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Synthetic biology in focus: Policy issues and opportunities in engineering life

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Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life

Synthetic biology promises to revolutionise a swath of industrial activities and create new ones by tailoring living systems to produce a range of products to boost economies, transform health and contribute to solving grand societal challenges. In 2023 and 2024, over sixty experts from around the globe came together regularly to explore where synthetic biology will have the most impact, identify the challenges and opportunities in developing and deploying synthetic biology around the world, and to explore areas where policy could help. This working paper provides a synthesis of this scoping activity, providing an accessible text for those new to the rapidly evolving area of synthetic biology.

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Foreword

The OECD Global Forum on Technology (GFTech) fosters strategic dialogue and enables cooperation on topics at the forefront of the digital and technology policy debates. The Forum was launched in 2023 to foresee and get ahead of long-term opportunities and risks presented by technology. It facilitates inclusive, multi-stakeholder and values-based discussions on specific technology policy topics, responding to gaps in existing fora.

This document reports on the discussions carried out within the OECD Global Forum on Technology (GFTech) expert focus group on synthetic biology. Starting from November 2023, it brings together 66 experts from research, government, academia, non-governmental and industry backgrounds from 32 countries to share insights and provided evidence on the technical, social and policy issues facing synthetic biology. It aims to inform policymakers of the key areas where experts believe action could be taken to foster a strong bioeconomy, provide wide-ranging societal benefits, and mitigate potential risks. By engaging frontline researchers and private sector innovators in mapping technological futures and their transformative potential for society, it also aims to articulate the policy implications and potential role of the OECD according to the views of the focus group experts.

This report also leverages the intelligence gained in the GFTech event "*Building our Bio Future: Policy issues and opportunities for next generation biotechnologies*" which took place in 22 April on the margins of the OECD Scientific and Technological Policy Committee meeting at the Ministerial level in Paris. Panels in the event were based directly on the insights from the focus group meetings, and many focus group experts participated as either speakers or attendees to help shape the discussion.

The Secretariat wishes to thank the focus group experts for their invaluable contributions, both across 16 meetings between November 2023 and September 2024 as well as via written input and reviewing this report. They have contributed in their personal capacity, and their input does not necessarily represent the views or positions of the organisations with which they are affiliated. A full list of experts is provided in the Annex.

Executive Summary

Synthetic biology combines science, technology and engineering to harness living systems, or compounds derived from them, in research and development. The field has rapidly developed in recent decades, a pace being further accelerated by its convergence with artificial intelligence, automation and robotics.

To this end, the OECD Global Forum on Technology initiated a synthetic biology expert focus group to landscape recent developments in synthetic biology around the globe, take a forward-look at emerging synthetic biology technology trends and where they will impact, articulate the main policy and governance challenges in the area and identify key policy issues of concern that could be further explored in future work.

Whilst synthetic biology has the potential to transform many sectors, the expert group identified **five high impacts areas** that could lead to transformative change in the economy and in society. These high impacts areas comprise of: human health and life sciences (e.g. with developments of personalised cell and gene therapies), food security and soil regeneration (e.g. improving crops' nutritional profile), circularity and emissions reduction (e.g. enabling bio-based products), synthetic biology convergence with AI and automation (e.g. accelerating pace of research), and decentralised and distributed manufacturing (e.g. shifting to localised production for sustainability and resilience).

Cutting across these application areas, experts discerned **five policy and governance themes** where major issues and opportunities arise with the advancement of synthetic biology towards a flourishing and inclusive ecosystem. These themes include: strong and resilient innovation ecosystems (e.g. financing, infrastructure and scaling technology), skills and workforce development (e.g. developing fit-for-purpose training programs), equity and access (e.g. tackling divides between advanced and developing economies), biosecurity and biosafety (e.g. promoting a culture of responsibility), and anticipatory governance and responsible innovation (e.g. the right tools for governance and two-way public engagement).

Laying out the state of play in the field - in terms of opportunities, challenges and knowledge gaps - generated implications for policy future work. These were framed using the foundational and technology-specific values identified in the OECD Framework for Anticipatory Governance of Emerging Technologies. For example, experts highlighted the use of agile and anticipatory governance for balancing innovation promotion and risk mitigation, as well as carrying out forward-looking technology assessments to understand the plausibility and impacts of different synthetic biology futures. They also suggested exploring novel public and private approaches to investment market reform to finance the scale of the transition to bioeconomies, or how regulatory capacity could be increased and made fit-for-purpose to match the pace of technological innovation.

Experts saw an active role for the OECD in addressing some of these implications, leveraging its global reputation and expertise. These included:

- **Recommendation for the responsible development of synthetic biology**: An official recommendation for the responsible development of synthetic biology, is seen by the expert group as necessary to enshrine political commitments and as an international standard to guide policymakers, researchers and civil society pursuing a responsible path for synthetic biology innovation.
- **Share best practices on technology appraisal for governance:** Supporting the Recommendation, the focus group suggested creating a dedicated space to convene stakeholders for sharing approaches to technology appraisal for governance (in line with the OECD Framework for Anticipatory Governance of Emerging Technologies). This includes, societal engagement, technology assessment, emerging risk assessment and impact assessment. Sharing of best practices in this area was seen as a key role that the OECD could play.
- **Support global bioeconomic growth through inclusive conversations with diverse stakeholders, including smaller or developing economies**. Focus group experts appreciated the diversity of country experiences shared in the focus group meetings, which opened many issues on how synthetic biology raises opportunities and challenges in different ways depending on national context. The group encouraged a continuation of an OECD forum that supports a diversity of country perspectives to support knowledge exchange and development.
- **Advanced Indicators:** The OECD's economic and statistical expertise could be used to develop indicators and evaluation methods for synthetic biology technologies and associated policies.
- **Holistic and innovative financing of synthetic biology and the bioeconomy:** Experts proposed that the OECD could bring together evidence on novel finance approaches by both public and private actors along the innovation journey, from fundamental research through scaling to diffusion into the market. Such an activity could provide guidance to policymakers to shape national policies and to identify where policy levers may be mobilised to support current financing challenges in the development and scaling of synthetic biology solutions.
- **Anticipate on the convergence of synthetic biology with artificial intelligence, automation and robotics:** Highlighting that the future development and diffusion of synthetic biology will be catalysed by further convergence with artificial intelligence, automation and robotics, the OECD could support the analysis of governance and innovation policies and inform these policies by anticipating on such convergence through forward-looking technology assessment.

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1 Introduction

Though there is no uniform global definition for synthetic biology, it is understood as a multidisciplinary area of biotechnology that seeks to harness living systems, or compounds derived from them, in research and product development. It combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and other biological systems. With a focus on recoding genetic sequences, the promise of synthetic biology is to engineer living systems in a controlled and increasingly predictable way.[1]

The last two decades have witnessed the rapid development of the field, in part thanks to foundational advances like the millionfold drop in the cost of sequencing DNA, a thousand-fold drop in the cost of synthesising DNA, and the development of CRISPR genome editing. Enhanced speed and predictability due to the rapid rise of artificial intelligence (AI) and other digital technologies, and their convergence with synthetic biology, is accelerating these transformational advancements.

Synthetic biology is already providing practical breakthrough innovations, for example, advanced research on treating genetic disorders, cancer or infectious diseases (e.g. personalized gene therapies for sickle cell disease), addressing food shortages (e.g. enabling alternative protein sources such as plant-based meats), mitigating the causes and impacts of climate change (e.g. production of more sustainable biofuels), and enabling more sustainable and distributed manufacturing (e.g. using renewable bio-based feedstocks instead of fossil-based feedstocks).

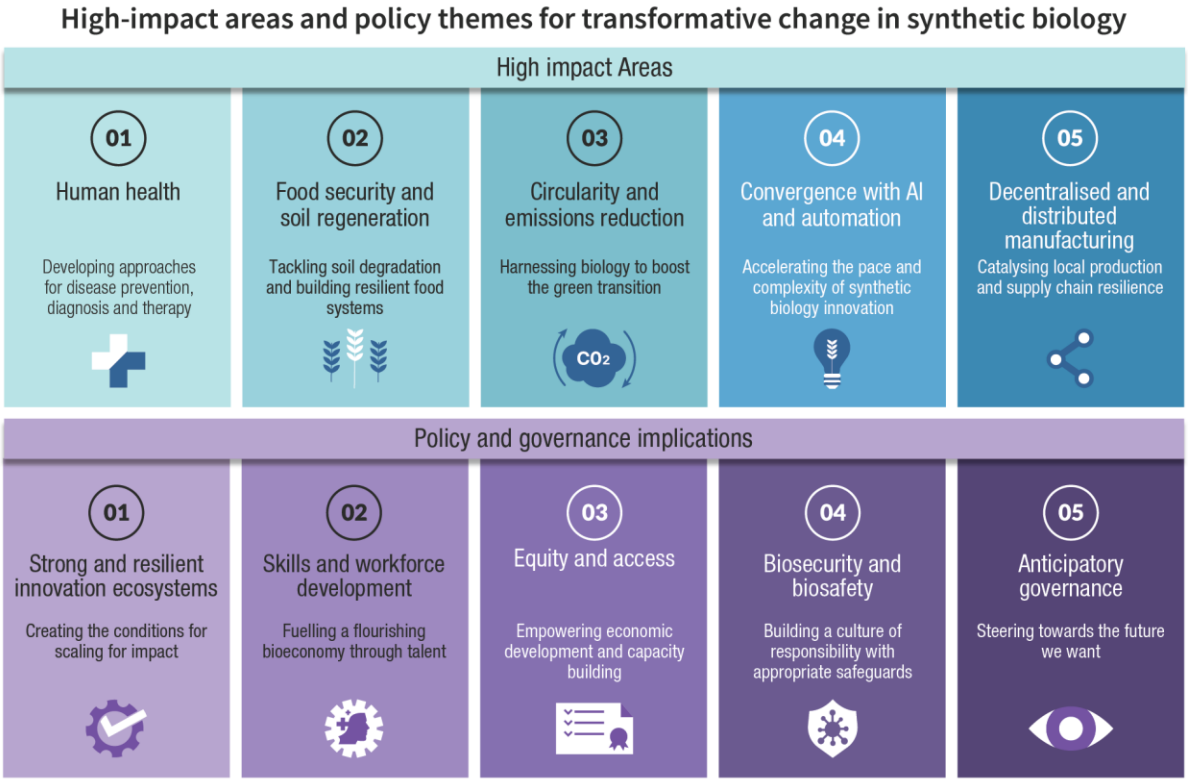
Countries around the world are rapidly ramping up their biotechnology capabilities to make the most of these promises. For example, the United States signed the '*Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*'[2] and the *'Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence'*, in 2022 and 2023 respectively, and the United Kingdom set out their '*National vision for engineering biology*'[3] in 2023. In 2024, the European Union published their '*Communication on Building the future with nature: Boosting biotechnology and biomanufacturing in the EU*'[4]; Japan updated their national '*Bioeconomy Strategy*'[5]; and Australia produced a progress report on their '*National Synthetic Biology Roadmap*'[6]. These strategies set the vision for advancing the strategic sector, identifying the challenges it faces and setting out actions to tackle them, from training to building value chains to investment.

However, policy challenges remain - building strong innovation ecosystems, and the skilled workforce to go with it, is a key challenge. Other challenges include appropriate and timely financing to scale innovation, bridging equity and access divides across the globe, balancing open science with biosecurity and biosafety considerations, and fostering responsible innovation and governance.

This report provides a synthesis of the Secretariat's engagement with the OECD Global Forum on Technology synthetic biology expert focus group, seeking to unpack the key policy implications and identify potential opportunities for future OECD work. It is structured as follows:

- **What is on the horizon: technology projections and anticipated high-impact areas** – This section summarises the focus group experts' expectations on where synthetic biology technologies are heading in the short, medium and long term, and unpacks the most promising tools, products and innovations. Five key areas were identified by the focus group where synthetic biology could have the most transformative impact.
- **Key policy and governance themes** – The expert focus group identified five key policy areas considered to enable synthetic biology to flourish and to provide widespread benefits to society, whilst mitigating the risk of negative impacts.
- **Implications for policy and future work** – Based on the previous sections, the Secretariat mapped where further research and policy action could be useful.
- **Outlook** – Based on these gaps and needs, and the views of the focus group experts, the Secretariat identified a number of potential future activities where the OECD could play a major role.

Figure 1.1. High-impact areas and policy themes for transformative change in synthetic biology



Source: OECD.

2 What is on the horizon: technology projections and anticipated high impact areas

Anticipating future technological developments and their impact is critical to fostering responsible, value-led innovation**.** Foresight activities like technology forecasting and horizon scanning can map these expectations to help fill the knowledge gap and better prepare for future developments. To this end, focus groups experts - many of which are frontline scientists and innovators – were asked to share what technology advancements they expected in the short (1-5 years), medium (5-10 years), and long term (10+ years), as well as the accompanying risks and challenges. This chapter presents a summary of these insights.

Foreseen foundational advances in enabling technology that could foster research and innovation across sectors are explored first, before delving into developments in five key areas identified by the focus group where synthetic biology could have the most transformational impact. More in-depth results of this technology forecasting exercise can be found in Annex B.

In the short term (within the next 5 years), **next-generation genome editing tools** that are more accurate, efficient, and versatile could enable precise modifications at multiple genomic sites simultaneously, facilitating complex genetic reprogramming for new therapeutics or creating engineered microorganisms with new capabilities whilst reducing errors. **Practical advances in fermentation and scale up technologies -** such as continuous fermentation, improvements in media formulation and downstream processing, in part enabled by AI analysis of big data sets and its predictive powers - could help reduce the overall cost of bio-based products and support translating innovations from the laboratory to market.

In the medium term (5-10 years), further **reduction of DNA synthesis costs** could improve accessibility of this technology and speed up the research process, which is currently a major bottleneck for innovators in developing countries. **Cellular biosensors** – cells engineered to detect and respond to target molecules - could enable real-time monitoring of compounds in production processes and in the environment in a cost-effective and highly sensitive manner. **Improved biocontainment methods**, which limit survival of genetically modified organisms (GMOs) outside the lab, could improve biosafety measures, reduce unintended consequences of environmental release and thus potentially provide safer organisms. **Engineered living materials** – fully or partially composed of cells or whole organisms - could provide new properties in sectors as diverse as packaging, fashion and construction.

In the long term (10+ years), advanced capabilities in **designing new genomes** could enable the bottom-up construction of **synthetic cells** and even novel synthetic organisms. This has long been a “moonshot” of the synthetic biology field, as it would represent a massive advancement in foundational knowledge and lead to applications across all sectors. A new era of **biological information storage**,

encoded in synthetic DNA molecules, could provide a more sustainable alternative to contemporary storage methods which require a lot of energy. The rise of **synthetic biology as a General Platform Technology** could have as drastic an impact on society as the digital revolution.

Whilst these selected examples (see annex B for more details) showcase the broad range of future innovations that could advance fundamental research and cross-sector applications, focus group experts expected new advances in **synthetic biology to impact certain fields to a greater extent and speed than others, given a longer history of biotechnology innovation in key sectors** (e.g. health and agriculture) **or alignment with other political priorities** (e.g. sustainability and circularity, AI and digital technologies). Technological developments and their impact in key fields are discussed below.

Human health

Growing health concerns (e.g. ageing populations, rare diseases, increasing cancer rates, epidemics…) **and health expenditures** (at a time of tighter national budgets) **call for innovative solutions to help ensure the health and wellbeing of populations.** Synthetic biology promises to be part of the solution, as it offers new approaches to tackle diseases, improve diagnostics and preventative medicine, and revolutionise service delivery. This was most widely exemplified by the COVID-19 pandemic, which shed light on the foundational societal consequences of health disruptions as well as the potential of synthetic biology advances like mRNA vaccines to tackle them.

Advances like **personalized cell and gene therapies**, which modify or deactivate a patient's genes to treat the underlying cause of a disease or condition, are already being used to tackle cancer, autoimmune and rare diseases. For example, the European Medicines Agency recently approved a cell-based gene therapy to edit a patient's blood stem cells as a one-off treatment for sickle cell disease (European Medicines Agency, 2023[1]), and the UK's Prokarium have developed whole bacteria based immunotherapies. In the future, personalised cell and gene therapies are expected to become more advanced whilst also cheaper and thus more readily available. **New methods to deliver therapeutic agents** - such as bacteria that are engineered to deliver drugs directly to tumour cells - could enhance the precision and safety of treatments, reducing side effects associated with traditional therapies.

Engineered cells could also be used to **improve production of active pharmaceutical ingredients and biological drugs** - such as enzymes or antibodies - taking advantage of industrial biotechnology knowledge in process engineering and scalability. Similarly beneficial could be leveraging the potential of distributed manufacturing to develop vaccines and other therapeutics locally but connected to global design and development capabilities. These **mobile drug labs –** if associated with trained personnel and following current Good Manufacturing Practices - could be a financially attractive alternative to centralised production of certain ingredients or to improve response speed during health emergencies like pandemics (Kitney, Bell and Philp, 2021[2]).

More long-term innovations could include **3D organ bioprinting or xenotransplantation** (using genetically engineered animals to grow human-compatible organs) that could revolutionise regenerative medicine and help address the critical organ shortages in healthcare, as well as **microbiome engineering** (the microbes living on and inside our bodies) to treat gut, skin and dental diseases. In diagnostics, the use of **biosensors** (engineered cells or protein-based sensing systems that can detect biomolecules like disease markers or agents like viruses) could offer quick and accurate detections of diseases and pathogens. This promising future is being **further accelerated by applications of AI**,

which could leverage the wealth of available health data to speed up understanding of biological systems and use its predictive powers to improve the design and production of new therapies.

Due to the vital importance of health to society, the field is well-funded with established pathways to market, which facilitates the pace of innovation. However, **several bottlenecks remain which hinder the diffusion** of these technologies. **Regulatory barriers** such as uncertain classifications of novel approaches and the large clinical trials needed to demonstrate their safety and efficacy can render the approval process lengthy and costly, restricting the return on investment which can already be limited for some applications. Robust and realistic assessments for healthcare applications, such as Health Technology Assessments, were identified as crucial (Kagermann and Süssenguth, 2024[3]).

Scaling is also key as new therapies are mainly initially developed by academic labs which need to move past the proof-of-concept stage to be translated to industry. Approaches like the France 2030 Investment Plan were shared as best practices: they support an academic network of facilities by providing industrial competencies to test the feasibility of industrializing new treatments or production technologies. In the field of rare disease treatments specifically (e.g. gene and cell therapy), the limited affected population within a single country makes reaching international scale for distribution key to economic viability. Moreover, engineering in more complex animal systems presents challenges in terms of longer delivery timeframes and more limited engineerability compared to working with microbial systems.

Affordability is important for all health applications to facilitate equitable access when privately purchased and to reduce government expenditures when publicly financed. This is a major challenge for personalized therapies which can be particularly expensive (the current cost of millions of euros per patient is not sustainable nor accessible to all populations). Whilst further technological advancements may reduce the cost (Ledford, 2023[4]), experts argued it may also require public reform of clinical trial frameworks and advanced medical therapies regulation (always keeping patient safety as a top priority) coupled with efforts by pharmaceutical companies to improve their R&D spending. Lastly, technological diffusion relies on **public engagement and resolving ethical concerns**, and whilst synthetic biology applications may be more readily accepted in human health than in other sectors, some applications (e.g. transplantation of organs produced by mammals) may require additional engagement and ethical debates to advance.

