and Marris C, 'Synthetic Biology and Biosecurity: Challenging the 'Myths'', 115 (2) *Front Public Health*, 2014, 1-13.

posing the risk of a far more serious situation.[105] Although this incident was fortunately resolved, the risk of unintentional accidents remains a significant concern in Synthetic Biology because the organisms produced by Syn-Bio are much more potent and can replicate as compared to traditional biotechnology.

In addition, considering that the application of Syn-Bio would not be limited to the traditional lab setup, the users can also apply the technologies out in the world and this could have various undesirable consequences.[106] For instance, some scientists suggest using a gene-editing technique called CRISPR (clustered regularly interspaced short palindromic repeats) to change mosquitoes' DNA so that they become resistant to malaria. Then, the mosquitoes would be released to mate with the malaria-prone population, producing malaria-resistant offspring. This could help reduce the number of malaria cases, but it could also cause unforeseen consequences if the offspring replicates, mutates and causes more harm than good.[107] To address this problem, biosafety is regarded as best practice, involving measures to prevent or mitigate the risks posed by biological hazards.[108] As such, biosafety needs to be a governance mechanism for unintentional Syn-Bio-related pathogen leaks.

b. Intentional Release of Pathogens

On the other hand, intentional release of pathogens refers to the misuse of biotechnology to cause harm.[109] Intent, therefore, is the key distinguishing factor between biosafety and biosecurity concerns. Two vital elements need to be present for such a situation to arise: 1) the actor needs to have the techniques, knowledge and information about how a certain organism can be used to cause damage, and 2) the actor needs to have the ability to use such knowledge to cause harm.[110]

Once again, misuse of such nature is not a far-fetched assumption since it has occurred before in the bioscience field. The history of biological agents being used in terrorist attacks is not extensive, but the few confirmed cases were far from insignificant. Rather than causing mass casualties, these events were targeted towards inducing panic and chaos. In 1984, the Rajneesh cult used

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105 Piper K, 'How deadly pathogens have escaped the lab — over and over again', VOX, 20 March 2019 —https://www.vox.com/future-perfect/2019/3/20/18260669/deadly-pathogens-escape-lab-smallpox-bird-flu on 15 February 2023.

106 Jefferson C et al, 'Synthetic Biology and Biosecurity: Challenging the 'Myths'', 1-12.

107 Li J, et al. 'Advances in Synthetic Biology and biosafety governance', 1.

108 Gronvall G, 'Mitigating the Risks of Synthetic Biology', 2-3.

109 Gronvall G, 'Mitigating the Risks of Synthetic Biology', 4.

110 Gronvall G, 'Mitigating the Risks of Synthetic Biology', 4.

Salmonella on salad bars in local restaurants to make potential voters sick and keep them away from the polls during Oregon elections.[111] Another incident involved the attempted use of botulinum toxin and anthrax by the Japanese Aum Shinrikyo cult between 1990 and 1995,[112] followed by the 'anthrax letters' sent to media outlets and members of the US Congress in 2001. The latter instance resulted in at least 22 cases of anthrax in total, with five fatalities.[113] While the impact of these attacks was not measured in terms of a high death toll, their ability to spread fear and disrupt society cannot be overlooked.[114] Synthetic Biology offers the additional advantage of allowing the creation of pathogens from scratch, which means that nefarious actors do not need to get access to dangerous pathogens, given that they can simply create them.[115]

Dealing with such intentional releases falls within the purview of biosecurity, which predominantly focuses on preventing such catastrophes from occurring and provides mitigating options in case of misuse. Given the eventual ease of access and affordability of synthetic biology, it is important to regulate actors who may resort to intentional releases, including considering good governance models in this area to bridge the boundaries between legal and scientific disciplines, national and international law, professional and amateur biotech developers.[116] Moreover, as discussed by Benjamin Trump in his paper, regulation ought to be incentivised.[117] They state that companies and institutions can be nudged into actively taking measures towards biosecurity without burdening them. The novel claim that this study proposes is to take Trump's claim one step further and extend it to biosafety. Biosafety and Biosecurity should be an investment for actors as opposed to a cost. The law should be used/or designed in such a way that this is reflected.

