ANNEX H

SSAC Report – Engineering Biology: Opportunities for Scotland

REVIEW OF INTERNATIONAL COMPETITION AND COLLABORATION OPPORTUNITIES

Executive summary

The global strategic landscape regarding Engineering Biology (EngBio) is varied with the allied global legislation and regulatory functions at different stages of development and application.

While some countries have introduced specific government-led initiatives – such as South Korea's forthcoming **Synthetic Biology Promotion Act (2026)** – any other nations rely on broader biotech or bioeconomy policies or non-governmental strategies. Regulation similarly diverges, and sometimes differentiated regulations are applied for genetically modified and precision-bred organisms e.g. UK's **Genetic technologies (Precision breeding) Act (2023)**.

In research, countries like **China**, the **United States**, and **India** lead in publication volume, though the **UK ranks high in citation impact**, demonstrating the quality of its output. Patent data shows the United States remains dominant, with **China's rapid growth** reshaping the innovation landscape. The UK has slipped in global patent rankings and is at risk of falling behind due to weaker international patent protection practices.

Economically, engineering biology is projected to generate up to **$4 trillion annually** in global impact within two decades (McKinsey, 2020). Countries like the **USA** have matched public investments with significant private capital, while the UK, despite over **£2 billion in public investment**, shows a lower private sector contribution. Still, the UK ranked **third globally** for private investment in engineering biology from 2017–2022.

A pressing global issue is the **STEM skills shortage**, exacerbated by misalignments between education and industry needs. The UK faces additional talent challenges due to restrictive immigration policies and limited support for mid-to-late career training. Programs like **ATAC**, **ATSTN**, and the **IBioIC** in Scotland are helping bridge skill gaps, though greater scale and breadth are needed. Countries like **France**, and **China** have implemented strategic skills development plans to futureproof their engineering biology workforces.

Infrastructure remains a major bottleneck. The **UK lags in scale-up capacity**, particularly for food-grade and non-pharmaceutical fermentation facilities, contributing to the offshoring of SMEs. Global collaborations such as **Pilots4U** (EU) and the **Global Biofoundry Alliance** provide platforms for infrastructure sharing, but national disparities in biomanufacturing capacity persist. The UK's limited scale-up

infrastructure (generally capped at 300–4000L) contrasts with facilities in France and elsewhere offering reactors up to **350,000L**.

In conclusion, while engineering biology holds transformative promise across health, agriculture, energy, and materials, global disparities in strategy, regulation, skills, and infrastructure remain substantial. The UK is currently among the global leaders across many aspects, but other countries are quickly developing their interest in the area and capabilities. Forming and maintaining strong international collaborations and taking an active role in the development of international regulations and standards will be important to maintain our future position.

Introduction

The accruing evidence-base on the need for change as a consequence of climate change[1] and projected global population increase have underpinned a global drive to shift towards biobased economies[2]. More than 50 countries now have national bioeconomy strategies[3,4] and alongside the UK, nations including China, Japan, South Korea and Singapore are all making Engineering Biology a strategic priority alongside these policies.

The potential offered by Engineering Biology (or synthetic biology) has proved attractive to the investment market which sees it as a major economic driver reshaping industries, creating new markets, and generating high-value jobs. Indeed, at the global level a market valuation of $13.4Bn has been identified by MarketsandMarkets (2023) whilst mid-to-long term potential is projected to be $35-40Bn (Grand View research, 2023) and $100Bn-4Tr (McKinsey, 2020) annually, respectively.

However, the rapid technological advances within Engineering Biology, differing national priorities and diverse range of public perceptions and cultural interpretations of the techniques and their application[5], have left a disconnected strategic landscape, and the allied global legislation and regulatory functions are at different stages of development. The considerable variation in the national approaches to engineering biology at strategy, policy and regulatory levels is highlighted in **Appendix Table 1**.

At policy and strategy levels the foci are varied and encompass national growth, the bioeconomy, industrial biotechnology and specifically genetic modification and gene editing. Unlike the UK, China, Japan, Singapore and South Korea, most countries do not have specific governmentally-driven engineering biology strategies. Australia, Canada and USA have non-governmental strategies or roadmaps developed by experts in the field, whilst in other countries any initiatives are embedded within existing wider strategies for innovation, bioeconomy or biotechnology. For example, EU Commission stated that "*biotechnologies and biomanufacturing are key to the competitiveness and modernisation of EU industry*".