Box 2.1. Example box: gene drives for malaria

Malaria is a major health issue in many tropical regions, particularly in sub-Saharan Africa, where millions of lives are lost annually to the disease. One proposed approach to limit malaria transmission is **synthetic gene drives.** These are genetically engineered mosquitoes that when released into the environment mate with wild populations and spread genetic traits that bias future mosquito populations towards males (which do not bite and transmit malaria) or reduce female fertility (decreasing mosquito populations and interrupting malaria transmission). Although they have not been used in the field yet, it is theorized that their use - in conjunction with traditional methods like mosquito nets – could significantly reduce disease incidence and potentially eradicate the disease.

Despite its promise, it has been difficult to move this technology outside of the lab for several reasons. Experts were divided in whether existing regulatory frameworks could guide robust risk assessment or whether additional guidelines and testing data would be needed. Regardless, since national authorities are ultimately responsible for approving and researching these technologies, countries would need to build the necessary capacity to assess, develop, and potentially use gene drives. This is particularly

complex given that modified mosquitoes can cross country borders, and thus consensus and international cooperation (e.g. in technology transfer and regulations) were identified as essential to move towards implementation. Public hesitance is another key factor, which calls for further engagement of relevant stakeholders from the onset to understand and address their concerns.

Food security and soil regeneration

With a growing world population, the combined effects of unsustainable agricultural practices, changing weather patterns, and climate change are presenting challenges for food security and soil health at the global level. Food shortages are due to armed conflicts, climate shocks and soaring fertilizer costs (World Food Programme, 2024[5]), and further exacerbated by the loss of biodiversity in pollinators and the **global degradation of soil health**. Synthetic biology advances in engineering crops and microbial communities could provide much needed solutions.

Crops could be genetically engineered to have new traits - such as enhanced photosynthetic yield, resilience to insect pests, pathogen-resistance and longer shelf lives, among others – to **improve agricultural production efficiency** and help meet the demands of a growing human population. Genetic engineering can potentially be used to **improve crops' nutritional profiles and lower their environmental impact**. As agriculture is particularly vulnerable to disruptions in temperature and weather patterns, genetic engineering to induce new traits – such as improved resistance to drought, better nutrient uptake and self-repair - could **enhance resilience and climate adaptation**, although this is still a matter of research and development[7]. Combined with AI and automated systems**,** these advances could further empower **precision agriculture** to help farmers sustainably optimize their agricultural production. Application of genetically engineered microorganisms and their products can act as **soil fertilizer, biopesticides, bioherbicides and engineered probiotics**. Food security could also potentially be improved by advancing sustainable and nutritious proteins with decreased carbon, land and water footprints (such as plant-based proteins, cell-cultured meat, or methods to reduce the environmental impact of animal protein production).

Soil engineering applications could also contribute to tackling the global degradation of soil health that is reducing soil fertility and productivity in addition to increasing the likelihood of floods. For example, plant and microbial communities' metabolic pathways could be **bioengineered to improve availability of nutrients in the soil**, such as nitrogen[8]. **Biosensors** could provide real-time monitoring of targeted environmental compounds, such as pollutants and heavy metals, and allow for early detection of environmental issues. **Bioremediation**, an established field that uses microorganisms to degrade contaminants, could be empowered by engineered microorganisms with enhanced capabilities to degrade pollutants, facilitating the clean-up of contaminated soil and water.

Yet many of these agricultural applications inherently involve the environmental release of genetically modified organisms, a topic that has been addressed in the four decades of using GMOs for agricultural and industrial purposes, with a focus on ensuring adequate **biosafety and responsible deployment**. Focus group experts drew attention to potential unintended risks of releasing genetically engineered microorganisms (such as those potentially impacting ecosystems or spreading genetic material encoding antibiotic resistance traits) and noted the value of **environmental risk assessments in regulatory biosafety frameworks**. It was noted that current regulatory approaches are non-uniform, as national jurisdictions have differing regulatory mandates and contexts, which may hinder deploying synthetic biology applications between countries and stifle translation of applications from the lab to the field. Multiple international bodies provide guidance on the regulation of GMOs[9], and any additional

work undertaken to review current policy frameworks and identify best practices to enhance science-based risk management approaches should be non-duplicative to these efforts. In addition, experts suggested more funding for foundational biosafety research (e.g. promoting technical advances in biocontainment strategies) could be beneficial.

Another key barrier to implementation is **public hesitance and ethical concerns** about the use of GMOs. Since the introduction of recombinant DNA technology in the 1970s, some stakeholders (e.g. scientists, environmental protection agencies, nature protection institutions and public advocacy groups) have cautioned against possible unintended consequences of genetically engineered foods, including potential environmental impacts or claims they could negatively affect human health, calling for further research or outright bans. One of the most recent examples is 'golden rice', a genetically modified fortified crop whose commercial propagation was rescinded in the Philippines following lobbying efforts by these groups (despite the lack of scientific evidence of any risk associated)[10]. To date, no genetically engineered product intended for consumer use has been demonstrated to negatively impact human, animal, or environmental health. In contrast, the use of genetically engineered crops has enabled no-till agriculture approaches and reducing greenhouse gas emissions; reduced insecticide applications; increased crop productivity by increasing drought-, heat-, and flood-resilience; saved crops from extinction (e.g. Hawaiian papaya).

Focus group experts suggest **two-way engagement efforts with the public from early research stages** could help scientists better understand these groups' position, whilst at the same time provide a venue for fact-based evidence sharing. They emphasized that **exchange** between research scientists and stakeholders (including citizens) would be mutually beneficial. However, there was agreement that this has to be done correctly, encouraging **transparent and open discussions**, being aware of biases. In this way, a productive exchange of perspectives could lead to trust building. This topic is further unpacked in section *5.3 Public engagement*.

Box 2.2. Open issue from the focus group: fostering agricultural innovation for good

A recurring discussion in the focus group centred on understanding that whilst synthetic biology has the potential to provide much needed sustainable solutions, it can also be used to maintain unsustainable practices. For example, in food production and soil health, some experts argued that farmers could use synthetic biology solutions to increase crop efficiency and enable models centred on monocultures and excessive use of chemicals. These practices have negative effects on biodiversity and the environment, and farmers could consider alternatives: integrated farming, fertilizer and pest management strategies.

Some experts also called attention to potentially unfair economic scenarios, particularly for small-scale farmers, around synthetic biology products. Given the increasing number of patented genetically engineered plants or synthetic biology-enabled breeding technologies and the high costs of putting new products through regulatory processes, small has the potential to effectively reserve the ability to bring products into the market to larger and wealthier companies - in fact, four firms are already responsible for the majority of crop seed and agricultural chemical sales (U.S. Department of Agriculture, 2023[6]) – and could call for supporting competition from small-scale famer innovators[11].

Despite this, most focus group experts believed positive applications (such as those detailed in this chapter) could outweigh the negatives - as long as good technology governance is implemented. They therefore highlighted the importance of considering the societal implications of synthetic biology developments, active engagement to realise positive visions of the future, and promoting equitable access to the technology and its benefits.

Circularity and emissions reduction

Greenhouse gas emissions are recognised as the key driver of climate change that is disrupting the world's weather patterns and leading to extreme temperatures, higher risk of natural disasters like floods and droughts, and putting the lives and livelihoods of millions at risk. The **shift towards a more sustainable, carbon neutral economy is one of the biggest international political priorities**, as well as **a key driver for building bioeconomies** that leverage synthetic biology-based advanced to reduce emissions and foster circularity.

Engineered microorganisms can utilize biological materials instead of fossil resources to produce feedstocks (the raw material being used as input into an industrial process) for **bio-based products**: reducing dependence on fossil resources, decreasing carbon emissions, and creating products that are easier to dispose of and recycle. In more closed-loop circular systems, they can also **convert agricultural, industry or municipal waste (including gases) into valuable feedstocks**, with microbes being less sensitive to certain contaminants or fluctuations in gas composition and being able to generate more complex molecules than chemical catalysts. LanzaTech offers a promising example, using microbial gas fermentation technology to produce platform chemicals from industrial waste gases. These approaches can help defossilize carbon heavy industries and reduce carbon emissions. **Biofuels** are rapidly developing for applications in the aviation and maritime transport sectors, with innovations currently undergoing the scale-up phase and approaching market readiness (TOPSOE, 2024[7])[12].

Meeting climate targets will not only require a rapid reduction in greenhouse gas emissions, but also a **massive scale up of efforts in carbon dioxide removal (CDR) from the atmosphere** to offset hard-to-eliminate emissions and recover from any overshoot in safe CO_2 concentrations (Smith, 2024[8]). **Biological fixation of CO2 from the atmosphere** (known as Bioenergy with Carbon Capture and Storage, or BECCS) is already naturally achieved by photosynthesis and currently being leveraged through **reforestation and afforestation** efforts. However, synthetic biology could improve or replace the natural photosynthesis process with new-to-nature pathways for carbon sequestration (Luo et al., 2023[9]). These solutions are technically challenging and still in their infancy, but micro and macroalgae are a promising vehicle for relatively rapid delivery of scalable technology in this space[13]. The **sequestered carbon could then be locked long-term into inert materials** (e.g. rocks, released to the bottom of oceans) **or valorized** into products like building materials for a carbon-negative economy.

Plastic pollution is a major environmental concern, but the rise of **enzyme-powered decomposition and re-use of plastics**, as well as growing **biodegradable plastics and materials** produced by microorganisms, show promising results. Examples include Japan's Kaneka Corporation, which has developed a microorganism-produced biodegradable plastic polymer using plant oil as raw material, or Australia's Samsara Eco, which uses engineered plastic degrading enzymes for recycling by breaking plastics down into their constituent monomers. The **circulation of various elements beyond carbon (e.g. nitrogen, phosphorus, rare metals…)** is also extremely important and where synthetic biology could make a big contribution. Engineered organisms could improve nitrogen fixation from the air or recover phosphorus from the water. Solutions like phytomining (using genetically engineered plants to accumulate heavy metals from the soil to be harvested) or biomining (using genetically engineered organisms to recover rare earth metals from waste) have potential to address broader issues of national security, economics and resilient supply chains.

Fostering sustainable technologies

The aforementioned technologies are at different stages of maturity and **further information is needed to assess their socioeconomic and sustainability values.** Starting points for this process could involve **cost-benefit assessments** (e.g. technoeconomic analyses), which could identify financially viable target technologies and key cost drivers for processes, whilst **environmental impact analyses** (e.g. life cycle analyses), which could improve understanding of these technologies' long-term implications for sustainability. For example, governments planning to develop a circular bioeconomy might find it useful to know whether synthetic biology-enabled waste-derived feedstocks would be able to fully meet demand[14] or whether land would still be needed to, for example, grow crops for biofuels. In addition, these analyses would provide a holistic view of how synthetic biology-based solutions fit into the broader landscape of sustainable solutions, like green chemistry and renewable energy sources.

Box 2.3. Open issue from the focus group: Barriers for bio-based solutions versus incumbent fossil-fuel based approaches

Focus group experts argued that an **enabling policy environment is currently not in place to foster synthetic biology sustainable technologies,** with a perceived general lack of understanding in the policy community as to their potential and how they could be deployed to support local communities while meeting net zero targets. For example, steel plants' waste gas is not eligible for incentives under the U.S. Renewable Fuel Standard program, hindering the rapid scaling and deployment of technologies for gas fermentation. One focus group member pointed out that some governments subsidise carbon capture and storage (CCS) projects, but not carbon capture and use, which is the basis of much of the bioeconomy. The result is that companies producing carbon dioxide as a waste material are favouring CCS initiatives instead of more circular initiatives.

Furthermore, focus group experts pointed out that **fossil fuels are still heavily subsidised** via tax breaks and write-offs, whilst already benefitting from more established infrastructure. This stacks the odds against bioeconomy approaches, including synthetic biology, that are currently more expensive than petrochemical incumbents but could provide benefits in the long run - essentially, emerging technologies like synthetic biology are not competing on a level playing field. Nonetheless, experts advocated against antagonising incumbents and instead encourage the exploration of a synergistic approach that enables a productive transition towards sustainable and climate positive solutions.

Policy levers could help advance sustainable technologies with proven economic and environmental viability, addressing the status quo which favours solutions with the cheapest cost and maximum profit regardless of environmental consequences. Experts' main suggestion was for a **policies that support accounting for the true costs of externalities (including carbon)**. Re-visiting tax subsidies for polluting industries in response to sustainability imperatives could help accelerate delivery of climate-positive alternative solutions - potentially enabled by synthetic biology - in the timeframes required to stabilise the climate. Other potential policy levers suggested include:

- **Target-based policies** encouraging or requiring a certain percentage of production at regional or national levels to be sustainable (e.g. bio-based), which could provide more certainty to investors and promote a staged approach to phasing out fossil fuel-based production whilst phasing in sustainable production methods like biomanufacturing. For example, the UK government has established a Sustainable Aviation Fuel mandate calling for it to comprise 22%

of UK jet fuel demand by 2024[15]. However, some experts contest these requirements as burdensome and the success of such policies remains to be confirmed.

- Developing national or regional **strategic plans for replacement** of carbon-intensive and polluting production processes with more sustainable approaches, such as synthetic biology-enabled biomanufacturing. This could prioritise sectors where sustainable technologies are already viable and could identify which strategic technologies would need to be developed to make additional sectors more sustainable.
- **Public procurement** could help establish strategic chemical reserves of bio-based production and support a staged transition approach[16]. **Tax and trade incentives** can also support hard-to-decarbonise sectors in finding uses for and circularise their waste. However, these solutions would need to consider the public's perspectives on tax money seeming to benefit industry, and how they compare to policies that, for example, prohibit fossil fuel-based production and force companies to innovate.
- **Import and export controls** were identified as enabling (and constraining) policies. However, it was agreed that such policies cannot be developed in isolation but as part of a coherent policy mix.

Box 2.4. Open issue from the focus group: target-based policies

Focus group experts debated the value of **target-based policies**, such as France's 2022 guidelines calling for 50% of building materials in public buildings to be bio-based[17] or Japan's 2019 Resource Circulation Strategy for Plastics aiming to introduce 2 million tons of bio-based plastics by 2030[18]. Some supported these efforts, citing a US annual bio-based industry analysis which found that 74% of company respondents supported quantifying their products' carbon intensity, and 82% supported a single, standardized label to foster greening efforts (Golden et al., 2024[10]). However, others brought up that target-based policies could set challenging and/or unreasonable targets that when subsequently not met could result in disillusionment and cynicism. As these types of policies are increasingly being deployed by actors across the world, experts believed **further research to clarify the extent to which such policies incentivise desirable innovation** would be useful, especially vis a vis other policies.

Overall, focus group experts saw the emergence of synthetic biology and its widespread potential impact as an **opportunity to reflect on how society can do better** in the face of major societal challenges such as climate change, instead of continuing the same systems with different building blocks. This could include transitioning from mass production to more conscious consumption, or from limiting environmental impact to sustainable coexistence with nature. Enacting widespread transformation would likely necessitate **systems thinking**: connecting the dots on how synthetic biology could affect different sectors and how diverse policies interact in governance structures.[19]

Box 2.5. Open issue from the focus group: technology agnosticism

A key nuance raised by focus group experts was that the shift to green economies does not necessarily imply a full transition to bio-based societies. Whilst synthetic biology may provide more sustainable alternatives to existing products and processes, as well as completely new ones, some fossil fuel-derived activities may still be needed until a viable substitute is found (and hence the need for negative emission technologies). Similarly, green chemistry solutions are also rapidly being developed to eliminate the use of hazardous and polluting chemicals in manufacturing processes. Some experts thus point to the value of remaining technology agnostic when seeking solutions to societal problems and being open to implementing a range of technologies based on each's unique advantages.

Synthetic biology convergence with AI and automation

Synthetic biology's redesigning of natural biological systems has traditionally required extensive time, high costs, and complex trial-and-error processes. With **recent advances in lab automation, high-throughput DNA synthesis/sequencing,** and now the **use of AI tools like machine learning and large language models, the pace of innovation can be significantly accelerated**. By leveraging AI's predictive powers, it can streamline and even automate the design-build-test-learn (DBTL) cycle, shifting to a design-build-work (DBW) model and driving down costs.

Using AI tools on increasingly available large biological datasets could **enhance our design capabilities**. Scientists could better elucidate biological processes and identify the patterns and design principles of biological systems. This AI-based generative design could enable the modification of known proteins with improved functionalities, completely new proteins that have never existed in nature, and the building of new metabolic pathways to produce chemicals of interest. For example, in medical applications, AI may be used to design therapies matched to individuals' genetic profiles (i.e. personalized medicine).

Given the broad range of AI applications, experts highlight the importance of **distinguishing AI and digital applications in general-purpose technology and in specialized biological design tools** when developing policies. Each comes with unique opportunities and challenges, and targeted approaches to each would be more efficient.

Dual use risks

AI tools like large language models, machine learning and biodesign tools could lower the barriers to entry to synthetic biology - the obstacles that new users need to overcome to participate in a field, such as specialised knowledge, techniques or tools. They can do so by increasing access to information and support in designing protocols, analysis, and methods (although conversely, niche expertise required to operate these tools or appropriately troubleshoot protocols and methods could present another barrier to entry). On one hand, this can positively support less experienced companies in exploring bio-based production without the need for significant and costly expert contribution, or support existing experts in rapidly troubleshooting difficult processes. However, it can also empower nefarious actors to develop bioweapons (e.g. by accelerating development of toxins or increasing pathogen virulence) and thus increase biosecurity risks - or accidentally by well-intentioned actors if proper precautions are not taken. As the research and commercial communities increasingly produce

and leverage biological data, to include human genomic and other -omic data, the risk of data misuse aided by AI tools will also increase, with significant implications for individuals and for biosecurity more broadly.

For example, generative AI and advanced design tools could be used to create new harmful sequences to evade current screenings that rely on homology to known threats. The risk compared to solely using existing tools like the internet is debated (Mouton, Lucas and Guest, 2024[11]) and practical barriers to turning sequences into bioweapons remain, such as developing the vectors. Nonetheless, international efforts to monitor associated security risks and developing mitigation strategies (like safeguards built into models and access control) are already underway. One such effort is **DNA synthesis screening**, which can help ensure that potentially harmful sequences (e.g. used to make toxins, reconstitute pathogenic organisms, or endow/enhance pathogenic traits upon an organism) are not accessible to potentially nefarious actors. Several public and private measures are being taken to expand this practice.

Box 2.6. Example box: DNA synthesis screening policies

The focus group shared examples of how countries and organisations were approaching DNA synthesis screening methods to illustrate how different actions were taking place at different levels:

- In October 2024, the United States government established requirements that researchers receiving federal funds can only use these to purchase synthetic nucleic acids of any type – or benchtop devices capable of producing them - from providers that attest to following a set of best practices in screening sequences and customers.[20]
- The Australia Group's Common Control Lists identify dual-use materials and technologies to inform trade controls with the aim of hindering the spread of chemical and biological weapons. They can form the basis for identifying sequences for which DNA synthesis providers should screen.[21]
- The independent International Biosecurity and Biosafety Initiative for Science (IBBIS) is developing a free, open-source tool for companies screening DNA and RNA sequences, as well as resources to support in customer screening.[22]
- The International Gene Synthesis Consortium is an industry-led group representing a majority of gene synthesis companies worldwide, formed to design and implement a common standard for the screening of both gene synthesis orders and customers.