111 MacIntrye R, 'Biopreparedness in the Age of Genetically Engineered Pathogens and Open Access Science: An Urgent Need for a Paradigm Shift' 180(9), Mil Med, 2015, 943-949.

112 U.S. Department of Defense. (2019). *Lest we forget: A historical analysis of biological weapons use* https://media.defense.gov/2019/Apr/11/2002115514/-1/-1/0/50LESTWEFORGET.PDF

113 United States Postal Inspection Service. (2021, October 15). *Anthrax mailing 20th anniversary*. U.S. Postal Inspection Service —< https://www.uspis.gov/press-release-anthrax-mailing-20th-anniversary>— accessed on 9 March 2025.

114 Tucker JB. 'Introduction' in: Tucker JB (ed) *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons*. Cambridge, MA: MIT Press, 2000, 1–14. Wheelis M, Sugishima M. 'Terrorist use of biological weapons' in Wheelis M, Rozsa L, Dando M (eds) *Deadly Cultures: Biological Weapons Since 1945*. Cambridge, MA: Harvard University Press, 2006, 284–303.

115 Gronvall G, 'Mitigating the Risks of Synthetic Biology', 4.

116 Winter C, et al. 'Legal Priorities Research', 57,

117 Trump B, et al, 'Building biosecurity for Synthetic Biology', 1.

VI. Legal Solutions in Kenya for a Safer Governance of SB

i. Legal instruments in place that can assist

a. International Legal Instruments

There are several international legal instruments that Kenya has ratified that have the potential to regulate Synthetic Biology development in the country. One such instrument is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD).[118] This Protocol provides a framework for the safe transfer, handling and use of living modified organisms (LMOs), including Synthetic Biology products. It requires that any bio-organism intended for release into the environment undergo a risk assessment to determine potential effects on the environment and human health.[119] This can assist in regulating pathogen risks arising from intentional and unintentional release.

Another relevant international legal instrument is the International Health Regulations (IHR) developed by the World Health Organisation (WHO).[120] These regulations aim to prevent the spread of infectious diseases across borders and have been used in the past to respond to outbreaks such as Ebola and Zika.[121] They require countries to develop and maintain their capacities to detect and respond to public health emergencies.[122] These could include those emergencies emanating from SB. The IHR can assist in regulating the potential risks associated with Synthetic Biology, including pathogen risks, by providing a framework for emergency response.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their utilisation, which is also under the CBD, aims to provide a legal framework for access to genetic resources and their associated traditional knowledge as well as the fair and equitable sharing of benefits arising from their utilisation.[123] This can promote bio-innovation by ensuring the fair and equitable use of genetic resources and traditional knowledge, fostering greater collaboration and research.

Kenya has also ratified the Biological and Toxin Weapons Convention (BTWC), which prohibits the development, production, and stockpiling of

118 *The Cartagena Protocol on Biosafety*, 11 September 2003; and Keiper F and Atanassova A, 'Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols', 7.

119 Article 2, *The Cartagena Protocol on Biosafety,* 2003.

120 World Health Organisation, *International Health Regulations,* 2005.

121 World Health Organisation, *International Health Regulations,* 2005.

122 See Article 5, World Health Organisation, *International Health Regulations,* 2005.

123 *Nagoya Protocol,* 12 October 2014.

biological and toxin weapons.[124] This can assist in regulating pathogen risks associated with Synthetic Biology by ensuring that the technology is not used for harmful purposes.

Finally, the World Intellectual Property Organisation (WIPO) treaties, such as the Patent Cooperation Treaty[125] and the Budapest Treaty,[126] provide a framework for the protection of intellectual property rights, including those related to Synthetic Biology. This can promote bio-innovation by providing legal protection for inventions and discoveries related to Synthetic Biology, which can encourage investment and research in the field.

b. National Legal Instruments

There are several national legal instruments in Kenya that can govern Synthetic Biology development in relation to pathogen risks and promote bio-innovation. The first one is the Constitution of Kenya (2010), which sets out the fundamental principles of governance and outlines the functions of various institutions.[127] The Constitution also recognises the right to a clean and healthy environment and provides for the protection of public health.[128] This right can be extended to regulate Synthetic Biology development by ensuring that any research or innovation is conducted in a safe and responsible manner, with due regard for public health and the environment.

The Biosafety Act (2009) is another important national law instrument that can regulate Synthetic Biology development in Kenya.[129] The Act provides for the regulation of GMOs and other biotechnology products. Section 2 defines GMO as 'any organism that possesses a novel combination of genetic material obtained through the use of *modern biotechnology* techniques.'[130] This definition, owing to its broad and open-ended nature, could be extended to SB organisms, as they are a combination of genetic material obtained using modern biotechniques. The Act also establishes the National Biosafety Authority (NBA) to oversee its regulation. The NBA is responsible for assessing and approving applications for the release of GMOs and other biotechnology products into the environment, which can include those developed through Synthetic Biology. This can be used to regulate pathogen risks from Synthetic Biology by ensuring that any release of synthetic

124 *Biological and Toxin Weapons Convention,*10 April 1972.
125 *Patent Cooperation Treaty,* 19 June 1970.
126 *Budapest Treaty,* 19 August 1980.
127 Article 10, *Constitution of Kenya,* (2010).
128 Article 42, *Constitution of Kenya,* (2010).
129 *BioSafety Act* (Act No. 2 of 2009).
130 Section 2, *BioSafety Act* (Act No. 2 of 2009).

organisms is done in a safe and controlled manner. Nonetheless, it is important to note that there will be a need for necessary amendments to the Act to extend its scope to organisms generated through SB.

In conclusion, Kenya has a few legal and regulatory instruments, both at the national and international level, that can be utilised to govern the development of Synthetic Biology while addressing pathogen risks and promoting bio-innovation. The existing framework can be adjusted so that the provisions can be extended to cater for SB development safely and responsibly. However, the effectiveness of these instruments will depend on their proper implementation and enforcement by the respective authorities.

ii. Legal fields that can assist

The aim of the study was to demonstrate different legal solutions that a developing country like Kenya should adopt to promote Synthetic Biology innovation and safeguard the country from bio-risks. In doing so, it is important to understand that there are areas of law that can assist in creating an enabling and protective culture surrounding this novel biotechnology. As such, the Section proposes that any solution adopted should be all-inclusive and holistic, by looking at the most impactful legal fields that can assist in achieving bio-innovation and protecting from bio-risks. Since SB is an emerging area in Kenya (and in the wider African region), there is a dearth of scholarly work in this area. The discussion on which areas of law can contribute to this effort can be explored in depth for each specific area. However, as explained elsewhere in this paper, the purpose of this introductory work is to provide a holistic and broad framework that can serve as a foundation and potentially inspire future research in this field. In line with this, this sub-section looks at various select areas and how these areas can be viewed in line with Synthetic Biology regulation.

a. Tax Law

In Kenya, the tax law can be used to regulate pathogen risk from Synthetic Biology by introducing tax incentives that promote biosafety and biosecurity. For instance, the government can provide tax credits and exemptions to Synthetic Biology companies that implement robust biosafety and biosecurity measures such as appropriate containment facilities, waste management protocols and safe disposal of genetically modified organisms.[131]

[131] Has been done elsewhere. See: 'Restrictions on Genetically Modified Organisms, March 2014 — <https://tile.loc.gov/storage-services/service/ll/llglrd/2014427358/2014427358.pdf> on 15 February 2023.

The government can use tax legislation to encourage the development of new and innovative biosafety and biosecurity technologies that can help mitigate pathogen risk in Synthetic Biology. For example, tax credits can be provided to companies that invest in research and development of biosafety and biosecurity technologies such as diagnostic tools, vaccines, and antimicrobial agents, which can help prevent or control pathogen outbreaks.

This study also aims to show how existing provisions in the system can be interpreted to cover Synthetic Biology development. Under Section 15 of the Income Tax Act, any expenditure incurred by a company in carrying out scientific research, including R&D activities, is tax deductible.[132] This provision can be amended to include R&D activities aimed at mitigating the risks associated with Synthetic Biology-related pathogens. Companies that invest in research and development activities leading to new products or services aimed at mitigating these risks can therefore claim a tax deduction on the qualifying expenditure incurred. Perhaps there can be an added provision that reads: *'A person or entity engaged in research and development (R&D) within the field of Synthetic Biology shall be entitled to deduct, for the purpose of ascertaining their taxable income, any expenses incurred in conducting research related to biosafety, biosecurity, and environmental risk assessments, subject to approval by the National Biosafety Authority (NBA) and the Kenya Revenue Authority (KRA).'*

Moreover, the Second Schedule of the Income Tax Act provides for a list of qualifying expenditure that can be claimed as a tax deduction under Section 15.[133] This list includes expenditure on research and development activities, including expenditure on the construction and equipping of research and development facilities. Companies that invest in Synthetic Biology R&D activities can, if the definition is extended to include SB, claim a tax deduction on the expenditure incurred on the construction and equipping of research and development facilities.