The growing interaction between biology and automation is also increasing the importance of cyberbiosecurity. Ransomware or DDoS[23] attacks in biological facilities could have economic consequences (e.g. delays, industrial espionage, etc.), environmental impacts (e.g. explosions, release of toxic substances) and human health issues (e.g. release of infectious agents). Yet much of the infrastructure for biological research and biomanufacturing has not been developed for resilience against these cyber-attacks, other than standard cybersecurity practices in facilities that are part of larger institutions like universities. This can particularly impact under-resourced communities, which often make use of secondary markets that are more likely to trade older equipment with outdated software. Under-resourced communities work on diverse specimens and focus group experts suggest further discussions on oversight and control mechanisms would help better map the issue and identify possible solutions.

Ethical guidelines, safety protocols and standards are being developed at an international level to govern AI in synthetic biology, providing regulatory clarity and promoting partnerships for sharing data and best practices. Experts suggest further research into the specific policy opportunities and challenges of AI use in synthetic biology[24], which could be **informed by regular horizon scanning of applications and their potential impact** to help actors keep pace with technological advancements, highlighting positive initiatives like the 2023 Nuclear Threat Initiative's report[25].

Box 2.7. Open issue from the focus group: biodata and intellectual property

Biodata is key to train AI-based models and tools, but opaque datasets and tools (both with regards to how the algorithms work but also how end-users are using the tool) carry concerns. Focus group experts drew attention to the **risk of monopolies on biodata dictating accessibility and thus the direction of research**. Although they acknowledged that many large biological datasets are currently public and generally follow FAIR principles (Findability, Accessibility, Interoperability, and Reusability), they called for further research on clearly defined biodata sharing mechanisms, including monetary and non-monetary benefit sharing (e.g. data pooling and commons) that encourage access to drive innovation whilst preventing its use by nefarious actors. They pointed to learning lessons from the discussions in other international fora, such as the Convention on Biology Diversity on Digital Sequence Information (DSI) on genetic resources; the World Health Organisation's international instrument on pandemic prevention, preparedness and response; and the World Intellectual Property Organisation's international legal instrument on intellectual property, genetic resources and traditional knowledge associated with genetic resources; and the OECD Recommendation on Human Biobanks and Genetic Research Databases.

This ties to open questions about how **contemporary IP rules and the associated innovation incentives and the associated innovation incentives will apply in the context of AI's novel capabilities**. For example, there may be disagreement about who would own a protein sequence developed by generative AI, or whether such a sqaurence would be patentable and under what circumstances, which could in turn impact how it could be used for basic research or commercialisation. Addressing these issues is seen as key to leverage the power of AI for synthetic biology.

Decentralised and distributed manufacturing

Current global supply chains are dominated by centralised manufacturing, given economic motivators such as economies of scale, lower risk of IP theft, and capturing a larger portion of a value chain. However, this also comes with accompanying challenges, such as the high logistics costs of shipping feedstocks, supply chain reliance or redundancy, and the opportunity cost of operational and capital efficiencies of outsourcing. **Given growing demand for sustainability and supply chain resilience, synthetic biology-enabled decentralised and distributed manufacturing is becoming an attractive alternative**.

Leveraging a "design anywhere, grow anywhere" approach, distributed biomanufacturing could enable regions to meet their unique challenges and capitalize on their specific strengths, **promoting self-sufficiency, enhancing efficiency, and reducing waste**. Not only could this foster economic development, particularly revitalizing rural communities, but if built with such capacity in mind could also allow for quick response and production of supplies during emergencies or natural disasters, as local facilities may more swiftly adapt to urgent needs.

For example, although **feedstock and product transport costs** change on a case-by-case basis depending on the value, volume and distance to be travelled, they can be a **significant contributor to production costs**. This is especially important when low-value high-volume bioproducts (e.g. commodity chemicals and fuels) are made. Avoiding these costs could help scale these processes and could be achieved by establishing distributed bioprocesses with local production close to feedstocks (e.g. sugarcane or waste from nearby industries).

It would also have important benefits from an **environmental perspective**, for example by reducing greenhouse gas emissions from transport. Experts from the focus group suggest implementing Life Cycle Assessments throughout the supply chain - considering factors beyond cost like global environmental impact reduction (greenhouse gases, energy, water and land use) and local industry creation – could provide concrete intelligence on these benefits and its comparative advantages. Obtaining and comparing such comprehensive data remains a challenge but may be seen as key to assess where distributed biomanufacturing could provide sustainable solutions and potentially a role the OECD could play in its capacity as a knowledge hub.

Another key opportunity and driver identified is enabling **resilient access to needed key products and materials**. Current supply chains are often opaque, with no end-to-end control, and thus susceptible to single points of failure that may result in long-lasting shortages difficult to resolve in meaningful timeframes. Furthermore, many nations are pursuing strategic autonomy in order to protect from supply chain shocks. Accompanying trends like decoupling supply chain ties between countries may provide an incentive to invest in distributed manufacturing.

Synthetic biology-enabled distributed manufacturing could also be leveraged **for products that do not have to be made at an industrial scale.** For example, it could produce propane or electricity at a small scale for domestic energy use, water treatment facilities or waste management. This could be particularly useful in developing countries or places where there is no proper infrastructure to provide such resources otherwise.

Box 2.8. Open issue from the focus group: innovation and economic growth

There was a debate amongst focus group experts on whether innovation always leads to economic growth and whether scaling up processes are always desirable. They pointed to a 2020 report by the OECD Secretary General's Advisory Group on a New Growth Narrative (OECD, 2020[12]) which calls attention to the harm caused by the current major patterns of economic growth: growing inequality, the climate crisis and environmental degradation. In this context, the benefits to society of technological innovation may need to be further assessed and the governance of science and technology aligned with new economic policy approaches. Some experts suggested to leverage the transformative power of synthetic biology to unlock new growth models that reduce the harms identified in the 2020 OECD report.

Challenges for decentralised bioproduction

The main challenge in transitioning to a distributed model is the need for a complete restructuring of existing global supply chains. There are multiple options for this organisation, each with accompanying obstacles. To shift from receiving supplies from around the world to developing them locally, technical barriers would have to be overcome, such as replicating bioprocesses currently carried out elsewhere and adapting them to local conditions (e.g. climate, available feedstocks,

instrumentation). It might also require moving away from single-purpose facilities towards those capable of running multiple processes to produce a portfolio of products. Technical obstacles include the predictability of bioprocesses at smaller scales and building versatile equipment and infrastructures. In other cases, instead of running many processes in one facility, it may be more advantageous to run a single process across multiple, non-identical facilities spread across a region.

There **may be times where centralization – if economically competitive, sustainable, and resilient to supply chain shocks – remains the most appropriate approach**. For example, smaller market products like specialized medical drugs may meet global demand with a single facility (although evolving geopolitical tensions mean that uncertainties concerning global supply chain resilience remain). Furthermore, as carbon neutral transport develops, the cost-benefit assessment on centralized manufacturing may become more favourable, especially if compared to the complexity developing a network of distributed plants. From a responsible innovation perspective, livelihoods at centralized facilities would not be at risk where economies of scale continue to support centralization.

These complex considerations may call for **different ratios of centralization and distribution across manufacturing processes to enable case-by-case solutions**, based on analysis of existing supply chains, knowledge of production processes, and existing local facilities and feedstocks. Experts suggested global smart specialization plans could be useful, based on relevant stakeholders' views of what sort of value chains are envisaged and considered necessary.

Box 2.9. Example box: building synthetic biology processes for existing structures

Focus groups experts highlighted existing **examples of synthetic biology technologies capable of slotting into existing manufacturing structures,** avoiding the need for major restructuring whilst still having a net positive impact. For example, UK-based Colorifix uses engineered microbes to produce bio-based alternatives to toxic chemical dyes for improved environmental impact, which can still be utilized in existing vat houses under the same processes or conditions. Whilst shifting towards bio-based manufacturing would often not be as simple, experts believed that finding and sharing examples that enable existing infrastructure to be used for new bio-based products could facilitate the transition by identifying which product and process features are most desirable and feasible in the near-term.

Even where some distribution of manufacturing is desirable, policy barriers remain. Regulatory questions, from waste transportation rules to patent and technology transfers, are seen as needing clarification, reform and harmonization. National strategies could **elucidate the division of roles between regions to facilitate the equitable and sustainable distribution of resources** for production and well as resources produced – for example to avoid unproductive competition for biomass, or where there is a critical mass of production scale and appropriate system design is required. EU Smart Specialization Strategies may offer insights (lessons learned) on how to build on the resources available in a region for their competitive advantage whilst reinforcing collaboration.

Smaller economies with limited access to feedstocks may seem disadvantaged by distributed models but may actually be able to take advantage according to their assets and needs. For example, such nations could participate in the global value chain via distributed R&D workflows and parts of a phased biomanufacturing process, as they would only need to compete for those unit operations where they are competitively advantaged, and do not need to engage in those for which they are disadvantaged. In addition, large, incumbent economies are often rigid and complexly structured, which hinders the building of new business and industry models. Smaller economies, on the other hand, are often nimbler and may have more appetite to transform to seize on competitive advantages. They

could therefore play a role in leading the transition by example - some Latin American countries like Costa Rica and Colombia are noted to be moving fast with building their bioeconomies.

3 Key Policy and Governance Themes

Technological innovations have the potential to provide societal benefits but also carry risks and uncertainties. Several sector-specific policy opportunities and challenges have been discussed in the previous section, but others are relevant across all application areas. Focus group experts identified five key policy and governance themes for actors to help ensure a safe, inclusive and positively impactful transition to sustainable bioeconomies. These five policy themes are summarised below.

Strong and resilient innovation ecosystems

Translating synthetic biology discoveries from the laboratory into products on the market requires a **broad innovation ecosystem that fosters the discovery, polishing, distribution, implementation and uptake of new technologies**, built on promoting collaboration amongst stakeholders (from public institutions to industry) and ensuring sufficient financing. Its vital role is explored in this chapter.

A 2020 McKinsey report looking at a pipeline of around 400 use case synthetic biology applications estimated that they could have a **direct economic impact of $2 to $4 trillion globally per year in the next 10 to 20 years** (Chui et al., 2020[13]). Furthermore, a Boston Consulting Group (BCG) study found that synthetic biology could be used in manufacturing industries accounting for over 30% of global output by 2030 – representing around $30 trillion of value (Candelon et al., 2022[14]). Synthetic biology could transform incumbent business models, not only for existing companies in traditional synthetic biology-influenced sectors like health and environment but also in fashion, information storage, energy efficiency, bio-based construction, etc. Companies pursuing bio-based solutions (e.g. to strengthen supply chains, reduce costs, meet sustainability goals, and offer new products) are leading the transformation to sustainable and resilient bioeconomies. Experts believed further efforts could help ensure that these innovation trailblazers are supported, particularly to address existing challenges around **scaling, infrastructure and investment.**

Scaling

Focus group experts highlighted the so-called “valley of death” that has shown the difficulties in translating technology from laboratory to market for synthetic biology innovators. However, they saw signs of **increasing market maturity in the evolution from large sectoral companies to individual players specialised in key parts of the ecosystem**, such as automation (e.g. biofoundries), R&D services, supply chain enablers (e.g. contract research organisations) and platform technologies. In addition, experts claimed the sector seems to be moving to a **new era of market realism**, paying increasing attention to profitability and how companies overcome legacy supply chains. Recent failures or contractions by first movers could demonstrate that the sector is advancing along the ‘Gartner hype cycle’ towards a more mature understanding of how to build successful synthetic biology companies, financial management and delivering on substantiated promises[26]. This **shift towards scaling up to commercially competitive levels** is no small task as **biological systems do not scale linearly**. It

leads to an additional layer of R&D required to move to large-scale manufacturing of biologically derived products, which can be particularly limiting for smaller firms with low capital investment.

From a scientific perspective, further foundational research is still needed on infrastructure engineering issues like fermenters and cooling technologies, improving the engineering of non-model microorganisms, or even broader work on metrology and standards which are critical for scaling. Yet experts believed **foundational research is becoming increasingly underappreciated and underfunded** as focus shifts to industrial translation and applications. Adequate public funding for both research streams would be beneficial, as this could then act as a catalyst for attracting private sector funding. Similarly, there is value in collaboration and **knowledge-sharing between foundational research and applied research spaces**. Design choices made early in the foundational research stage (e.g. choosing microorganism species) can have a significant impact later on in scaling capabilities.

From a policy perspective, **strengthening partnerships between pre-industrial scale demonstrators and contract development and management organizations** could integrate industrial constraints and specifications at an early stage, which has been shown to help speed up time-to-market and reduce investment costs. Optimizing supply chains could speed up delivery times and avoid uncertainties, as could making funding available and secure for production lines. **Clarity on novel legal issues** that arise as the ecosystem develops - such as IP, design rights, access to data, and liability – will be crucial to foster private sector activity by enabling insurance and commercial risk-taking. Broader trade and competition policy will also play a role.[27] Efficiency and cost are not the only drivers of innovation, with the **drive for sustainability as a major gamechanger**. Aforementioned tax reductions, better accounting for industries' carbon output, or even mandated targets could help move towards initially more expensive bio-based solutions until they become cheaper with scale.

Box 3.1. Example box: accelerators

Launched in 2011 and funded by the French National Research Agency, the **Toulouse White Biotechnology demonstrator** is a public-private consortium of 46 members that aims to become a centre of excellence of national and international renown to accelerate the development of industrial biotechnology and promote the transition to bioeconomies. It brings together researchers and companies in collaborative public-private R&D projects, as well as an accelerator of start-ups' launch, to develop new bio-based products and processes across a range of industries and from the laboratory level to pre-industrial pilot level.[28]

Infrastructure

Experts found that **current worldwide infrastructure and capacity is insufficient to enable the bioeconomy transition, creating a major bottleneck for synthetic biology**. To move to real-life impact and truly transform industries, they believe the biomanufacturing sector's overall aim should be to shift from mainly successfully producing high-value, low-volume products to financially viable, high-volume, mass-produced ones. This could require increased emphasis on translational research and a major transformation of existing infrastructure.

Fields like physics boast great successes in setting up major research infrastructures[29] like CERN or the James Webb Space Telescope, in part due to their ability to convince governments to invest funds and enabling the collaboration and data sharing at the international level to foster technology development and scaling. Some experts suggest **synthetic biology could learn from such fields and**

change its current archipelago model (where hotspots of research are isolated from each other) **into a more connected and coordinated approach** focused on scaling and promoting partnerships between academia and industry. Initial models (e.g. Global Biofoundries Alliance) and public-private partnerships (e.g. BioMADE and SynbiCITE/SBV) within the synthetic biology space could offer guidance.

Box 3.2. Example box: international research infrastructures

A world-class example presented in the focus group was **IBISBA**: a pan-European distributed research infrastructure which aims to bring together the continuum of skills and assets needed to advance industrial biotechnology. It aims to promote transnational access to cutting-edge infrastructure across the continent by creating a single-access point to academic and industrial researchers, streamline investments by creating common strategic roadmaps and improving visibility of financing authorities, and stimulate public-private partnerships to improve translation of results. Fostering knowledge sharing between actors is a key goal, which they have pursued by implementing a data fabric with data and metadata standards that generates high-quality FAIR datasets.

Whilst this transition would need considerable financial and political resources, and ideas like creating a (fictitious) “European Biotech Agency” akin to the European Space Agency may seem necessary to some experts to funnel these, others believe **current political frameworks offer the means to go forward**, **as long as researchers can muster enough political interest**. The UK’s Centres of Excellence, for example, have had a positive impact, but at the same time European researchers have called for biofoundries for years and find there are still not enough. Concrete analyses on research needs (e.g. identifying the biofoundry capacity necessary to advance biomanufacturing) could strengthen scientists’ arguments and gain political will.

As countries develop infrastructure within their borders, experts suggested **not spreading too thinly** in trying to develop equally everywhere as there are significant costs involved, for example in developing a Centre of Excellence. They identified a key role for structured exchange programs and upscaling (for both talent and facilities) to allow local development and building shared pilot facilities, with the EU’s smart specialization strategies offering learnings on successes and failures. It could be particularly **challenging for smaller economies to build infrastructure capacity** as economies of scale may not really exist and they may have limited funds to invest, and thus tend to be generalists to make the most impact.

Biodata is already a key resource and will only increase in importance as the field of synthetic biology converges with AI, yet progress is hindered by infrastructure bottlenecks to data sharing such as the lack of standardisation or the need for curation. Frameworks for trustworthy sharing and new tools ensuring sufficient levels of security could help improve collaboration between research groups and avoid possible monopolies of data in the long-term, but a **broader assessment of existing incentives and structures to support data sharing** - especially across borders where bigger issues arise – would help further elucidate the challenges and opportunities. This could also support ongoing debates around players’ roles in standardization or how data owners and producers could retain control and access to their data. The speedy convergence with AI may accelerate the need to address these questions as actors realise that few individual players would have sufficient data flows to train their algorithms, making collaboration essential to develop robust AI models. Simultaneously, it will be critical to consider the risks associated with the misuse of biodata for nefarious purposes—and to help ensure

that data sharing mechanisms appropriately account for these risks while enabling sharing among trusted researchers.

Box 3.3. Open issue from the focus group: comparing regional challenges and solutions

Focus group experts, leveraging their broad geographic representation, shared their regions' unique challenges and potential solutions:

- In New Zealand, there are often talks of consolidation as well as collaborating with the rest of the world, but it is challenging to facilitate accessibility for all researchers. Geographical and financial isolation (especially in terms of access to private investment funds) remains an issue. **Cross-cutting agencies that overlap oversight or dedicated agencies for biomanufacturing** have been explored as solutions to address this, but bottlenecks like ensuring sufficient local talent and fundamental supply chains remain.
- In Australia, the synthetic biology community came together in 2014 to form Synthetic Biology Australasia (SBA), a society for Australia and New Zealand to start coordinating and collaborating across the ecosystem. Despite the challenges of being a new and relatively small group at the time, it has seen rapid growth, catalysed by major funding for Future Science Platforms from Australia's national science agency CSIRO, as well as a national Centre of Excellence in Synthetic Biology funded by the Australian Research Council. These initiatives, together with international conferences organised every two years by SBA, have significantly grown the community, particularly for early career researchers. As the ecosystem has matured, there has been a growth in commercial activities with 16 new start-ups in the region in the last 3 years.
- Singapore has developed advanced infrastructure in its universities (such as the University of Singapore's biofoundry) by **leveraging its advances in fundamental research to attract private sector investment through public-private partnerships**. For example, it has established joint industry-academic labs focused on getting research into the market, partnering with companies and with co-funding from the national funding agency. They have also followed a **project-driven approach**: first identifying their projects' needs, then obtaining a critical mass of their mosaic elements, and then seeking funding. This may allow governments to be more agile, help justify spending limited funds and avoid infrastructures with short life expectancy.

Finance and investment

The bioeconomy transition would involve a major reorganisation of societies, from building biomanufacturing plants, to organising new supply chains and shipping systems, to additional research and development. **Funding these changes at speed and scale is a major challenge**. Whilst capital markets have not yet been capped, the sheer scale of transformation would require considerable funding which may only be delivered by a major change to contemporary finance models.

Leapfrogging the petrochemical economy is only available to a few countries with sufficient funds to build a bio-based system from scratch. For others, experts agree on the **need for both public and private funding, recognising the responsibilities and limitations of each.** Public funding is often the main driver of foundational research but could also play a role in company maturation. For example, during the critical growth phase it could support pre-competitive pilot plants and prototype developments, and in more established enterprises it could better account for the costs of R&D under

tax laws. However, some national governments may not legally be able to fund activities too close to the market due to state aid rules.

Focus group experts pointed out that some of the synthetic biology solutions entering the market, such as more sustainable aviation fuels, may have reached sufficient maturity in large part due to heavy subsidies. This is likely not possible (or even desirable) for all synthetic biology solutions, as tighter national budgets require **clear rationale for policymakers to spend limited funds**. They suggest an **assessment of the role of government incentives** could identify for which technologies and/or sectors it would be most needed and impactful, as well as which tools (e.g. tax breaks, labelling, public-private partnerships, procurement, etc.) are the most appropriate. Furthermore, additional awareness on the impact of synthetic biology may support finance ministries, international financial institutions and development banks when deciding budgetary priorities[30].

There is already growing **recognition by governments of the bioeconomy's potential: up to 50 countries have dedicated national strategies** (Gardossi et al., 2023[15]). However, some of these may be more focused on issues of biodiversity conservation and circularity than the underlying synthetic biology technology. Experts suggest deeper understanding on how to increase political interest in synthetic biology and what role developed bioeconomies could play in terms of leading or listening would aid further discussions.

Nonetheless, in the context of growing economic nationalism and techno-protectionism, experts believed **synthetic biology is now a key domain for strategic geopolitical competition and national security**, which is driving increased policy attention and investment. For example, they pointed to countries like China and India as having major concentrations of excellence for converting synthetic biology discoveries to economic and public benefit at scale.

Venture capital has been key to take innovations in the lab to the market. In 2021, following the COVID-19 pandemic, global venture investment in synthetic biology peaked at over 20 billion USD. In 2023, that number had fallen to just over 5 billion USD, although this echoed trends in venture investment in other sectors (SynBioBeta, 2024[16]). Lack of this funding, especially vis a vis other regions, is often cited as a barrier to translational research and developing local bioindustries (Kagermann and Süssenguth, 2024[3]). Some countries indeed benefit from depreciation options for losses that may make investments more attractive. However, experts noted that venture capital's seeking of short-term returns may be incompatible with synthetic biology timeframes that require years to be at scale and financially viable. It may be preferable to combine this with **more patient capital with long-term vision**, such as pension funds, R&D tax credits and carbon tax/credits, which is currently under-deployed.

Maximising the availability of capital could require a major restructuring of finance models: **de-risking the investment toolkit, expanding the use of capital market and finding new ways to pool investment**. Experts shared examples of banks and pension funds beginning to look into how they can invest in synthetic biology, and how legislation proposing "BioBonds" (government bonds for biomedical research) had been introduced in the U.S. Congress (Congress.gov, 2024[17]). The advantage of these initiatives is putting the private sector - which some saw as a better allocator of capital than governments - in a position to decide when to invest and empowering them to carry out due diligence, improving impact.

Box 3.4. Open issue from the focus group: funding along the innovation path

Focus group experts drew attention to the importance of **facilitating resources and investment along the innovation path**. In Australia, for example, it was noted as an issue that many university technology transfer organisations may obstruct efficient and effective technology transfer, mainly because of poor understanding of IP value and monetization and thus unreasonable royalty or equity expectations. In the case of Southern Europe, some experts found that sufficient funding was currently available for lab-to-market transition (e.g. series A) whilst not so for critical growth phases (like series B and C). These differences across regions become important in the context of strategic competition and where innovation develops. Experts believe a **mapping of current funding bottlenecks, opportunities and vacuums could help policymakers better understand the funding landscape and apply targeted policies.**

Skills and workforce development

As seen in the first section of this report, the future bioeconomy promises to revolutionise many sectors by integrating new technologies and developing new processes, which would demand skills and knowledge from trained workers to run. Fulfilling this potential for economic growth and job creation requires the **labour market to be equipped with the skills, tools and capacity to succeed**.

Evolving from innovation in the lab to public uptake requires not only highly specialized skill sets (e.g. PhD-level material scientists, bioengineers, data scientists, ethicists…), but also technicians and those with manufacturing experience. **Identifying the relevant skills that will make the bioeconomy flourish and the programs to foster these** was identified as a top priority for further discussions. Suggestions from the focus group include developing training capabilities in advance, such as building capacity in community colleges and technical programs to avoid critical shortages that would hinder development. Learning from established technician training routes in other fields and how they engage accreditation bodies would also be useful.

As AI tools become increasingly powerful for facilitating synthetic biology solutions, there will be a growing need for computational skills: at a basic level for technicians and biologists in order to operate the tools, and at a more specialised degree for those developing new tools and models. Investing early on in educational programs that integrate data science with biology could help prepare new and existing generations of scientists skilled in both domains and close the emerging skills gap in the sector. At the same time, increased integration of AI may develop tools (e.g. automated workflows) that require less training to understand and use.

Box 3.5. Example box: technical and training support programs for bioeconomies

An example raised by focus group experts was Japan's New Energy and Industrial Technology Development Organization (NEDO)'s initiative "*Development of Bio-based Product Production Technology to Accelerate the Realization of Carbon Recycling*". It aims to promote sustainable bioproduction by establishing a biofoundry that universities and companies can use to develop and verify their technological approaches. In parallel, they have also launched a special course on human resources development to promote the social implementation of biomanufacturing. Students of this course combine theoretical lectures with practical learning on production cells and how to construct

bioprocesses and apply them to biomanufacturing. This ultimately aims to cultivate talents who can bridge advanced research and industry to nurture the Japanese bioeconomy.[31]

International training programs that **foster the circulation of talent across borders are known to enrich the workforce's experiences**. For example, student and faculty exchange programs promote cultural exchange that provide exposure to diverse perspectives on synthetic biology, sharing of biosafety practices[32] and foster more developed workers[33]. However, these are not accessible to all, especially as cross-border funding and visas are often very difficult to obtain. Moreover, advanced economies may not always accept credits from developing countries, hindering students from the latter in pursuing further education (and even employment) in the former. Whilst digital resources are increasingly sophisticated and popular and could thus enhance access to educational content or facilitate remote collaboration between students and educators internationally, they do not offer the same breadth of experiences.

Nonetheless, a top priority for countries investing in training will likely be a **balance between promoting international training to build a stronger workforce and address bottlenecks whilst also avoiding brain-drains**. Countries with weaker economies may be most affected as they may have fewer high-paying jobs and economic incentives for newly trained workers to remain, and thus an important issue to address if all countries are to equitably benefit from the synthetic biology transition. Experts suggested combatting brain-drain would likely require **establishing flourishing local bioindustries that speed up the availability of specialised and non-specialised jobs**. It could involve high-income countries investing in joint R&D programs in low- and middle-income countries to stimulate local job production, as well as over time driving a harmonization of standards and creating an enabling economic environment (e.g. supportive IP policies, public-private partnerships…).

Box 3.6. Example box: train-and-return programs

A key example shared by focus group experts relates to foreign aid often involving train-and-return programs where scientists from developing countries are sent to train in advanced economies to obtain degrees and bring the knowledge back to their communities. However, the labs they return to often only have limited resources and lack suitable laboratory facilities. These skilled researchers have the knowledge but not the tools to continue their research, which limits the type of science they can do and may even make it harder for them to find local jobs, potentially forcing them migrate to countries with better research facilities (Zink, 2017[18]). Whilst this could be partially addressed through increased collaboration opportunities (e.g. continuing to work with their university abroad), brain drain remains a major consequence and challenge. Experts suggested international funders of these programs may wish to reflect on the impact of their interventions and carry out evidence-based resource allocation to determine whether these or other initiatives (e.g. infrastructure development) are most impactful.

As bioindustries develop, they could replace traditional industries such as those centred on fossil-based production, which will inevitably face workforce reductions as factories and offices close down. This will be particularly impactful to lower-income regions that currently produce many of the world's consumer products and benefit from the established centralized manufacturing set-up. Experts believed the global community has a responsibility in **supporting responsible job replacement and retraining programs** in these regions and see it as critical for the bioeconomy transition to be fair, inclusive and supported by the public. Better forecasting the labour losses that may arise from the transition can help actors prepare policies, with positive examples are already taking place that could serve as best practices. If

these programs are well anticipated and strategized, they have the potential to greatly assist the development of the new workforce necessary to grow the synthetic biology industry.

Equity and access

Equity in synthetic biology centres on facilitating widespread *access to the technology* and *access to its benefits*, recognising that actors across the globe have different starting circumstances and thus resources and opportunities need to be allocated in a just manner to promote equal outcomes. Building equity is **important not just from a moral standpoint, but also because innovations made equitably and accessible will enhance a technology's effectiveness and acceptability**.

There are several dimensions to equity, such as geography, socioeconomics, access to education, representation of different genders, races, ages, and different knowledge sources (e.g. traditional knowledge). **Avoiding systemic disparities involves ensuring voices from across these dimensions participate in scientific research and decision-making conversations**, as well as have equitable opportunities for ownership of IP, raw materials and resource flows. Although some experts claimed synthetic biology has benefited from strong community-level practice sharing and early discussions on responsible technology democratization, several disparities remain to be addressed.

One key example is **inequitable access to synthetic biology products and benefits at the user level**, most recently and notably around the limited availability of COVID-19 vaccines in some developing countries, but also relating to access to diagnostics and consumer products. However, disparity does not arise only at the end stage, and in fact is partly due to **disparities at the scientific research level** where limited infrastructure, supply chains, training, and investment constrain the ability of researchers from developing countries to innovate at the same pace as those in advanced economies. This is illustrated by the latter vastly outnumbering the former in terms of synthetic biology scientific publications (Shapira, Kwon and Youtie, 2017[19]).

Whilst inadequate access to reliable electricity and internet is sometimes part of the issue, another big reason is **developing countries' reliance on importing basic equipment and reagents from companies in advanced economies**, which is not only more costly for them but also lengthens the process of logistics and transportation (average of 24 – 48 hrs in advanced economies as opposed to weeks or months in developing countries). This makes the iterative cycle of science and innovation much longer and hampers fundamental research which is key for scalability. At the government level, these delays may be due to insufficient awareness of storage conditions by customs officers or policies requiring exporters to have licensing, whilst at the manufacturers' level there may be limited financial incentives for large companies to organise faster shipping routes for small markets.

Experts suggested further discussions were needed to **find practical solutions, unpacking who is responsible and which levers can be mobilized** so actors can access the same resources regardless of where they work – acknowledging that different situations will call for different resources to facilitate equal outcomes. At the research level, baking in from project inception the goal of equitable access could help shape the design of products to overcome existing infrastructure barriers (e.g. designing vaccines without need for expensive cold chains), as well as incorporating diverse perspectives into value chains to ensure better understanding of decision consequences although identifying how and where these are most needed remains challenging.

The long-term solution according to focus group experts may include **tackling structural dependence by creating appropriate capacity locally.** Although this is an area of great political interest for both advanced and developing countries (for the latter, given rising supply chain instability and the need to increase resilience, as explained in section *5. Decentralised and distributed manufacturing*), it will be more challenging for the former given it is an **all-encompassing endeavour**: requiring community creation (networks for knowledge exchange and distribution), enterprises (to deliver access at scale), making the technology available, and enablers (training, lab space, reagents...).

International research partnerships and collaborations between advanced and developing economies could aid (such as cross-border education programs, covered in section *2. Skills and workforce development*), but more best practice examples are needed of the advanced economies engaging with developing countries in a way that promotes tech transfer and indigenous development rather than exploitation. This could be favoured by **more inclusive representation of countries and stakeholders in conversations shaping the direction of international synthetic biology research and resource allocation** (e.g. international organisations, think tanks, multilateral agreements etc.).

Box 3.7. Example box: Africa's opportunities and challenges

Focus group experts highlighted Africa as an example of a region holding great potential to advance synthetic biology research and innovation, but whose scientists and innovators face ongoing challenges. For example, funding constraints – including unsustainability of international funding - make it difficult to sustain long-term projects, which would help move from fundamental research to scalable solutions. This is compounded by the lack of translational research infrastructures, supply chain issues and the regulatory landscape for biotechnology generally still being underdeveloped or inconsistently applied that creates uncertainty that deters investment. However, growing awareness of the potential of synthetic biology across African governments is leading to more policies fostering innovation (e.g. tax incentives for R&D and establishing innovation hubs), as well growing regional and international collaborations (e.g. the African BioGenome Project) to facilitate knowledge exchange and capacity building, although issues around bioethics, biodata ownership and benefit sharing remain.

Box 3.8. Open issue from the focus group: nuancing disparities

A discussion in the focus group centred on **nuancing the distinction between advanced economies and developing countries in relation to synthetic biology equity disparities, as these are not always as clear-cut**. For example, although Australia and New Zealand are typically considered advanced economies, experts from the region confirm they face slower science cycles than Europe or North America as reagents are mainly delivered from regional production hubs like Singapore and China. In turn, experts from Europe asserted that even if reagent access has traditionally not been a big of issue for researchers in advanced economies, growing customs rules and export controls in biology may change this, and delays to research arise instead from paperwork, extensive regulations and long waiting times for approvals. The focus group thus called for nuanced discussions going forward on the access challenges facing each region to effectively facilitate equity.

Biosecurity and biosafety

Although synthetic biology can provide breakthrough innovations with the promise to solve many current and future global challenges, it remains **a potential dual use technology**. While synthetic biology **can play an essential role in combatting biological threats** (e.g. rapid vaccine development against pandemics) **it can also create them.** Highly skilled and well-resourced nefarious actors could use synthetic biology to carry out biocrimes and bioterrorism, such as developing harmful engineered organisms as biological weapons. Having robust biosafety and biosecurity measures is important in mitigating these risks to realize the full benefits of synthetic biology. There are many efforts by a range of international stakeholders to support norms against biological weapons and the importance of biosecurity, with the Biological and Toxin Weapons Convention (BTWC) being one of the primary fora. However, experts caution that globally we have an uneven landscape of biosafety and biosecurity policies, practices, and oversight mechanisms, and that the **established norms and assumptions around biosecurity which underpin these global efforts may not hold -** highlighting the need to strengthen these measures globally. As synthetic biology develops, it is important to develop and integrate biosecurity measures to prevent misuse, including bioproduction of new weapons or soldier enhancement.

Aside from intentional harm discussed in biosecurity conversations, synthetic biology could cause **unintentional damage via accidental release of engineered organisms into the environment** (either by escape due to lab accidents or a well-intentioned release for a specific application with unintended side effects). These **biosafety concerns could have a major impact**, such as the spread of antibiotic-resistant bacteria, the disruption of ecosystems, or the loss of biodiversity. Effective biosafety practices and containment measures aim to mitigate the risk of potential lab accidents. With over four decades of experience in intentional release of genetically engineered organisms, some countries are able to apply their existing frameworks for the regulation of new products and applications, whilst other countries question the suitability of existing frameworks. Novel technological solutions continue to be developed, such as engineered kill-switches to inactivate released organisms, which may impact future risk assessments.

These risks could be exacerbated by the lowering entry barriers to synthetic biology – that is, the reduced obstacles to new users in participating in synthetic biology, like specialised knowledge or techniques. Increased democratised access to information and tools **empowers individuals to conduct their own experiments outside of traditional safety oversights of institutions and the regulatory framework**. Whilst this DIY-Biology field has existed for decades, AI tools like large language models are further increasing accessibility to knowledge (explored in section *4. Synthetic biology and AI convergence)*. No major crises have yet arisen and technical hurdles remain which limit the practical risks (e.g. thousands of litres of yeast would be needed to produce a single dose of opiates via biosynthesis (Galanie et al., 2015[20])), but governance tools are already being set up in anticipation, such as the aforementioned measures for DNA synthesis screening.

The major challenge is contemporary research culture tending to see a trade-off between academic freedom and national security, with **security considerations seen as a compliance burden and passive check-listing**. Yet those in the frontline of innovation are best positioned to identify and mitigate such risks, so mobilizing them to integrate biosafety and biosecurity as a key enable of innovation is seen as crucial. Focus group experts suggested the following approaches:

- **Greater awareness that life science research has the potential to be dual use** and could cause unintended risks, rather than subcategorizing research types by perceived level of risk, could ensure more widespread attention. Experts believed with more humility in the research

design process, capability could be built up from early stages to mitigate harms, such as following secure-by-design principles. For example, the WHO's 2022 guidance on responsible use of life sciences[34] advocated a concept of 'biorisk management' centred on ways for researchers to deal with harm regardless of intent.

- **Finding ways to make biosecurity a zone of curiosity (rather than a taboo) for researchers** could speak to their intellectual curiosity and foster its incorporation into research projects as a component of innovation.
- **New incentives for scientists to be more transparent and proactive about risks**. Researchers already face huge responsibility in driving their work forward and competing for funding, and are thus often reticent to discuss risks for fear it will hinder progress. However, fostering a community of practice culture to openly discuss and learn from each other could improve risk management. Solutions suggested include upstream education initiatives relocating attention to safety and security, like iGEM's Human Practices Program[35], or trying to break the taboo by documenting risk management practices, like VIRS Biorisk Management Casebook[36].
- **Transforming research funding structures**. Funding risk assessment and management projects could help build capacity to integrate safety and security more effectively into technology research, and fostering multidisciplinary teams that involve social scientists (e.g. making them available to natural scientists during project development) could help identify ethical, legal and social issues (ELSI) associated with technology development and use.

Box 3.9. Example box: from biosecurity to biorisk management

An example raised in the focus group discussion was the World Health Organisation's 2022 '*Global Guidance Framework On Responsible Use Of The Life Sciences: Mitigating Biorisks And Governing Dual-Use Research*'[37], which provides guidance and practical cases for how actors could shift from the language of biosecurity which has been prominent for decades and towards the concept of 'biorisk management' which aims to address harm in all forms and regardless of intent. The advantage of this approach is that it **allows actors to think about risks beyond weaponization, and includes more qualitative and quantitative assessments**. On the other hand, experts suggested it may make the discussion too broad and thus hard to take into concrete national policies, or that some actors like law enforcement require 'biosecurity' language to be engaged.

The major challenge is balancing risks and innovation, an issue which has plagued many emerging technologies before synthetic biology, including the internet**.** Whilst there are risks (including the aforementioned and those harder to control like state-sponsored terrorism), **the same technology that powers nefarious uses can be used to prepare for, prevent and respond to natural, accidental and deliberate biological threats** (e.g. mRNA vaccines against COVID-19). As risk management practices develop, some experts advocated to avoid overregulation that could stifle these beneficial applications, and encourage countries to develop frameworks that match the level of risk posed by a synthetic biology solution with appropriate biorisk management approaches – assessing which communities will be most impacted, and looking at both short-term risks and long-term gains. The historical opposition to recombinant DNA technology in the 1970s makes some experts fear that nuanced and risk-based governance approaches in synthetic biology – which account for cultural,

ethical and socioeconomic aspects - would be opposed by the public and some policymakers. Engagement efforts would need to learn lessons from past experiences (explored in the next section).

Whilst research and industry communities alone have made great strides, involvement of funding agencies and policymakers could help further improve impact. At a time of simultaneously pressing priorities, experts believed incentivizing attention to security could require **strategic and personalized messages for different stakeholders**. For example, policymakers may be more supportive of arguments integrating competitiveness and bioeconomy, whereas researchers may be more responsive to creative funding mechanisms for responsible innovation projects.

There is **a lot of innovative ideation and experimentation taking place on biosecurity and biosafety approaches**, leveraging different actors' unique needs and capabilities. Orchestrating these internationally across actors and types of research could have benefits but there may also be value in having different procedures implemented across the world. Experts believed further work **analysing different approaches to learn what works, what doesn't and why** would be beneficial. By speeding up experimentation processes of building and implementing new tools and seeing whether and how they fail, the synthetic biology community could understand the strengths, weaknesses, and perverse incentives faster and potentially fix them before they endure.