Furthermore, the tax incentives provided under Section 15 and the Second Schedule of the Income Tax Act can be used to promote bio-innovation in Kenya. Companies that invest in Synthetic Biology R&D activities aimed at developing new products or services can claim tax deductions on qualifying expenditure incurred, which can reduce their overall tax liability. This, in turn, can free up resources for the companies to invest in further research and development activities, leading to the development of new products and services that promote economic growth and development in the country.

132 Section 15, *Income Tax Act Kenya,* (Act No. CAP 470).

133 Second Schedule, *Income Tax Act Kenya,* (Act No. CAP 470).

b. Criminal Law

The criminal law system in Kenya can be used to regulate Synthetic Biology and the related pathogen risks by providing legal frameworks for holding individuals or organisations accountable for their actions in the context of Synthetic Biology. Regulating Synthetic Biology through a criminal law perspective has both pros and cons. On the one hand, criminal law can provide a legal framework for holding individuals and organisations accountable for their actions related to Synthetic Biology. This can include the creation or mishandling of synthetic organisms or pathogens, which could cause harm to public health or the environment. By establishing criminal liability, the law can deter individuals or organisations from engaging in reckless or harmful activities related to Synthetic Biology.

However, this approach also has some drawbacks. Criminal law is often reactive, meaning that it is only applied after harm has been done.[134] This can be particularly problematic in the case of Synthetic Biology, where the potential risks and harms may not be fully understood until after an incident has occurred. Additionally, criminal law may be limited in its ability to regulate the complexities of Synthetic Biology research and development, which can be difficult to monitor and regulate. Another challenge is the potential for over-regulation and stifling of innovation in the field. Criminal law may be overly broad in its application, leading to the criminalisation of legitimate research and development activities. This could discourage investment and growth in the field of Synthetic Biology, which could ultimately limit its potential benefits.

Section 186 of the Penal Code of Kenya criminalises the act of negligently causing any disease dangerous to life.[135] It states, '*Any person who* **unlawfully or negligently does any act** *which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, is guilty of a misdemeanour.*' This provision can be used to regulate pathogen risk arising from Synthetic Biology by providing a legal framework for holding individuals or organisations responsible for any negligent actions that result in the spread of dangerous diseases. In the context of Synthetic Biology, Section 186 can be interpreted to include the negligent handling of synthetic organisms or pathogens that could lead to the spread of dangerous diseases. By holding individuals or organisations responsible for their negligent actions related to Synthetic Biology, this provision can help regulate the risks associated with this field of study.

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[134] Sutton V, *Law and Biotechnology: Cases and Materials,* Carolina Academic Press, USA, 2007.

[135] Section 186, *Penal Code* (Act No. Cap 63).

The Prevention of Terrorism Act (PTA) of Kenya is primarily concerned with the prevention of terrorist activities within the country. While the Act does not explicitly mention Synthetic Biology or related risks, the provisions therein can be applied to SB. Synthetic Biology can be used to create biological agents that can be used for malicious purposes such as bioterrorism. As shown in an earlier section, this has been done with biotechnology in the past. The use of biological agents in a terrorist attack could have devastating effects on public health and safety.[136] The PTA provides for the prevention and suppression of terrorist activities, which can include those related to biological agents.

Section 11 of the PTA provides for the prohibition of the possession of certain articles that could be used to commit or facilitate a terrorist act.[137] This provision could be interpreted to include Synthetic Biology-related materials or equipment that could be used to create biological agents for use in a terrorist attack. Furthermore, Section 16 of the PTA provides for the imposition of penalties for individuals found guilty of preparing or planning a terrorist act.[138] This provision could be interpreted to include individuals or organisations that engage in Synthetic Biology research and development activities with the intention of creating biological agents for terrorist purposes. While deciphering intent is an uphill task, the previous interpretations of Section 16 (in other cases of planning such terrorist activities) could be borrowed in applying it to SB governance, in line with anticipatory governance being the framework of this paper.