Anticipatory governance and responsible innovation

Scientific and technological innovations do not exist in a vacuum. They impact the society in which they arise whilst also being affected by society's values. Moreover, as some social groups can have more influence on the design and development processes, science and innovation are intrinsically political. In this context, anticipatory governance and responsible innovation play a key role in guiding synthetic biology development in a desirable direction for the benefit of society.

Tools for anticipatory governance

The benefits of **anticipatory governance systems that shift** the focus from exclusively managing downstream risks to upstream engagement of stakeholders involved in the innovation process itself (e.g. funders, researchers, civil society…) have been well documented (OECD, 2023[21]). They include fostering technological development in a positive direction and delivering impact in a reasonable timeline whilst ensuring utmost protection of values and rights. A balance of hard and soft law approaches could help target different stages of technology development, but further understanding and experimentation could provide guidance on how to achieve this in synthetic biology.

Legally binding regulation provides enforceable regulatory provisions to guide emerging technologies, but should be considered thoughtfully given nascent understanding of the effects of regulatory systems in determining which synthetic biology products succeed in the market, which companies will develop them and where in the world they will be produced (Tait, Banda and Watkins, 2017[22]). For example, genome editing can develop plant, animal, and microorganism varieties that cannot be distinguished (in appearance or even genetically) from varieties evolved by more 'conventional' methods like selective breeding, directed evolution, or random mutations. Some countries (e.g. United States, Canada, Thailand, Latin American countries…) have exempted some of these products from transgenic/GMO regulatory processes, whereas other countries have not (e.g. South Africa, European Union has pending legislation…). These diverse interpretations of what is considered a GMO leads to products facing different labelling, regulatory environments and decision timelines, and marketing obligations across jurisdictions, and thus different market success and uptake.

Aligning regulations could have the advantage of providing regulatory clarity, clarifying when risk and safety assessments are needed, and ensuring more equitable access.

On the related issue of **diverging interpretations of 'synthetic biology'** - in contrast to other commonly used terms like 'engineering biology' and 'biotechnology' – experts held different views. Whilst they believed commonly agreed terminology would clarify the scope of discussions and regulations, they also pointed to the arduous, time-consuming political process that would likely be needed to reach a definition (e.g. years of discussions at the Convention on Biological Diversity have still not reached an agreement on the definition of 'digital sequence information'). Given the many urgent opportunities and challenges facing the field, and the fact this diverging terminology has often stemmed from branding exercises in response to public perception, many experts believed it would be most efficient to follow a broadly encompassing approach and focus instead on other key issues.

Experts believed there could be a **growing disconnect between the pace and complexity of synthetic biology technology and the regulatory capacity to assess it in the long term**. Whilst regulatory regimes as they stand now addresses the realistic current and near-future uses of synthetic biology, they may not be prepared or sufficiently resourced to efficiently manage the amount, complexity or pace of new synthetic biology products in the longer term - in terms of knowledge, staff or budgets. Experts believed further investment in regulatory science could help ensure these bodies do not become a bottleneck to the rate of diffusion and can continue fulfilling their role of ensuring the safety and efficacy of products.

Box 3.10. Example box: product-specific regulation

A potentially positive example for some focus group experts is the **shift from process-based regulatory systems to those regulating synthetic biology on a product basis**. As different end characteristics and functions will make different products carry different levels of risks, experts believed that there is merit in exploring whether they should be regulated differently.

The UK's Regulatory Horizons Council (RHC) has called for this shift in previous reports[38]. This can now be seen in the UK's Genetic Technology (Precision Breeding) Bill, documented in the 2023 UK report on engineering biology[39]. Experts suggested to **learn from these early experiences to determine what regulation works in which circumstances**, and that this could require setting up institutions with supra-regulatory governance responsibilities like the UK RHC.

Non-binding governance approaches can complement or serve as a precursor to enforceable regulation by **enshrining commitments in more flexible approaches or providing technical guidance**. They can play a key role in early-stage governance by overcoming some of the challenges to formal regulations, as they can be developed faster, via multistakeholder co-operation and work across jurisdictions (OECD, 2023[21]).

- **High-level principles**, such as those on safety-by-design and sustainability criteria, provide stakeholders general norms and directions to follow which they can adapt to their unique technologies.
- **Codes of conduct** aim to embed cultural responsibility within stakeholder groups by promoting self-governance, such as the '*Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists*'[40]. More detailed behavioural standards for innovators have also been developed by national standards bodies[41]. Experts suggested that in the future, these could go beyond explicitly focusing on researchers' individual actions and focus instead on systematizing those

researchers to be reflexive about the broader (social, economic, political, ethical…) contexts and impact of their work.

- **Technical standards** provide specifications to support interoperability and technology diffusion, for example on the description of biological components. With automation and data science convergence with synthetic biology, a growing range of standards are arising to make data and metadata FAIR (findable, accessible, interoperable and reusable). The challenge is in having these standards adopted by the research community, as implementing them may require additional work and can be viewed as a burden. There is strong evidence standards only succeed when co-developed by academic researchers, industrial players and often policymakers - funders also play a key role in promoting their use. This collaborative approach of sharing and co-evolving standards seeks to ensure they address the needs of all stakeholders and could be adopted on an international basis, in turn driving harmonization and interoperability, reducing redundancy and ensuring scalability across regions and applications.

As mentioned in the previous section, much experimentation on governance approaches is taking place, which could be desirable to allow for a speedier process of learning what types of governance are successful, in which cases and for which reasons. Experts argued further exploration of experimentation methods available (e.g. sandboxing) and how to set them up to enable comparative analysis could be useful. The **role of international organisations, particularly the OECD, could thus be convening the players to see what can be learnt from each other's experimentation**. In fact, previous successes (such as the shaping of biotechnology standards and regulations via the OECD's Green and Blue Books) relied on the organisation's ability to accumulate evidence, share best practices, harmonize understanding of concepts and methods and build consensus (Matsuo, 2023[23]).

Responsible innovation

Promoting technology with the assumption that its development will automatically benefit all of society was considered by many experts as **overly simplistic**. Particularly when innovations replace an existing field, they can lead to harm (e.g. job losses) and unintended consequences (e.g. need for costly adaptions), as seen in the rise of AI. A robust debate about the future of synthetic biology could challenge assumptions on how it will develop and recognise that by default many of the transformational changes promised by synthetic biology may not happen. Technology pathways are hard to predict, and it would be useful to **consider how plausible the envisioned futures are under real-world circumstances** (such as neoliberal policies in capitalism) and **realistically understand how they could lead to harm** (such as perverse incentives and unintended consequences).

Such considerations could help **avoid being prescriptive or overly assertive about the role of synthetic biology and remain open to alternative solutions where needed**. Certain societal challenges could be addressed by non-technological means, or at least with technology as part of a holistic solution. For example, food security could in part be tackled by improving food distribution across the world and tackling food waste, not just by synthetic biology advancements in crop engineering. However, if only scientific experts are engaged when discussing societal issues and solutions, technological innovations are likely to be hailed as the main solution. Moreover, technical experts may miss certain knowledge such as consumer choices, community values and potential societal impacts - including issues of equity and justice. Engaging in multistakeholder discussions can partly address this, as discussed in the following section.

Box 3.11. Open issue from the focus group: balancing consensus and non-agreements

Many scientific governing processes are presently structured around the need to find consensus. Some focus group experts debated whether ubiquitously seeking this goal was perhaps a drawback since finding a useful, unanimous agreement for major issues if all perspectives are represented is unlikely. Making governance conversations more effective and future-proof could require **restructuring to consider productive disagreements as a strength that could enhance democratic processes**: bringing in different values into technological development, building capability to determine how concerning certain issues would be, helping better assess chosen paths and opening the door to revisions in the future as new information becomes available. At the same time, other experts called for **nuance: distinguishing situations** where academic disagreements may enhance healthy debates from those where regulations and standards are developed, as bad decisions in the latter could have serious safety and security consequences.

Box 3.12. Open issue from the focus group: synthetic biology as a driver for broader societal change

Focus group experts acknowledged the reality of science taking place within existing societal systems and cultures, and thus the importance of learning the right lessons from past technologies: how were they envisioned in the design and development stage and how did they end up once introduced into society? Some experts believed that since synthetic biology is still at a stage where funds need to be requested and justified towards governments and private investors (as opposed to the IT field where individuals with enough private funds can singlehandedly pursue their desired innovation pathways), there is still time to narrow down what future vision of synthetic biology society sees as desirable. Whilst a consensus on what is a desirable future may be challenging, the process of collective visioning and assessment will reveal commonalities and divergences in opinion, which is essential for technological progress underpinned by democratic values. The **emergence of synthetic biology could be leveraged as an opportunity to practice anticipatory governance and reflect on how things can be done better instead of just continuing the same systems with different building blocks**.

Whilst synthetic biology is not a silver bullet and issues like biosecurity are valid concerns, experts raised the importance of evaluating the risks of synthetic biology together with its potential to deliver much-needed transformative solutions for the health, food, climate and sustainability sectors. The **opportunity cost of not implementing new technologies** is a key consideration, although this also holds true for alternative transformative approaches which may not be further developed or applied due to lock-in consequences of focusing on single technological solutions.

A better understanding of who is foreseen to be impacted by synthetic biology could help identify which synthetic biology products are most valuable to society and should be fostered, and which would simply create more products with little added benefits. This knowledge could come from comprehensive, realistic and inclusive anticipatory exercises focused beyond expected technological developments. **Foresight tools like technology assessments and horizon scans could help develop an evidence base** on expectations around advancements and their accompanying challenges and opportunities, allowing innovators and policymakers to anticipate consequences and better guide technology

development. For example, experts highlighted the Engineering Biology Research Consortium's technical research roadmaps[42] for the broader synthetic biology field as well as for specific sectors like climate and sustainability.[43] [44]

Anticipatory practices can also include **integrating responsibility and the social dimension of synthetic biology early in the innovation process**. For example, research funding bodies could allocate a minimum percentage of R&D to ethical, legal, and social issues (ELSI), or encourage multidisciplinary teams of natural and social scientists in research projects and life cycle assessments. In education, including issues on governance, responsible innovation and dual use in undergraduate and postgraduate courses (as is already the case in some universities) could raise awareness amongst future scientists.

Box 3.13. Example box: novel responsible innovation approaches

Focus group experts shared examples on how government and civil society actors were embedding responsible innovation in synthetic biology development via research programs and raising awareness amongst students:

- In Australia's national science agency CSIRO, their '*Synthetic Biology Future Science Platform*' aimed to support synthetic biology development based on responsibility and striving for ethical and socially acceptable outcomes. It embedded a social science program looking at the accompanying ethical, legal and social issues, and monitoring them by maintaining a dialogue with the public[45]. Running from 2017-2022, the work is now continuing until 2027 in a new '*Advanced Engineering Biology Future Science Platform'*. A separate '*Responsible Innovation Future Science Platform*' was also established to explore the broader risks and opportunities of emerging technologies (including synthetic biology) in society[46].
- In the Netherlands, the Rathenau Instituut and Delft University developed a free card game raising biosafety awareness amongst students as part of the *Tools for Translation of Risk Research into Policies and Practices* project. The game presents different biosafety scenarios, as well as possible risks and solutions that players pick and argue in support for, leading to a broader discussion around safety[47]. Another game by the Dutch National Institute of Public Health and Environment focuses on promoting safe-by-design principles as players try to develop a prototype biotechnology[48].

Public engagement

Democratic, long-term and multistakeholder partnerships are key to support an inclusive synthetic biology implementation. This involves engaging not only policymakers, academia and industry, but also societal stakeholders like non-profits, labour unions and the broader public. Focus group experts recalled the fierce debates around recombinant DNA technology and GMOs starting in the 1970s where strong public pushback hindered the technology's implementation and stressed the importance of **learning lessons from the past**.

The traditional view amongst scientists has been that improving the public's understanding of what synthetic biology is and what it could provide using positive narratives would shore up public support. However, focus group experts believed in the need to go beyond into **two-way engagement**: creating spaces for civil society to share their values, needs and interests so scientists and policymakers can understand why they may have different views on synthetic biology. For example, they may not always

want solely technological solutions or may question the long-term consequences. Unpacking the nuances in engaging the general public compared to those stakeholders most affected by synthetic biology products or that risk being left behind by a transition to a bioeconomy could also be important.

Although the public may not have advanced technical knowledge, **technology developers incorporating the public's view on what future society should look like** could lead to more robust technology development. Upgraded technology assessments could serve to collect these opinions and concerns upstream and translate them into implementable policy language.

Whilst some focus group experts were hesitant of early public engagement potentially leading to a backlash against genetic engineering technologies, others highlighted that public opinion has shifted over time, with **studies showing openness by the public to certain applications of genome editing technology** (Dias Ramos, Strecht Almedia and Olsson, 2023[24]). A Dutch exercise engaging citizens on crop genetic engineering discovered they are not necessarily against the technology, but would like strict rules to ensure it actually achieves its stated goals of contributing to food security and improving sustainability, and not replace solutions to the root causes (Rathenau Institut, 2023[25]). As synthetic biology products become more widespread and the public further engages with them firsthand, some experts believed growing acceptance would follow.

The sudden **rise of AI as a general-purpose technology could offer a learning experience** for synthetic biology, as innovators' and policymakers' scramble to shape the narrative and regulate quickly has often been accompanied by fearmongering. Experts suggested synthetic biology should be careful not to overpromise its potential when developing positive narratives, but highlighted the challenge in avoiding this when contemporary funding structures are often hardwired to reward big promises, and believed a deep dive into these incentives and alternatives could be useful.

Box 3.14. Open issue from the focus group: communication approaches

Focus group experts debated the level of public attention which would be desirable for synthetic biology. Some experts highlighted the key role of early public involvement in technology development to improve the design and development of synthetic biology and to avoid knee-jerk reactions. Open dialogue can build trust and provide a more fine-grained deliberation on merits and concerns. Other focus group experts raised the benefits to 'flying under the radar' to avoid raising potentially political or uninformed opposition on the early stage technology until a solution can be developed and judged on its merits. However, to this last point, some experts questioned whether it was even possible (or desirable) for synthetic biology to be kept away from the mainstream public discourse as an increasing number of countries, such as the U.S. and U.K., have designated it as a key growth area for their economies.

4 Implications for Policy and Future Work

Throughout this Working Paper, several open issues and avenues for further discussions have been identified. These were interrogated during two dedicated two-hour focus group meetings on 16th September 2024, where the experts identified the key implications for policy and future work. These are clustered in two broad areas: (1) issues and opportunities for governance of synthetic biology, and (2) challenges for enabling research and innovation in synthetic biology.

Governance issues and opportunities

Anticipatory governance - including regulation and standards, responsible innovation and public engagement - was identified as a key policy and governance theme by the focus group (see *section 5. Anticipatory governance and responsible innovation*). It is clear that responsible development of synthetic biology requires a careful balance between encouraging rapid innovation and establishing effective governance to mitigate negative socio-economic effects and avoid risks.

At the OECD Science and Technology Policy Ministerial Meeting on 23rd-24th April 2024, Ministers and high-level representatives from OECD countries, the European Union and partner economies welcomed in their Declaration[49] a new OECD Framework for Anticipatory Governance of Emerging Technologies that promotes responsible innovation and offers tools to help governments identify and address the ethical, social, and legal implications for technological developments before they become entrenched. The Framework proposes a set of governance mechanisms and practices aimed at preparing for and shaping future technological developments to benefit society and building longer-term capacities to shape innovation more effectively[50]. It identifies a set of *foundational* and *technology-specific* values - common across liberal democracies - that could be used to frame potential future implications of synthetic biology technologies and guide their development.

To complement the governance discussions in the focus group meetings, and to provide a useful lens for identifying some of the key issues and governance implications of synthetic biology, the Framework's 12 values (see box 2.1. below) were mobilised. A preliminary diagnosis was made and summarised in Table 2.1 and Table 2.2 below.

Box 4.1. Values for the anticipatory governance of emerging technologies

Six Foundational values

Foundational values express shared commitments to certain ideals of ethical, political, economic or cultural importance - whether they be individual or social, professional or institutional, community or nation.[51]

- **Respect for human rights**, including protections of human dignity and basic liberties such as freedom of thought, freedom of expression and freedom from harms.
- **Safety and security** involve the adoption of measures to minimise risk of harm to economy, environment and human well-being.
- **Privacy**, including the basic interest in being free from interference with other basic rights and liberties, including the protection of personal data.
- **Democratic values**, including the rule of law, equality under law, representation and participation in public life and debate, procedural justice and the advancing the public interest.
- **Sustainable development**, including the responsibility to protect and enhance biodiversity and ecosystems, promote nature-based solutions, and address climate change while promoting human well-being.
- **Equity and inclusion**, recognising diversity and accessibility in its many forms, ensuring fair treatment and full participation of individuals or groups that are vulnerable and/or have been historically excluded or marginalised, and providing fair access to the benefits of innovation.

Six Technology-specific values

While foundational values convey broadly held, shared commitments and beliefs, technology-specific values guide policy decisions in a particular technology context.

- **Trustworthiness** includes ensuring that technologies, actors and their decisions can be counted on for accuracy, reliability and regulatory compliance.
- **Responsibility** involves the attribution of the consequences, positive or negative, of actions and decisions related to technologies, as well as accountability to those affected or to society in general.
- **Transparency** involves giving an open and honest description of information conveyed, its justification, and limitations, in language that is understandable and accessible.
- **Technology stewardship** places a duty on those with sufficient expertise and knowledge to create and use technology in ways that are aligned with foundational values (e.g. those above) and promote public goods.
- **Innovation for public good** emphasises the important benefits to society from technology innovation, and the need to lower unnecessary barriers to achieve that goal.
- **Responsiveness** requires meeting the expectation that promised technological outcomes are delivered in a timely way.