In conclusion, while the Prevention of Terrorism Act of Kenya does not explicitly mention Synthetic Biology or related risks, it may be interpreted to govern these risks in the context of terrorism. The Act provides for the prevention and suppression of terrorist activities, including those related to biological agents, and imposes penalties for individuals or organisations found guilty of preparing or planning a terrorist act. If any amendments are necessary, then a definitional addition of the term biological agent to include Synthetic Biology would be reasonable.

c. Constitutional Law

The 2010 Constitution of Kenya provides a framework for regulating Synthetic Biology development in the country. One way that the Constitution can be interpreted and applied to regulate Synthetic Biology development is through

136 Carus S, *Biocrimes and Bioterrorism: The Illicit Use of Biological Agents Since 1900*, Fredonia Publishing, 2002, 3.

137 Section 11, *Prevention of Terrorism Act* (Act No. 30 of 2012).

138 Section 16, *Prevention of Terrorism Act* (Act No. 30 of 2012).

its provisions on national values and principles of governance. Article 10 outlines the national values and principles of governance that guide all public entities and individuals in Kenya.[139] These values include transparency, accountability, and participatory decision-making.[140] These values can be a guiding pole used to regulate Synthetic Biology development by ensuring that relevant stakeholders, including communities and civil society organisations, are involved in the decision-making process.[141] This can include providing opportunities for public consultations and stakeholder engagement in the development of policies and regulations related to Synthetic Biology.

In addition, the Constitution can be used to regulate Synthetic Biology development through its provisions on the right to a clean and healthy environment. Article 42 guarantees every person the right to a clean and healthy environment.[142] This can be used to regulate Synthetic Biology development by requiring that research and development activities related to Synthetic Biology are conducted in a manner that minimises environmental risks and preserves the natural resources and biodiversity of Kenya.

The principles of transformative constitutionalism can also be applied to regulate Synthetic Biology development. Transformative constitutionalism is a legal and political philosophy that emphasises the transformative potential of constitutional law in promoting social justice, democracy, and human rights.[143] It recognises that constitutional law is not just a set of rules but a tool for achieving broader social goals. Therefore, transformative constitutionalism can be used to ensure that Synthetic Biology development is aligned with the values and principles of the Constitution, including social justice, human rights and sustainable development.

However, it is also important to recognise that regulating Synthetic Biology development through the Constitution has its limitations. The Constitution provides a general framework for regulation, but it may not provide specific guidance on how to regulate emerging technologies such as Synthetic Biology. Therefore, it is necessary to develop specific policies that are designed to regulate SB safety and SB innovation in the country that consider the unique risks and benefits of SB and balance them with other societal values.

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139 Article 10, *Constitution of Kenya* (2010).

140 Trump B, 'Synthetic Biology regulation and governance', 2.

141 Trump B, 'Synthetic Biology regulation and governance', 2.

142 Article 42, *Constitution of Kenya* (2010).

143 Klare K, 'Legal culture and transformative constitutionalism', 14(1) *South African Journal on Human Rights*, 1996, 188.

d. Intellectual Property Law

Intellectual property law, particularly patent law, plays a crucial role in governing and regulating the development of Synthetic Biology in Kenya. The Industrial Property Act, No. 3 of 2001 (IPA), is the main law that regulates patents in Kenya. The Act governs the registration, ownership, and use of patents in the country.

Patent law protects inventors' exclusive rights to their inventions and ensures that they reap the benefits of their research and development efforts.[144] Synthetic Biology, being a field that involves the creation of novel organisms and biological systems, can be patented in Kenya. Patents give inventors the exclusive right to make, use, and sell their inventions for a specific period, which is typically 20 years from the filing date of the patent application.[145] This exclusivity incentivises innovation and investment in Synthetic Biology, as it provides inventors with a financial incentive to continue their research and development efforts.

The IPA provides for the registration of patents in Kenya. Section 24 of the Act sets out the criteria that an invention must meet to be eligible for patent protection.[146] The invention must be new, involve an inventive step and be capable of industrial application. In the context of Synthetic Biology, an invention that involves the creation of a new organism or biological system that meets these criteria would be eligible for patent protection in Kenya.