Table 4.1. Possible synthetic biology effects on foundational values

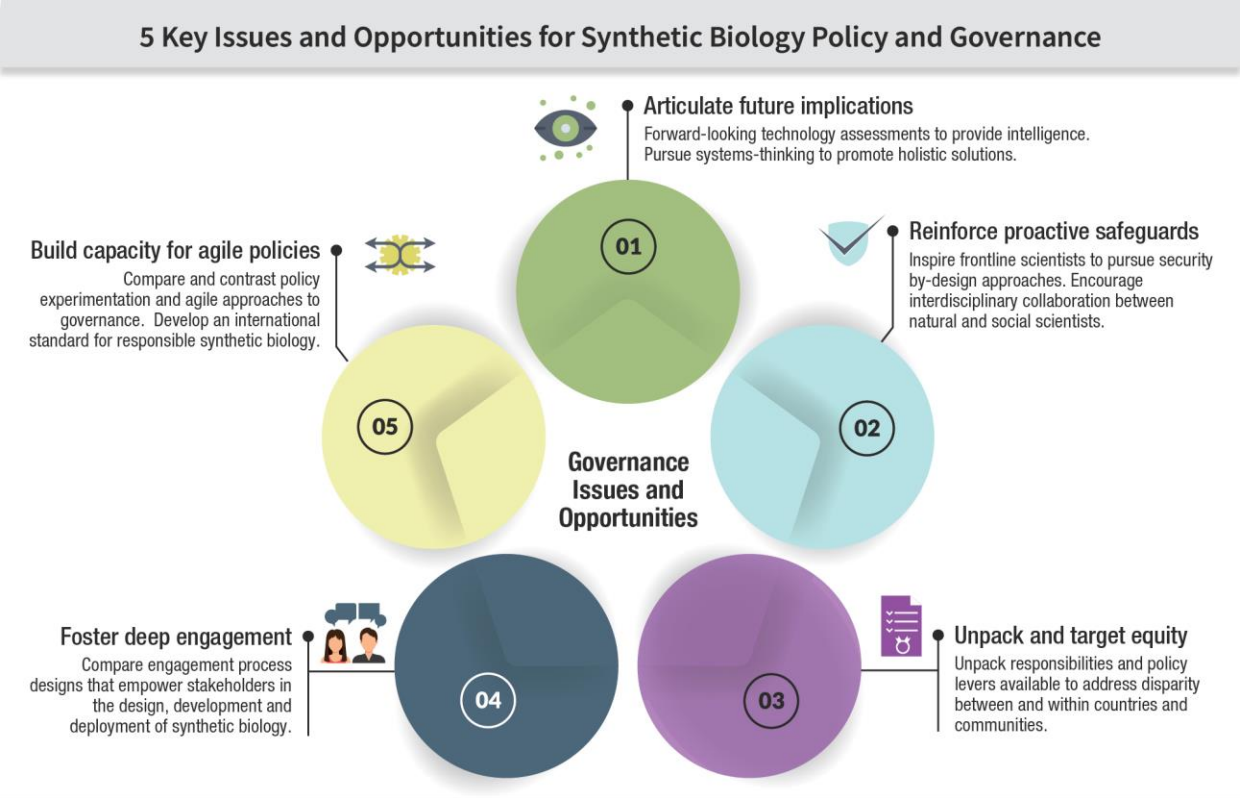
Framework value	Potential synthetic biology contributions	Potential synthetic biology challenges
Respect for human rights	Distributed biomanufacturing processes could empower local communities to leverage their local resources to better meet their needs for key products (e.g. health, food or energy), democratizing access and improving their living standards.	Genetic engineering of bacteria, viruses and other organisms have the potential to be intentionally used for harm, accidentally cause harm (through poor practice), or evolve into harmful agents. Similarly, human biological data could be used to cause harm to individuals or populations if intentionally misused by nefarious actors.
Safety and security	Synthetic biology advances can be used to tackle health and environmental crises, such as the use of mRNA vaccines in tackling the COVID-19 pandemic.	Increased access and reduced costs of synthetic biology tools (especially in converging with AI) could empower malicious actors to leverage the technology for biocrimes (e.g. illicit drug production) or bioterrorism (e.g. harnessing pathogens to endanger human health). Accidental lab leaks or unintended consequences from deliberate releases of engineered organisms could also have negative consequences for human and environmental health (including by-passing national borders) – although not damage has yet been observed.
Privacy	Due to strong privacy values in some countries, synthetic biology applications utilizing private information (e.g. genomic data for healthcare treatments) may only be developed with informed consent. The focus group also raised the potential of synthetic biology for data storage, providing a secure means of storing data, coded into living organisms (and thus very difficult to hack).	Increased availability and cost-effectiveness of DNA sequencing tools is enabling broader access to people's genomic and other biological data. This creates new privacy risks and problematic uses, such as discrimination by health insurance firms based on genetic or other data-based profiles. The focus group identified the potential of biodata monopolies which may have a consequence for privacy.
Democratic values	Extensive fora have been developed to exchange insights into synthetic biology advancements between scientists, policymakers and civil society to jointly develop awareness and even safeguards (e.g. iGEM, SynBioBeta). Free and transparent exchange on research, development and exploitation of synthetic biology would enhance democratic values. Lab open days, public dialogues, hackathons and participatory technology assessment are approaches that have demonstrated success in synthetic biology.	Engineered organisms would not be stopped by country borders, and thus regulatory decisions taken in one jurisdiction could affect others who may hold different views and would not have been able to give their consent. International agreements that have already been developed and take this into account should be considered. Another concern from the focus group was the risk of public engagement focused on public enrolment and education, rather than an open dialogue where both sides can learn and adapt.
Sustainable development	Developments in carbon capture, biofuels, agricultural efficiency and use of biobased feedstocks for biomanufacturing could reduce carbon emissions and foster more environmentally sustainable and circular practices across sectors.	Developments could be misused by certain actors to maintain unsustainable and environmentally harmful systems like monocultures or extensive pesticide use. Sustainable productivity growth must balance economic, social and environmental dimensions. Recommendations on best practices to support sustainable agrifood systems may .be helpful.
Equity and inclusion	Promoting distributed and decentralized biomanufacturing technology and know-how could increase the availability of essential resource production in communities which may not have access to them nowadays. Systems that can adapt and take advantage of local feedstocks could ensure regions are not disfavoured because of limited availability of natural resources (e.g. fossil fuels).	Access to synthetic biology technology and its benefits is currently not equitably distributed: advanced economies tend to have better access to resources for scientific research and biomanufacturing than developing countries. Improving supply chain logistics, skilling opportunities and inclusive decision-making processes on tech research and governance, as well as enhancing science-based and risk-proportionate regulatory frameworks, could help ensure broader equity.

Table 4.2. Policies responses to technology-specific values

Technology-specific value	Potential policy achievements	Potential policy pitfalls
Trustworthiness	Inclusive two-way conversations between innovators, policymakers, and civil society can ensure the latter are aware of the technology's positive and negative impacts, whilst the former can understand and incorporate public needs into technology development.	Focus group experts raised that contemporary research funding structures are often hardwired to reward big promises, but overpromising the impact of synthetic biology applications can harm the trust and reputation towards the technology.
Responsibility	Increased awareness amongst frontline scientists driving synthetic biology innovation of the fundamental social impact of the technology and its dual use risks could create a culture of responsibility and build practices to mitigate harm from early research stages. This could take the form of awareness coursing in (under)graduate education or new funding incentives for considering risks.	Contemporary research culture tends to see a trade-off between academic freedom and national security, with security considerations sometimes seen as a compliance burden and passive check-listing.
Transparency	Enhanced transparency in the form of open-source models, safety benchmarks and monitoring frontier developments may increase safety and accountability. Sharing of challenges faced by scientists in mitigating risks, as well as best practices, could improve learning and inform future approaches.	Ongoing challenge to balance open science and biosecurity. For example, it may be advisable to not openly share certain pathogenic genetic sequences to prevent malicious actors from leveraging it to develop bioweapons. The risks of data misuse also extend to human genomic and other biological data; these risks—and associated safeguards--must be carefully considered to identify solutions that minimize risk while supporting legitimate research and development by trusted actors. Increasingly complex technologies can be hard to explain and prone to misunderstandings and fearmongering.
Technology stewardship	Technology Stewardship specifies that those developing the technology have the responsibility to guide the development of technologies with a view to the foundational values described above. In synthetic biology, there are examples of fostering Technology Stewardship, for example, the training in Responsible Research and Innovation for small firms and startups (see SynBioVen, UK).	Approaches to foster Technology Stewardship are developed in specific national or organizational contexts without sharing of best practices or an emerging global (or regional) guidelines. This not only leads to challenges for those wishing to "do better", but also the lack of a global guidelines means those who invest in Technology Stewardship require the investment of resources, giving unfair advantage to those firms that "move fast and break things".
Innovation for public good	Engaging civil society to develop democratically agreed visions of what society should look like and how technology can contribute to it can lead to technological applications that address societal needs, and thus are more robust and accepted.	As private funding for synthetic biology increases and innovators are less beholden to public funds (which are more accountable to societal priorities and safety obligations), technological developments could be more guided by the desires of large companies and less scrutinized by the public.
Responsiveness	Product developers engage with potential users to tailor their product and improve its beneficial societal embedding. Focus group members shared anecdotal evidence of firms that adapted their designs to reduce overall costs to the consumer (e.g. developing a solution that did not require cold chain delivery options, which are expensive – a departure from the original business model).	Additional research on risk assessments, clarity on regulatory approval processes for novel technologies and internationally aligned guidelines could improve speed at which synthetic biology applications reach people whilst ensuring utmost safety and security.

The tables above provide some illustrations of how synthetic biology developments could align with (reinforce), or misalign with (diminish), the 12 values of the OECD Framework for Anticipatory Governance of Emerging Technologies. This informed the identification of a number of open issues which have policy implications, presented below.

Figure 4.1. Five key issues and opportunities for synthetic biology policy and governance



Source: OECD.

Issue 1 - Balancing innovation promotion and risk mitigation requires agile and anticipatory governance. The problem of balancing innovation and mitigating risks is an ongoing governance challenge for emerging technologies. This is complicated by the dual-use nature of synthetic biology, particularly given the convergence with AI.

- Potential ***pathway forward:*** A lot of experimentation in governance approaches is taking place. Experts believed comparing and contrasting these could generate useful insights on what works, what doesn't and why that is the case. A key suggestion was that an international standard or code of conduct could be developed, bringing the best elements of these approaches together, to guide the responsible development and deployment of synthetic biology in real-time.

Issue 2 - Consideration of potential futures based on shared values. Experts underlined the need for articulating a range of diverse but plausible futures for synthetic biology and assessing (a) their desirability, (b) the plausibility given real-world circumstances and (c) the means to achieve them. Given the interconnected root causes of global crises, tackling them will likely require integrated and holistic solutions. This suggests avoiding prescriptive roles for synthetic biology and pursuing technology openness. At the same time, experts pointed out the opportunity cost not implementing synthetic biology solutions, especially in the context of growing economic nationalism and techno-protectionism where synthetic biology is now a key domain for strategic geopolitical competition and national security.

- ***Potential pathway forward:*** Forward-looking technology assessment exercises could be undertaken to inform anticipatory governance approaches. These exercises would best be done with a diverse range of stakeholders. Pursuing a systems thinking approach that connects the dots in how synthetic biology technology and policies impact across sectors could best leverage synergies and promote holistic solutions.

Issue 3 – Engagement (not communication) between synthetic biology developers, civil society and other stakeholders. Experts emphasised that the emerging synthetic biology ecosystem should be inclusive and uphold the democratic values of engagement and mutual exchange between developers and those potentially impacted by synthetic biology. This includes the preservation of the ability to dissent in productive ways. By truly engaging civil society actors, especially those most affected by synthetic biology or that risk being left behind in a transition to the bioeconomy, there is hope to co-develop a desirable vision of synthetic biology futures that avoids historical opposition to these technologies.

- ***Potential pathway forward:*** Exploring practices of stakeholder engagement via collection of case studies on process designs would be useful. To prevent disappointment and backlash, experts cautioned against overpromising synthetic biology's potential but highlighted that contemporary funding structures often reward big promises. Deep diving into these incentives and developing alternatives could help address the issue.

Issue 4 - Mapping structural equity barriers could inform efforts to find practical solutions. Experts identified a range of equity challenges – such as supply chain bottlenecks, education barriers and investment gaps – that are driving inequitable access to synthetic biology products and benefits. These disparities between advanced and developing economies, starting at the scientific research level, create structural dependence and constrain the ability of researchers from developing countries to innovate.

- Potential ***pathway forward:*** Unpacking which actors are responsible and which policy levers can be mobilised could address disparity between advanced and developing economies. Such an activity could learn from, or input into, other conversations in international fora, like the Convention on Biological Diversity's Nagoya Protocol which aimed to address the potential exploitation of genetic resources from developing countries. Another area would be to explore barriers to foundational research, such as supply chain issues in chemical reagents and equipment.

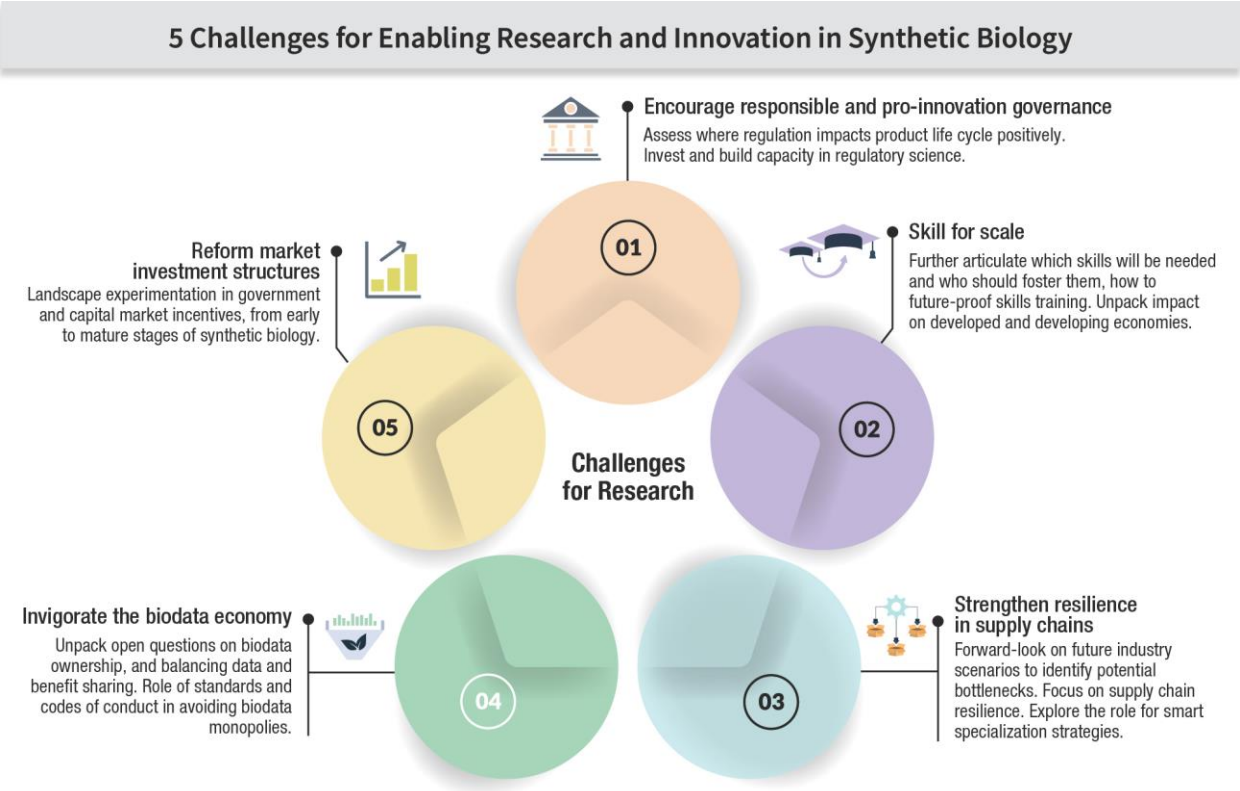
Issue 5 - Biosecurity and biosafety. Like many other scientific areas and technologies, synthetic biology is inherently a dual-use technology that can be mobilised for both beneficial and harmful ends. In addition, the nature of synthetic biology research and development requires good biosafety regulations, protocols and practices.

- ***Potential pathways forward:*** Experts suggested further multistakeholder discussions should consider how to enact foundational change in the risk management culture. For example, it could be desirable to shift from burdensome tick-the-box exercises to inspiring frontline scientists to consider security by-design approaches. This could involve exploring incentives to encourage researchers and developers to be transparent about biosafety and biosecurity risks and promote exchange of best practices. Similarly, funding structures could be transformed to encourage responsible research and innovation approaches, such as fostering increased collaboration between natural and social scientists, as well as to promote research in interdisciplinary technology assessment or relevant for risk assessment and management.

Research and innovation opportunities

The focus group identified a range of challenges for enabling research and innovation, all described in previous sections. On 16th September 2024, in two virtual meetings of two-hours, the expert group came together to discuss the key challenges for enabling research, innovation and diffusion of synthetic biology, described below.

Figure 4.2. Five challenges for enabling research and innovation in synthetic biology



Source: OECD.

Issue 1 – Reforming market investment structures. The size, urgency and sustainable timeline of investment required to realise the bioeconomy transition – both to promote synthetic biology and biomanufacturing development but also capacity building - calls for a major reform of financial structures. This could be informed by experimentation in government incentives (e.g. subsidies, public procurement, carbon tax, etc.) and innovation in capital markets (e.g. de-risking, new ways to pool investment, etc.), as well by better understanding of the long-term impact and interaction between public and private R&D funding. Incumbent industries may play a role if win-win solutions are developed (e.g. procuring from SMEs).

- ***Potential pathways forward:*** Organisations including the OECD could landscape different, and novel, investment approaches from early to mature stages of synthetic biology and biomanufacturing development.

Issue 2: Fit regulatory approaches to innovation. Regulatory barriers - such as complex processes, uncertain classifications for novel technologies, and internationally fragmented rules – are hindering the diffusion of innovation[52]. Some experts' fear this is leading to self-censorship by innovators who would pursue products that work most easily with current regulatory systems rather than those that may have the most transformative impact.

- ***Potential pathways forward:*** A detailed understanding of where in the product development cycle regulation is impacting the most could aid discussions on this matter. Early experiences in more fit-for-purpose, risk-based approaches to synthetic biology are welcomed by some experts. Assessing their long-term impact will better elucidate what regulation works in which circumstances. In addition, investment and capacity building in regulatory science could support these regimes in keeping pace with rapidly evolving products. This could help ensure regulatory bodies continue ensuring maximum safety whilst not becoming a bottleneck to synthetic biology diffusion.

Issue 3 - Building skills for the bioeconomy transition. Countries require a workforce with the necessary skills to leverage synthetic biology and biomanufacturing for building a flourishing bioeconomy. Yet barriers remain to ensuring a just and responsible transition. Issues like brain-drain disproportionally affect developing economies, and minimising or compensating for negative consequences like job losses stemming from closures of traditional industries should be a top priority.

- ***Potential pathways forward*:** Integrating existing studies, and taking them further to gain better understanding of what new skills will be needed, how they can be fostered, and which players should be engaged (e.g. unions, accreditation bodies, etc.) would be highly valuable. Further unpacking the impact on developing economies and traditional industries (e.g. by better forecasting labour losses and how to best promote responsible job replacement and retraining programs) would be useful. The long-term (even generational) process may also call for further discussions on how to future-proof skills training.

Issue 4: Complexity of transforming global supply chains with a view to hybrid centralised and decentralised production. The promise of synthetic biology and biomanufacturing to transform incumbent petrochemical industry is coupled with the promise of distributed and decentralised manufacturing. These two different industry models will likely co-exist and, in some cases, blend together. This creates great complexity in global supply chains, particularly with issues such as export controls, supply chain resilience issues due to polycrisis such as war and climate change and issues emerging from increasing geopolitical tensions creating a shift to technological sovereignty.

- ***Potential pathways forward:*** A forward-look on alternative industry models and scenarios of the bioeconomy would help identify the hurdles, bottlenecks and brick walls that may hinder the emergence of a flourishing bioeconomy. A focus on supply chain resilience, as well as a deeper understanding on centralised and decentralised value chains would be highly beneficial. Similarly helpful would be scoping approaches to national development plans or regional smart specialization strategies.

Issue 5 - Barriers to sharing biodata. Biodata is essential for synthetic biology innovation, especially as synthetic biology converges with AI and automation, but obstacles to data sharing remain. Addressing these may require unpacking open questions around biodata ownership and control, and will also require nuanced consideration of how to balance the benefits of open sharing of biodata with the risks associated with data misuse by nefarious actors,. Discussions in the focus group raised issues such as potential industrial monopolies of biodata, the lack of quality standards in biodata sets, and fragmented regulatory frameworks for the exchange and use of biodata.

- ***Potential pathways forward:*** The development of international biodata standards would be beneficial, along with exploring the tensions and opportunities in sharing and mobilising biodata in future research and development of synthetic biology and biomanufacturing – such as further consideration of mechanisms to enable biodata sharing among trusted actors while protecting sensitive data from misuse. Regarding data monopolies, whilst regulation may not be fully equipped, current regulatory frameworks could be complemented by codes of conduct developed at and endorsed at the international level, to provide a benchmark of good practice. Developing and dissecting future scenarios of synthetic biology's convergence with AI and automation could shed further light on the field's biodata needs, challenges and potential solutions.

Outlook

Providing a complement to existing reports that describe synthetic biology and its promise, this document reports on the findings of the Global Forum on Technology's expert focus group which over a 12-month period has explored the landscape of synthetic biology innovation, further articulated expectations about future developments and their impacts, and identified key policy and governance implications – described in previous sections. Building on this, this *Outlook* section outlines potential roles for the OECD put forward by the expert group as a whole and where the expert group sees the OECD's expertise and institutional role could be most impactful.

OECD recommendation for the responsible development of synthetic biology. A key potential area identified was the need for agile governance that anticipates and co-evolves with synthetic biology. Soft-law, non-binding codes and regulatory sandboxes that focus on learning whilst fostering responsible development offer a possible route to lay the groundwork for and complement the development of legally binding regulation. The focus group suggested that the OECD could play a role through the development of a recommendation for the responsible development of synthetic biology. This would build on the OECD's extensive experience in governing emerging technologies, as seen in the recommendation for neurotechnology [OECD/LEGAL/0457] and the aforementioned OECD Framework for Anticipatory Governance of Emerging Technologies. Such a recommendation could enshrine political commitments (such as equity, multidisciplinary collaboration or public engagement) in an international standard that guides policymakers, innovators and civil society in implementing responsible innovation practices.[53]

Space for exchange on best practices in technology appraisal. As showcased in this report, there is a great deal of ideation and experimentation taking place on governance approaches – from reframing biosecurity culture to two-way public engagement. Being able to learn what approaches are successful (and which aren't) is key to supporting a speedy implementation of responsible innovation and avoid duplicative efforts. Leveraging the OECD's reputation as an international knowledge hub, the focus group suggested it could provide a space to convene relevant stakeholders, collect and compare best practices in engagement, technology assessment, risk appraisal and agile governance approaches. Previous successes like the 1986 Blue Book and 1993 Green Book which shaped biotechnology standards and regulations, as well as the more recent OECD.AI Policy Observatory, could provide inspiration.

Provide a voice to smaller or developing economies. Experts believed policy and governance examples should come from countries beyond OECD membership, as a truly global perspective is necessary to understand how synthetic biology can benefit all. In fact, the Global Forum model that allowed the group to engage experts from all five continents was critical to providing rich insights into

shared global challenges as well as regional differences in the design, development and governance of synthetic biology and associated biomanufacturing technologies. This is demonstrated in cases throughout the report, such as those contrasting research constraints in advanced and developing economies, or those on the different challenges and approaches to building national infrastructures across continents. The OECD could ensure this by continuing to provide a platform for smaller economies to share the unique challenges they face in the transition to flourishing bioeconomies (e.g. limited funds for infrastructure, need for specialization in a global ecosystem, etc.) but also how they are leveraging their unique attributes (e.g. finding niches for contributing to a global bioeconomy market). It could also facilitate similar regional dialogues for developing economies, for best practice sharing and to encourage public-private partnerships. These efforts should taken into account existing regional fora (e.g. ASEAN).

Develop advanced indicators and evaluation methods for synthetic biology and associated policies. As a growing number of countries establish national bioeconomy strategies, the next policy step is likely to be moving from these abstract, high-level commitments to detailed implementation measures. For this transition to be successful, experts believed concrete, evidence-based insights should be available to guide these efforts. The OECD could contribute by developing new advanced voluntary indicators and evaluation methods for tracing the scientific, economic, environmental and societal impact of synthetic biology technologies and related policies. It could leverage the OECD's extensive statistical experience, for example in in economic indicators or environmental indexes, could be a great asset. Such information would help innovators and policymakers identify which technologies and/or policies add value and should be incentivised.

Provide holistic assessment of finance approaches. The focus group identified the need for a fresh look at financing of synthetic biology research and innovation, with a view to the broader bioeconomy, in response to the scale of transformation – and thus investment – needed. The OECD could bring together evidence on novel finance approaches by both public and private actors along the innovation journey, from fundamental research through scaling to diffusion into the market. Such an activity could provide guidance to policymakers to shape national policies. Given the urgency of the climate crisis and the potential solutions provided by synthetic biology, the OECD's economic expertise could also be leveraged to assess methods promoting the delivery of climate-positive solutions (e.g. pricing in externalities via carbon taxes), provide evidence-based insights on related economic arguments (e.g. the impact of such taxes on incumbent industries), or identify win-win economic models for incumbent and nascent industry actors. It could also analyse climate cooperation mechanisms (e.g. green bonds, carbon credits) given the opportunity they represent for smaller economies to raise funds for environmental and climate change mitigation projects where synthetic biology developments could be applied.

Further anticipate the convergence of synthetic biology with artificial intelligence, automation and robotics. The expert focus group identified convergence as a high impact area, highlighting that the future development and diffusion of synthetic biology will be catalysed by further convergence with artificial intelligence, automation and robotics. For example, distributed and decentralised manufacturing and circular solutions are envisioned to be accelerated by such convergence. The OECD could future-proof governance and innovation policies by anticipating on such convergence.

Annex A. Process and focus group experts

Methodology

The focus group met a total of 16 times (8 sessions held twice a day to allow maximum representation across time zones) between November 2023 and September 2024. With the aim to follow a bottom-up approach, early discussions were structured as open roundtables to allow experts to voice their thoughts on which were the key issues in synthetic biology and in which sectors it would have the biggest impact. This mapped the high impact areas and key policy themes reflected in this report and guided more focused discussions going forward.

A **working document** was developed for each of these two sections to act as an information repository for focus group experts and provide them a platform between meetings to add information and to respond to comments. The Secretariat developed an initial set of guiding questions and curated the input received.

These working documents were also built up by the **regular meetings**, which included thematic discussions deep-diving into each of the key policy themes that were identified. Every meeting, one or two selected experts provided an opening presentation to kick-start the conversation among the broader group. The insights gained from these conversations were captured in the working documents for experts to reflect and add to.

In parallel, a **technology forecasting survey** was sent to experts to collect their expectations on which synthetic biology developments would be most impactful in the short (5 years), medium (5-10 years) and long (10+ years) term, as well as the accompanying challenges. Some experts took the initiative to conduct an additional survey among their national experts to provide further input[54].The results of this exercise are reflected throughout the report and can be found in more detail in Annex B.

This report also leverages the insights gained from the OECD Global Forum on Technology (GFTech) **event "*Building our Biofuture**: Policy issues and opportunities for next generation biotechnologies*" held on 22 April 2024 in the margins of the OECD Scientific and Technological Policy Committee meeting at the Ministerial level at the OECD Headquarters in Paris, France. The insights from the focus group helped shape the agenda and content of the event, in addition to many focus group experts attending as speakers or participants. Details can be found in Annex C.

Focus group experts were able to review and comment on the draft version of this report, both via written feedback and in the final meeting.

List of focus group experts

The focus group on synthetic biology has 66 experts from 32 different countries - representing Africa, Asia, North America, Latin America, Europe and Oceania - as well as a number of non-profit organisations operating internationally. Experts' backgrounds include academia (natural and social science), government, innovation associations, industry and civil society organisations.

Experts were chosen based on recommendations from delegations of the OECD Committee for Scientific and Technological Policy (CSTP) and complemented by experts chosen by the OECD Secretariat to improve representation from non-OECD countries as well as fill gaps in expertise on specific topics.

Table A.1. Focus group expert list

Country	Name	Affiliation
AT	Markus Schmidt	Biofaction
AU	Claudia Vickers	Queensland University of Technology
AU	Robert Speight	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
BE	Delphine Thizy	Outreach Network for Gene Drive Research
BE	Patrice Soumillion	Université catholique de Louvain (UCLouvain)
BG	Slavil Pejkov	University of Sofia
BR	Danielle Biscaro Pedrolli	Sao Paulo State University - UNESP, Brazil
CA	Vincent Martin	Concordia University
CH	Martin Fussenegger	ETH Zurich (Swiss Federal Institute of Technology, Zurich)
CH	Yolanda Schaerli	Univeristy of Lausanne
CL	Luis Larrondo	iBio Millennium Institute for Integrative Biology (iBio)- P. Universidad Catolica de Chile
CR	Montserrat Jarquín Cordero	Costa Rican Institute of Technology (ITCR)
DE	Christine Lang	MBCC group
DE	Tobias Erb	Max Planck Institute for Terrestrial Microbiology
DE	Harald Koenig	Karlsruhe Institute of Technology, Institute for Technology Assessment and Systems Analysis (ITAS)
DZ	Halima Benbouza	National Council of Scientific Research and Technologies of Algeria
ES	Marc Güell	Universitat Pompeu Fabra (UPF)
ES	Alfonso Jaramillo Rosales	i2sysbio (CSIC)
ES	Germán Alejandro Rivas Caballero	Spanish National Research Council (CSIC)
FR	Nina Youssoufou	Ministère de l'Europe et des Affaires étrangères
FR	Jean-Loup Faulon	French National Research Institute for Agriculture, Food and the Environment (INRAE)
FR	Fayza Daboussi	French National Research Institute for Agriculture, Food and the Environment (INRAE)
FR	Gilles Truan	French National Centre for Scientific Research (CNRS)
FR	Emmanuel Dequier	Ministry of higher education and Research
FR	Sophie Perreson	Sciences Po University
GT	Alejandra Sierra Aguilera	Universidad del Istmo
IE	Mark Tangney	University of Cork
IN	Krishna Ravi Srinivas	NALSAR University of Law & Research and Information System for Developing Countries
IT	Mauro Magnani	Università degli Studi di Urbino Carlo Bo
IT	Diego di Bernardo	University of Naples "Federico II", Naples, Italy
IT	Paolo Magni	University of Pavia
JP	Wataru Mizunashi	NEDO New Energy and Industrial Technology Development Organization
JP	Takeo Miyake	Graduate School of Information, Production, and Systems, Waseda University
JP	Makiko Matsuo	University of Tokyo
JP	Akihiko Kondo	Kobe University
KR	Byung-Kwan Cho	Graduate School of Engineering Biology / KAIST

KR	Buhm Soon Park	Graduate school of STP/ KAIST
NL	Michelle Habets	Rathenau Institute
NZ	Emily Parker	Victoria University of Wellington, New Zealand and the Ministry of Business Innovation and Employment, New Zealand
PA	Ediner Fuentes-Campos	National Research System (Sistema Nacional de Investigación - SNI), National Secretariat for Science, Technology, and Innovation (Secretaría Nacional de Ciencia, Tecnología e Innovación - SENACYT) of Panama
PT	Paula Tamagnini	University of Porto
SE	Lars Friberg	Sweden's Innovation Agency – Vinnova
SG	Chueh Loo Poh	National University of Singapore
SI	Roman Jerala	National institute of Chemistry
TH	Alisa Vangnai	Chulalongkorn University & BIOM
TH	Pakpoom Subsoontorn	Naresuan University
TR	Urartu Seker	Bilkent University
UG	Geoffrey Otim	SynBio Africa
UK	Isabel Webb	Dept for Science, Innovation and Technology, UK Government
UK	Richard Kitney	Imperial College / SynbiCite
UK	Joyce Tait	Innogen Institute, University of Edinburgh
UK	Diego Oyarzún	University of Edinburgh
UK	Eriko Takano	Manchester Synthetic Biology Research Centre, SYNBIOCHEM
UK	Jenny Molloy	University of Cambridge
US	Richard Johnson	iGEM / BIAC
US	Bianca Garner	National Science Foundation
US	Sam Weiss Evans	US National Security Commission on Emerging Biotechnology
US	Nathan Hillson	Lawrence Berkeley National Laboratory
US	Megan Palmer	Ginkgo Bioworks
US	Mary Maxon	Carnegie Sciences
US	Drew Endy	Stanford University
US	Ryan Morhardt	Ginkgo Bioworks
ZA	Deepak Govindaraj	Council for Scientific and Industrial Research
INT	Fiona Mischel	SynBioBeta
INT	Becky Mackelprang	Engineering Biology Research Consortium
INT	Pam Dixon	World Privacy Forum

Annex B. Technology forecasting

To identify and unpack the most impactful scientific and technological developments expected in the short, medium and long term, focus group experts were asked to complete a survey sharing their expectations for future synthetic biology advancements. Some experts took the initiative to conduct an additional survey among their national experts to provide input to the OECD survey[55]. The insights are summarised and put into context in the body of this report, but are also shared in more detail in this Annex. They are classified into four tables, the first for the foundational and cross-sectoral developments, and the remaining on three impact areas identified by the experts and explored in the first section of this report (health, food security and soil regeneration, circularity and emissions reduction).

Table B.1. Expected foundational scientific and technological developments

1 - 5 Years	5 - 10 Years	10 + Years
Next-generation gene editing tools - More accurate, efficient and versatile than current technologies (e.g. CRISPR-Cas9), enabling more precise genome modifications at multiple sites simultaneously.	**Biocontainment measures** - More complex recoding of bacteria for biocontainment (e.g. synthetic auxotrophy) could enable more control of environmentally released organisms.	**Synthetic cells** - Bottom-up creation of artificial, fully autonomous cells can help scientists better understand life. Cells can be leveraged for production of cheap molecules, where classical metabolic engineering is not competitive and might never be.
DNA sequencing and synthesis - Improving affordability, speeding up process and expanding synthesis length could address current bottleneck for cost and time (especially in developing countries)	**Tools in more complex organisms** - Expanding beyond engineering single cells/organisms towards plants and animal cells for new opportunities, such as efficient synthesis of new high value and complexity molecules	**Living computer platforms** - Advanced biological computing integrating biological and digital systems for complex problem-solving
Gene and whole genome synthesis - Enzymatic synthesis could herald era of low-cost access to drive further research, as DNA sequencing or PCR has done for molecular techniques	**Developing a BioNet** - Building a global ecosystem of synthetic biology organisations, talent and infrastructure could create a network effect to improve the design, development and deployment of synthetic biology, and thus increase access and resilience.	**Massive genome editing and genome rearrangement** - Orders of magnitude bigger than current methods for faster development and new engineering possibilities.
Engineering of non-model organisms - Easier and faster processes could better explore use of new bacteria for research and product design, improving flexibility	**Biosensors for real-time monitoring** - Including whole-cell biosensors, designed to detect target compounds e.g. in environment (pollutants, heavy metals), in vivo in cattle (health monitoring) and in vitro human diagnosis	**Space applications** - For long-term space missions, such as production (e.g. food, materials) and terraforming other planets
More robust synthetic biological circuits - Current circuits only function under controlled lab conditions and for a limited time. Improved	**Wider access to biofoundries** - Maturing technology will allow lower prices and	**Information storage** - Encoded information in synthetic DNA molecules could be an alternative to

robustness could deal with environmental fluctuations and evolutionary pressures, aiding real-world applications.	address current bottleneck of expensive access, mainly by elite organisations	current data storage methods and reduce cooling needs. Bio-based semiconductors could further advance the field.
Faster design-build-test-learn cycles - By routinizing bioengineering workflows, improving genome programming and screening methods, the pace of innovation can be accelerated.	**Engineered living materials** - For packaging, fashion, construction, electronics... with new features. Vice versa, incorporation of new-to-nature elements into living systems e.g. bio-fluoropolymers	
Practical advances in fermentation - Scale up technologies like continuous fermentation, with improvements in reducing media, media formulation, and downstream processing will help reduce cost of synthetic biology products.	**New analytics and visualization technologies** - For example, quantum analysis of single proteins or spatial omics to understand presence of molecules within a tissue architecture	
Bioproduction of valuable biomolecules - Advances in using engineered cells to produce substances which could not be biomanufactured before (e.g. flavonoids), enable alternative and more sustainable production		

Table B.2. Expected scientific and technological developments in health

1 - 5 Years	5 -10 Years	10 + Years
Precision and personalized genome editing therapies - Therapies could be tailored to patients' individual genetic profiles for treating genetic disorders, cancers, and rare diseases. Include cell and gene therapies like CAR-T, but may rely on new DNA-editing tools. Improved non-viral delivery methods will advance the technology.	**New drug design and delivery strategies** - New molecular biology design tools, as well as new materials for in situ delivery (e.g. non-viral vectors to efficiently deliver DNA/RNA/proteins in vivo)	**Regenerative medicine and tissue engineering** - Synthetic biology could enable the creation of complex tissues and organs based on stem cell biology and scaffold design (e.g. 3D printing, cultures, embryo-based...). Long-term advancements could allow growing functional organs for transplantation, develop personalized regenerative therapies and treat organ failure and complex tissue injuries.
Immune cells engineering - Reprogramming patient's immune cells to treat diseases like cancer (e.g. CAR-T cell therapy), autoinflammatory diseases and ageing. Already available but further reductions in cost will increase accessibility.	**Xenotransplantation** - Optimized synthetic animals for growing human-compatible organs to address shortages, long waitlists and even improve compatibility.	**Organoid engineering** - Would enable the creation of complex, functional tissues for research, drug testing, and therapeutic applications.
Engineered probiotics - For enhancing gut health or even delivering therapeutic compounds	**Biosensors** - Engineering of cells to detect chemical contaminants, pathogens and diseased cells for innovative diagnostics tests.	**Living therapeutics** - Engineered cells performing therapeutic functions within the body, providing continuous and regulated treatment, reducing the need for frequent dosing and improving patient outcomes. Particular breakthroughs for chronic disease management and regenerative medicine.
RNA-therapeutics - RNA used to develop therapies, most notable mRNA vaccines used against COVID-19	**Microbiome therapies - Engineering the microbial communities** in the skin, gut or mouth to target diseases in those areas.	

Improved bioproduction of biological drugs - Using engineered cells to produce antibodies, enzymes, viruses for gene therapy	**Engineered living materials for biomedical applications** - Biological instructive materials containing living cells in and provide signals to surrounding cells and tissues. These could be used for healing wounds, drug delivery, or diagnostics.	
Antibiotic alternatives - Such as engineered bacteriophages, to tackle the antimicrobial resistance crisis		

Table B.3. Expected scientific and technological developments in food security and soil regeneration

1 - 5 Years	5 -10 Years	10 + Years
Edited crops for improved nutritional profiles - Crops could be engineered to produce larger quantities of existing nutritional components as well as completely new ones	**Microbiome engineering** - Understanding interspecies interactions and designing synthetic consortia with desired functions will open new possibilities for probiotics, bioremediation, and crop enhancement. Advances in this field will require integrated approaches combining microbiology, ecology, and synthetic biology.	**Modification of complex plant organs** - Engineering new capabilities into plants, such as self-repair
Plants with enhanced properties - Such as drought resistance, adapted response to environmental challenges (e.g. delayed blooming...) for increased climate resilience, CO2 fixation for geoengineering	**Cross-species cell fusion** - To enhance new breeding technologies for crop development.	**Soil health** - metabolic pathways for plants and microbes could be engineered to better fix nutrients into the soil (e.g. nitrogen)
Synthetic food and ingredients - Alternative food sources, such as lab-grown meat and plant-based proteins, as well as novel food ingredients. These can address food security challenges, reduce the environmental impact of agriculture, and provide healthier food options.	**Biofertilizers** - Such as engineered microbes to self-fertilize plants, aiming to avoid use of chemical fertilizers.	
Bioremediation - Genetically modified microorganisms could degrade pollutants and facilitate the clean-up of soil and water in contaminated areas.	**Biopesticides and bioherbicides** - Help increase crop yield by tackling pests and weeds using engineered microbes and crops instead of toxic chemicals.	
Engineered probiotics - Designed to perform specific functions, such as promoting plant growth, improving nutrient absorption, and protecting crops from pests and diseases - as a more sustainable practice than existing methods	**Biosensors** - Real-time monitoring concentrations of analytes of interest in the environment (pollutants, toxins, heavy metals…).	
Precision agriculture, empowered by AI - Automated systems, big data and machine learning can help farmers optimize production by leveraging data insights on their fields' soil conditions, crop health and weather patterns. Combined with synthetic biology advances in developing new crop varieties, it could pave the way for vertical farming systems for small-scale biofabrication.		