Patent law also plays a role in promoting innovation and collaboration in Synthetic Biology. Section 75 of the IPA provides for compulsory licensing of patents in certain circumstances, such as when the patent holder has refused to license the invention on reasonable terms or when the patent holder is unable to meet the demand for the invention.[147] Compulsory licensing in areas where synthetic biology offers undeniable public benefit can promote its development by allowing others to use patented inventions for further research and development. It would be important to determine how such licences should be granted and to establish clear parameters for defining what constitutes a 'public benefit.

However, patent protection also has its limitations. For example, under Section 25 of the Industrial Property Act, patents cannot be granted for inventions that are contrary to public order or morality or that may be harmful to human,

144 WIPO, 'Innovation and Intellectual Property', WIPO — <https://www.wipo.int/ip-outreach/en/ipday/2017/innovation_and_intellectual_property.html> on 15 February 2023.

145 *Industrial Property Act* (Act No. 3 of 2001).

146 Section 24, *Industrial Property Act* (Act No. 3 of 2001).

147 Section 75, *Industrial Property Act* (Act No. 3 of 2001).

animal or plant life or health. This provision empowers the government to prevent the patenting of inventions that pose a risk to public health or safety. Given that synthetic biology development often involves experimentation with potentially dangerous materials, obtaining patents in this field may be challenging. Patent law can also be useful in terms of allowing the country to have a way to keep track of the actors engaging in developing and procuring Synthetic Biology tech, therefore, it would be a good way to keep a record in case of any risks in the future.

e. Health Law

The Public Health Act (Cap 242) (PHA) is also a crucial national law instrument that can govern Synthetic Biology development in Kenya. It is an important piece of legislation in Kenya that provides for the protection and promotion of public health. While the PHA does not specifically mention Synthetic Biology, it contains provisions that may be relevant in regulating Synthetic Biology activities in Kenya.

The Act provides for the control of infectious diseases and outlines the measures that can be taken to prevent the spread of diseases. This can be used to regulate pathogen risks from Synthetic Biology by requiring researchers and innovators to adhere to specific health and safety guidelines when working with synthetic organisms.

Section 28 of the PHA provides for the mandatory notification of certain infectious diseases, presumably including those caused by Synthetic Biology-related pathogens as well.[148] This means that medical practitioners and laboratory personnel are required to notify the Director of Medical Services of any cases or suspected cases of Synthetic Biology-related infectious diseases. The Director of Medical Services can then take appropriate measures to control the spread of the disease, including quarantine and isolation of affected individuals and disinfection of contaminated materials or areas.

Section 35 of the Act provides for the power of the Minister of Health to make regulations for the prevention and control of infectious diseases.[149] The Minister can use this power to regulate the development, production, and handling of Synthetic Biology-related pathogens to ensure that they are safely contained and do not pose a threat to public health. The regulations can also specify the requirements for handling and disposing of Synthetic Biology-related materials and waste to prevent their release into the environment.

[148] Section 28, *Public Health Act* (Act No. CAP 242).

[149] Section 35, *Public Health Act* (Act No. CAP 242).

Furthermore, section 36 of the Act provides for the power of the Director of Medical Services to issue orders for the prevention and control of infectious diseases.[150] This power can be used to issue orders related to Synthetic Biology-related pathogens, such as orders to close down facilities that pose a risk of releasing or spreading Synthetic Biology-related pathogens, or orders to restrict the movement of individuals who have been exposed to Synthetic Biology-related pathogens.

f. Tort Law

Tort law in Kenya provides individuals with the right to seek compensation for harm suffered as a result of the actions of others. These laws are intended to provide redress to individuals who have suffered harm due to the negligence or intentional actions of others.[151] In the context of Synthetic Biology, tort law can be used to regulate the use and development of Synthetic Biology products and technologies. One way in which tort law can be used to regulate Synthetic Biology is through the imposition of liability for harm caused by the use or release of Synthetic Biology products. For example, if a company releases a Synthetic Biology product that causes harm to individuals or the environment, individuals may have the right to sue the company for damages.