Table B.4. Expected scientific and technological developments in circularity and emissions reduction

1 - 5 Years	5 -10 Years	10 + Years
Bio-based production - Engineered microorganisms can use bio-based feedstocks instead of fossil fuels to develop bio-based products. This would help reduce reliance on fossil fuels and enable more sustainable production systems.	**Advances in bio-based production of chemicals** - One of the most fossil-intense sectors globally. Some foundational chemicals such as ethanol are already being made via synthetic biology (e.g. biocatalysis and enzyme-based reactions) but advances in more complex chemicals are needed. Synthetic biology doesn't produce the same toxic byproducts as the petrochemicals industry.	**Improved biological fixation of CO2 from atmosphere** - Also known as Bioenergy with Carbon Capture and Storage (BECCS), this is already naturally done by photosynthesis, but synthetic biology could combine and rewire native CO2 fixation pathways to increase rate and efficiency of carbon fixation. Could be done in several autotrophs (e.g. plants, algae, cyanobacteria) as well as cell-free systems.
Waste treatment and revalorisation - Engineered microorganisms can convert waste materials (e.g. from agriculture, industry) into feedstocks for further production processes, enabling circular systems.	**Carbon Dioxide Removal (CDR) from the atmosphere** - Needed to reduce CO2 concentration in the atmosphere, offset hard-to-eliminate emissions and recover from any overshoot in safe CO2 concentrations. Many methods for this (e.g. Carbon Capture and Storage, Direct Air Capture...) which synthetic biology could contribute to.	**Improve circulation of non-carbon elements** - Nitrogen and phosphorus, for example, are extremely important for ecosystems and societies. Engineered microorganisms or plants could improve nitrogen fixation from the air or recover phosphorus from the water.
Biofuels - Demand for sustainable fuels is rapidly increasing, particularly in maritime and aviation sectors, which synthetic biology methods could meet to enable carbon neutral shipping and transport.	**Carbon sequestration into biomass** - Locked long-term in rocks, building materials, products, or even released to the bottom of oceans.	**Phytomining** - Genetically modified plants to accumulate metals in the soil and be harvested for their metal content
Biodegradable plastics and enzyme-powered plastic decomposition - Plastic pollution is a major environmental concern. Synthetic biology can produce biodegradable plastics, or develop solutions to degrade plastic and/or convert it into useful chemicals for re-use.	**Gas fermentation** - Using microorganisms to convert gaseous feedstocks into chemicals/products/fuels... Could be applied to municipal waste gasification or to help decarbonise carbon-intensive industries. However, requires additional support as fundamental fermentation technology is different and not nearly as advanced as traditional fermentation technology.	

Annex C. 'Building Our Biofuture' Event

The OECD Global Forum on Technology (GFTech) event "*Building our Biofuture: Policy issues and opportunities for next generation biotechnologies*" took place on 22 April 2024 in the margins of the OECD Scientific and Technological Policy Committee meeting at the Ministerial level at the OECD Headquarters in Paris, France.

It aimed to bring together diverse stakeholders for an in-depth dialogue deep diving into the promise of next generation biotechnologies, the associated policy challenges and the opportunities to address them. The agenda and discussions built on the work of the GFTech expert focus group on synthetic biology, whose insights helped shaped the event and to which many of the speakers belong.

Over 300 participants from 50 countries attended the event onsite and online. This included senior policy makers, such as the Ministers of Science and Technology from Chile and New Zealand, as well as industrial actors at the CEO level, frontline natural and social scientists, and civil society.

Following opening remarks by high-level policymakers on the role of policy and international collaboration, as well as an industry keynote on the promise of synthetic biology, discussions were arranged as four panels deep-diving into four key areas of synthetic biology: human health, agrifood and environment, anticipatory governance and responsible innovation, and sustainable production. A final session collected closing remarks from selected speakers and attendees, highlighting what they found the most striking from the day's discussions and how to take the conversation forward.

Policy perspectives: the promises and challenges of emerging technology

Policymakers from three continents agreed on the immense promise held by biotechnology in addressing global and local challenges, from climate change to food security, but noted that managing associated risks was crucial. Ensuring equitable access to technological benefits was identified as key and requiring inclusive stakeholder engagement to prevent deepening societal divides. Governments could improve their ability to regulate rapidly evolving technologies by building their anticipatory governance capacity, although they recognised the difficulty of this at a time of seemingly constant crises. International collaboration was deemed essential, with organizations like the OECD providing value by acting as knowledge hubs and norm setters and facilitating evidence-based dialogues.

Keynote address

Synthetic biology has the potential to be as transformative as the digital revolution and whose pace of innovation is being further accelerated by its convergence with other technologies like lab automation and cheaper DNA synthesis and gene editing, as well as AI tools like GenAI and large language models. Countries aiming to leverage this potential by developing their national bioeconomies could focus on building flexible biomanufacturing capacity and strengthening their biosecurity infrastructure.

Panel 1: Human health innovation and resilience

Novel treatments for infectious diseases like malaria and non-communicable diseases like cancer could be enabled by synthetic biology, especially when combined with AI and data technologies. To keep pace with the speed of innovation and provided legal clarity for developers, speakers argued that regulatory frameworks needed to be updated and harmonized globally whilst keeping safety and efficiency top of mind. Developing infrastructure, especially in low-resource settings, is vital for rapid deployment and adoption of health solutions, as is public trust built through transparent communication.

Panel 2: Agrifood and environmental resilience

In the face of food and climate crises, synthetic biology solutions like genetically modified organisms and synthetic microbial communities can enhance environmental sustainability by improving soil health, boosting agricultural productivity, and reducing the environmental impact of food production. However, speakers found that regulatory barriers and public concerns are hindering the implementation of these technologies, and thus called for agile regulatory frameworks and transparent public engagement to address risks, build trust and ensure safe deployment. The role of international partnerships was highlighted for fostering practical measures like common standards whilst also promoting values like equitable access.

Panel 3: Anticipatory governance and responsible innovation

Finding the balance between maximising the benefits of synthetic biology to revolutionise key sectors while preventing risks and misuse is an ongoing governance challenge. For example, whilst synthetic biology can pose biosecurity risks, it can also offer solutions to these very risks. Speakers advocated for anticipatory approaches that improve foresight capacity, inclusive governance involving input from diverse stakeholders and the public, and engaging the next generation of scientists to foster a culture of responsibility early on.

Panel 4: Sustainable production: the bioeconomy and beyond

Biomanufacturing – leveraging microorganisms genetically engineered to produce desired molecules – can transform the production industry by enhancing efficiency and resilience, and improve sustainability by enabling the replacement of petrochemicals with biobased feedstocks to reduce carbon footprints. However, scaling from lab to industrial production remains challenging and speakers argued for more research, supportive policies, and workforce development. Other solutions could involve integrating traditional knowledge with modern biotechnologies, which can boost local economies if quality is ensured and resistance is managed, and ensuring effective data sharing via trusted networks and quality standards.

Panel 5: International and multistakeholder comments

Selected speakers reflected on the day's discussions by stressing synthetic biology's transformative potential for addressing global challenges and driving economic growth, especially given the promising convergence with digital tools and AI. They also highlighted the importance of national and international actions to ensure risks are mitigated and the benefits are shared equitably. Continued dialogue and collaboration, including through forums like the OECD Global Forum on Technology, were considered crucial to advancing these goals.

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Endnotes

1 At the time of writing, there is no internationally agreed definition of synthetic biology. Sometimes broadly defined, for example the definition in the Convention on Biological Diversity (https://www.cbd.int/synbio), or more specifically defined based on technical approaches mobilised, for example the Engineering Biology Research Consortium (https://ebrc.org), the lack of a standard definition of synthetic biology is seen as a challenge by the expert focus group, particularly for developing or adapting legislation.

2 https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy.

3 https://www.gov.uk/government/publications/national-vision-for-engineering-biology/national-vision-for-engineering-biology.

4 https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_24_1610.

5 https://www8.cao.go.jp/cstp/bio/bio_economy_en.pdf.

6 https://www.csiro.au/en/work-with-us/services/consultancy-strategic-advice-services/csiro-futures/future-industries/synthetic-biology-roadmap.

7 Whilst many of the induced beneficial traits mentioned in this paragraph can and have already been achieved in crops via more 'conventional' or biotechnological methods (e.g. selective breeding, directed evolution, or random mutations), synthetic biology and genome editing provide alternative approaches which have the potential to be more efficient or accurate.

8 It should be noted that biofertilizer applications may also have unintended detrimental effects requiring safety assessment protocols, as detailed in "Biofertilizer microorganisms accompanying pathogenic attributes: a potential threat" by Tariq et al. and accessible here: https://pubmed.ncbi.nlm.nih.gov/35221573). In addition, there are still many unknowns around the composition of microbial communities and their role in soil ecosystems, and further research is needed to understand the complex interactions of genetically modified microorganisms with the environment.

9 For example: the Cartagena Protocol on Biosafety, the OECD Working Parties on Harmonization of Regulatory Oversight in Biotechnology (WP-HROB) and Safety of Novel Foods and Feeds (WP-SNFF), the Codex Alimentarius, and the UN Food and Agricultural Organization. In addition, the International Union for the Conservation (IUCN) of Nature has prepared a policy paper for synthetic biology, which will be delivered for adoption by IUCN members at the 2025 World Wildlife Congress. The OECD has done extensive work on environmental risk assessments, such as the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology's Consensus Document on Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants (OECD, 2023[34])and the series Safety Assessment of Transgenic Organisms in the Environment

https://www.oecd.org/en/publications/safety-assessment-of-transgenic-organisms-in-the-environment-volume-10_62ed0e04-en.html.

10 “Golden rice” is a genetically modified strain of rice fortified to produce the precursor to vitamin A and aid populations facing dietary vitamin A deficiency. In 2021, the Philippines became the first country to approve its commercial propagation. However, after campaigns by local farmer associations and Greenpeace Southeast Asia, the Court of Appeals in the Philippines revoked the biosafety approvals despite no scientific evidence of any risk associated with golden rice (McKie, 2024[31]).

11 A recent study by Agbio Investor (a UK-based consultancy and analytical firm), found it takes 16.5 years and costs $115 million to bring a new GM crop trait to market. The regulatory phase accounts for 40% of the total cost and 51% of the total time. More information here: https://gm.agbioinvestor.com/gm-trait-study.

12 Scale up of biofuel production with genetically modified microalgae is most likely involving production in semi-open pond systems. Unintended environmental release of significant amounts of these organisms from such production facilities cannot be avoided, particularly in accidents or extreme weather events. There are therefore biosafety risks associated with this technology. For more information, see “Environmental applications of GM microorganisms: Tiny critters posing huge challenges for risk assessment and governance: by Eckerstorfer et al. submitted to IJMS.

13 Japan’s New Energy and Industrial Technology Development Organization (NEDO) is funding the world's largest facility of microalgae production facility. "CHITOSE Carbon Capture Central (C4)" in Malaysia aims to demonstrate the cultivation of microalgae as a source of Sustainable Aviation Fuel that would lead to a stable mass cultivation technology. More information can be found here: https://www.nedo.go.jp/english/whatsnew_00302.html.

14 Further discussions may unpack what is considered “waste” and the regulatory barriers to its use (e.g. many countries do not allow waste to be used for food or feed processes). Redefining the term may be needed to allow its use as feedstock and promoting circular approaches.

15 https://www.gov.uk/government/speeches/sustainable-aviation-fuel-initiatives.

16 The USDA BioPreferred Program was created in 2002 to foster the bio-based product market via mandatory purchasing requirements for Federal actors and voluntary product certification and labelling. However, focus group experts this initiative’s impact was limited by the lack of regulation on how many bio-based inputs companies need to use, as well as the lack of specific procurement codes for bio-based products.

17 https://www.bdcnetwork.com/france-mandate-all-new-public-buildings-be-50-timber-or-other-natural-materials?page=152.

18 Japan’s Resource Circulation Strategy for Plastics: https://www.env.go.jp/content/000050297.pdf.

19 The Institute for Future Initiatives at the University of Tokyo recently published a working paper as part of its academia-policymaker collaborative program “Promotion of Biomanufacturing That Enables

Bioeconomy: Visualization of Policy Challenges and Institutional Design". Written together with government officials involved in biomanufacturing policy, it recognises that fragmented governance structures are hindering the possibility of anticipatory governance. It calls for a holistic approach that goes beyond the silos created by different policies (e.g. promotion and management). Via a framework, it identifies the full portfolio of activities which should be considered, showing how different policies are interconnected and how they can be interconnected. More information can be found here: https://ifi.u-tokyo.ac.jp/en/wp-content/uploads/2024/09/WP032.pdf.

20 https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.

21 https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/common-control-lists.html.

22 https://ibbis.bio/our-work/common-mechanism.

23 DDoS (distributed denial-of-service) attacks are a type of cyberattack which aim to overwhelm the traffic of a targeted website, server, or network with a flood of malicious Internet traffic, disrupting normal activity. More information at: https://www.cloudflare.com/learning/ddos/what-is-a-ddos-attack.

24 The results of the Ad Hoc Technical Expert Group on Synthetic Biology of the Convention on Biodiversity (CBD/SYNBIO/AHTEG/2024/1/3) are relevant. It identifies some of the main challenges for the risk assessment of organisms genetically modified using synthetic biology tools converging with AI : the lack of certainty regarding the taxonomic identification of parental microorganisms, the lack of non-modified comparators with a history of safe use, the complexity of the receiving environments, the very limited understanding of microbial interactions in environment and their consequences and the limited availability of environmental data for risk assessment.

25 https://www.nti.org/analysis/articles/the-convergence-of-artificial-intelligence-and-the-life-sciences.

26 The 'Gartner hype cycle' aims to graphically represent the stages of technology development over time, from inception to productive maturity. It states that inflated expectations of a new technology will lead to disillusionment and company failures as it inevitably fails to meet all promises. However, as more realistic criteria are set out, next-generation products can see mainstream adoption. More information is accessible here: https://www.gartner.com/en/research/methodologies/gartner-hype-cycle.

27 Four legal matters in particular were identified as being critical to a flourishing synthetic biology industry. First, addressing a range of intellectual property right issues, such as patents, design rights, copyright, and the risk patent thickets. Second, liability concerns (around design defects, trying to get legacy companies to transition to SynBio, data issues from collaborators or data-sharing organizations…) that would need to be resolved to foster an insurance industry that can price risks and thus support corporate adoption of SynBio. Third, supportive competition policy and national innovation/industrial policies. Fourth, implications of trade policies like decoupling.

28 https://www.toulouse-white-biotechnology.com/en.

29 Research infrastructures are facilities or groups of facilities that provide resources and services to research communities to facilitate their work and scaling up have been proven to advance innovation and its applications. They can be single-sited, distributed or virtual, and include major scientific equipment/instruments, collections and archives of scientific data, computing systems and communication networks, and any other R&I infrastructure which is open to external users.

30 New and existing global funds could support capacity building and technology transfer, developed by international organisations like the Convention on Biological Diversity (CBD) and other UN fora. For example, the CBD's upcoming Multilateral Mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources will include a global fund. This will be paid by those using such resources (such as pharmaceutical and biotechnological companies) and the funds will be used to address biodiversity loss. More information at: https://www.cbd.int/doc/press/2024/pr-2024-08-16-dsi-en.pdf.

31 https://www.nedo.go.jp/news/press/AA5_101556.html.

32 Training programs do not only focus on technical skills needed for research and development, but also support dissemination of biosafety-related knowledge and awareness. This is one of the pillars of Safer Innovation Approaches (SIA) in Biotechnology, as currently discussed and developed by the OECD Working Party for Harmonisation of Regulatory Oversight in Biotechnology (HROB) in the Environment Directorate under the Chemicals and Biotechnology Committee (CBC).

33 One of the most well-known examples is the Marie Skłodowska-Curie Actions postdoctoral fellowships, created by the European Union to support PhD holders wishing to carry out their research activities abroad, to enable them to acquire new skills and develop their careers. More information can be found here: https://marie-sklodowska-curie-actions.ec.europa.eu/actions/postdoctoral-fellowships.

34 https://www.who.int/publications/i/item/9789240056107.

35 https://responsibility.igem.org/human-practices/what-is-human-practices.

36 https://biopolis.stanford.edu/virs.

37 https://www.who.int/publications/i/item/9789240056107.

38 https://assets.publishing.service.gov.uk/media/62c809d5d3bf7f3004d17f6f/regulatory_horizons_council_report_on_genetic_technologies_july_2022.pdf

39 https://www.gov.uk/government/publications/advice-on-engineering-biology/report-on-engineering-biology-opportunities-for-the-uk-economy-and-national-goals-html.

40 https://centerforhealthsecurity.org/our-work/research-projects/international-guidelines-for-biosecurity-ethics.

41 For example, the British Standards Institution (which acts as the UK's National Standards Body) published PAS 440:2020 Responsible Innovation Guide to provide companies, regardless of domain, an overarching guidance on how to structure responsible innovative thinking and processes. More

information is accessible online: https://knowledge.bsigroup.com/products/responsible-innovation-guide?version=standard.

42 https://roadmap.ebrc.org.

43 https://roadmap.ebrc.org/engineering-biology-for-climate-sustainability.

44 Another example is the United Nations' Convention on Biological Diversity Ad Hoc Technical Expert Group, which was established to support regular horizon scanning and monitoring and assessment. Accessible here: https://www.cbd.int/synbio/current_activities/ahteg.

45 https://www.csiro.au/en/research/production/biotechnology/synthetic-biology.

46 https://www.csiro.au/en/research/environmental-impacts/sustainability/Responsible-Innovation.

47 https://www.rathenau.nl/en/knowledge-transitions/cards-biosafety-educational-game-biotechnologists-about-safety.

48 https://biotechnologie.rivm.nl/safe-by-design/serious-game.

49 https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0501.

50 https://www.oecd-ilibrary.org/science-and-technology/framework-for-anticipatory-governance-of-emerging-technologies_0248ead5-en.

51 It is important to note that values are subject to evolution, and technological change can reshape them. An example here is privacy, where the adoption of new technologies may drive or reflect new attitudes with respect to the protection of personal data.

52 The September 2024 report "The future of European competitiveness - Part A | A competitiveness strategy for Europe", led by former European Central Bank President Mario Draghi, highlights the role restrictive and fragmented legislation plays in hindering innovators commercialising their technology or scaling up.

53 A potential bottleneck was identified in that a standard definition of synthetic biology does not exist and is often used interchangeably with words like 'engineering biology' or 'biotechnology'. Experts underlined that having an internationally agreed term would provide clarity of scope for policy discussions and regulations, but may be political and time-consuming.

54 Matsuo et al. (2024) Mini Horizon Scanning Round-Table Discussion by GteX Members: Report. Accessible here: https://www.gtex-microbe.jp/wp-content/uploads/2024/09/20240905_mini-HS.pdf.

55 Matsuo et al. (2024) Mini Horizon Scanning Round-Table Discussion by GteX Members: Report. Accessible here: https://www.gtex-microbe.jp/wp-content/uploads/2024/09/20240905_mini-HS.pdf.