Strict liability means that a person or company is liable for harm caused by their products even if they were not negligent. Strict liability is recognised in Kenya under the Sale of Goods Act (Cap 31), which provides that a seller of goods is liable for any harm caused by defects in the goods sold, regardless of whether the seller was at fault.[152] Strict liability under the Sale of Goods Act and other related legislation can be applied to regulate and govern Synthetic Biology development in Kenya, particularly in relation to the sale and distribution of synthetic products and materials that pose a risk of harm to individuals and the environment. For instance, in the case of synthetic organisms or viruses that are intentionally or accidentally released into the environment, the developers or sellers of such organisms could be held strictly liable for any harm caused to individuals or the environment. This would provide an incentive for developers and sellers to ensure that they take appropriate measures to minimise the risk of harm, such as implementing containment protocols and conducting risk

150 Section 36, *Public Health Act* (Act No. CAP 242).

151 Kamau C, 'A Brief Outline of Tort Law in Kenya, -< https://www.studocu.com/row/document/university-of-nairobi/law-of-tort/244653606-law-of-torts-in-kenya-the-university-of-nairobi/2414674 >- accessed on 15 February 2023.

152 *Sale of Goods Act* (Act No. CAP 31).

assessments prior to releasing such organisms into the environment.

However, one criticism of strict liability is that it may discourage innovation, as developers may be hesitant to pursue risky research and development projects for fear of liability. This could stifle the growth and development of Synthetic Biology in Kenya, which could ultimately limit the potential benefits that could be derived from such technologies.

To address this criticism, a possible solution would be to establish a regulatory framework that balances the need for safety and risk mitigation with the need to encourage innovation and growth in the Synthetic Biology industry. This could involve the establishment of regulatory bodies that work in collaboration with industry stakeholders to develop standards and guidelines for the development, sale, and distribution of synthetic products and materials. This would provide a clearer understanding of the risks involved and how they can be managed, while also providing a level of certainty for developers and sellers regarding their potential liability.

VII. Conclusion

In conclusion, the proper regulation of Synthetic Biology in a developing country like Kenya requires a holistic approach that considers various legal systems and laws. Considering that the creation of new laws is not always the most effective solution, amendments to the present ones can suffice for now. The potential risks associated with Synthetic Biology, such as accidental release of pathogens or deliberate misuse, cannot be addressed by a single legal system or law alone. The legal model that can best protect the country and promote beneficial bio-innovation is a complete one that draws on various legal systems and laws, such as tax law, criminal law, health law, intellectual property law and tort law.

By taking a comprehensive approach to regulating Synthetic Biology, Kenya can address the potential risks while also promoting beneficial bio-innovation. However, it is important to recognise the limitations and criticisms of each legal system and law. For example, the criminal law approach has been criticised for being reactive rather than proactive, and the patent law approach may result in exclusivity that limits access to beneficial innovations. Therefore, a balanced approach is needed that recognises the benefits and risks of Synthetic Biology and ensures that the legal framework promotes innovation while also safeguarding public health and safety. This requires ongoing collaboration among policymakers, scientists, legal experts and other stakeholders to ensure that the legal framework evolves to keep pace with technological developments and changing societal needs.

Synthetic Biology holds immense potential for Kenya to bridge the historically disadvantageous global political economy by providing opportunities for bio-innovation and economic growth. However, the double-edged sword perspective attributed to Syn-Bio and the pathogen risks associated with it pose significant challenges to its adoption. It is crucial to adopt a cautious approach that balances the risks and benefits of Syn-Bio and engages all stakeholders in developing a robust governance framework. By doing so, Kenya can harness the transformative potential of Syn-Bio while mitigating its potential risks.

In light of the immense potential of Synthetic Biology for developing countries like Kenya, it is absolutely essential to look at governing Syn-Bio from a legal perspective. A holistic legal model is crucial for balancing the pursuit of socio-economic benefits with the need to prevent pathogen release. By adopting such a model, Kenya can effectively manage the risks associated with Syn-Bio development, allowing for bio-innovation while protecting the country from potential pathogen risks. It is only through a robust legal framework that Kenya can navigate the complex terrain of Syn-Bio governance, creating a safe and enabling environment that fosters innovation and socio-economic growth. This study's findings unequivocally prove that the adoption of a comprehensive legal model is vital for Kenya to harness the transformative potential of Syn-Bio while mitigating its potential risks.