The regulation of the products of Engineering Biology also varies considerably across the globe (**Appendix Table 1**). The International Cartagena Protocol on Biosafety[6] aimed to regulate risks to biodiversity and human health from trade in GMOs, however the implementation around the world varies[7]. Historically there has been a division between product vs process focussed regulation, but more and more

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1 IPCC, 2023: Summary for Policymakers. pp. 1-34, doi: 10.59327/IPCC/AR6-9789291691647.001

2 "A global analysis of bioeconomy visions in governmental bioeconomy strategies" (Proestou *et al*, 2023)

3 Engineering biology metrics and technical standards for the global bioeconomy (EBRC, 2023)

4 Bioeconomy national strategies in the G20 and OECD countries: Sharing experiences and comparing existing policies (Gardossi *et al,* 2023)

5 The different regional approaches to regulation and policy for Engineering Biology were summarised in an Engineering Biology Research Consortium report (based on findings from their regional stakeholder workshops)

6 The Biosafety Protocol, adopted on Jan. 29, 2000 in Montreal, Canada, 2226 United Nations Treaty Series 208, and effective as of Sept. 11, 2003

7 https://doi.org/10.1093/jlb/lsaf011

countries are applying a mixed approach, with increasing differentiation between the regulatory approaches for transgenic (genetically modified) organisms containing foreign DNA and gene-edited products (specifically those which have used new genomic techniques to make changes which could have arisen through conventional breeding methods).

As a platform technology with multi-sectoral applications, each application area is often governed separately, and not necessarily consistently, even within a country. In some countries, intra-agency regulatory approaches are undertaken with Canada arguably a standout here with their comparatively light touch process.

At the UK level, the products determine the regulatory route: for engineered crops, the Advisory Committee on Releases to the Environment (ACRE) within the Department for the Environment Food and Rural Affairs (DEFRA) advises government on requests for permission to release genetically modified organisms (GMO) into the environment, whereas advanced therapy medicinal products (ATMPs) are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). More recently the aforementioned Genetic Technology (Precision Breeding) Act 2023 has come with a science-based and streamlined regulatory system to facilitate greater research and innovation in precision (gene edited) breeding, with stricter regulations remaining in place for genetically modified organisms (GMOs).

Research capabilities

Engineering biology capabilities vary significantly at the global level. As for regulation, this varies according to targets (food, feed, pharma etc). Table 2 outlines the engineering biology outputs in terms of referred publications and Field-Weighted Citation Impact based on SciVal analysis. This accesses the research performance data of over 24,000 research institutions and their associated researchers based across more than 230 nations worldwide.

Table 2 Refereed Publications (2018–2022) and analysis based on Sci Val. (FWCI >1 indicates above-average citation impact)

Rank	Country	Publications	Field-Weighted Citation Impact (FWCI
1	China	24,521	1.41
2	United States	19,682	1.5
3	India	10,370	1.51
4	Germany	5,886	1.42
5	United Kingdom	5,505	1.54
6	Japan	4,072	1.09
7	South Korea	3,556	1.56
8	Italy	3,004	1.64
9	Spain	2,821	1.39
10	Iran	2,779	1.62

The UK ranks fifth in publication volume but fourth in research impact, demonstrating high-quality outputs despite a smaller volume compared to leading nations. While

specific data for Scotland's publication volume in engineering biology is not readily available, Scotland plays a significant role in the UK's synthetic biology landscape and this is discussed elsewhere.

Global biotechnology patent landscape

As broadly highlighted in the DSIT report “Life sciences competitiveness indicators 2023”[8], patent activity reflects innovation and commercial readiness. While specific data for the exact phrases "engineering biology," "synthetic biology," and "industrial biotechnology" are limited, broader biotechnology patent statistics provide insight into national trends. A 2013 study[9] analysing synthetic biology patent applications from 1990 to 2010 found the following distribution (Table 3).

Table 3. Synthetic biology patent applications from 1990 to 2010 (van Doren et al, 2013)

Country	Share of Synthetic Biology Patents
United States	45%
Japan	9%
Germany	7%
United Kingdom	5%
France	5%
Canada	3%
South Korea	2%
Australia	2%
Russia	2%
Spain	2%
Netherlands	2%
Denmark	2%
Switzerland	2%
China	2%
Italy	1%
Rest of World	9%

A more recent analysis (**Table 4**) identifies a relative drop of the UK in the patent rankings from third in Table 3 to 7th globally in biotechnology patent filings, with 498 patents in 2019. There is concern that UK firms are not protecting their inventions abroad as effectively as counterparts in countries like France and Germany. This underrepresentation in international patent filings could impact the UK's competitiveness in biotechnology sectors, including synthetic biology and industrial biotechnology. Notably, China has increased its patenting outcomes considerably from the 199-2010 to 2013 rankings.

[8] https://www.gov.uk/government/publications/life-sciences-sector-data-2023/life-sciences-competitiveness-indicators-2023

[9] van Doren, D., Koenigstein, S. and Reiss, T., 2013. The development of synthetic biology: a patent analysis. Systems and synthetic biology, 7, pp.209-220.

Table 4. Top Countries by Biotechnology Patent Counts (2019, NationMaster)

Rank	Country	Number of Patents
1	United States	5,941
2	Japan	1,608
3	China	1,552
4	South Korea	984
5	Germany	639
6	France	526
7	United Kingdom	498
8	Canada	241
9	Netherlands	222
10	Switzerland	222

UKIPO analysis of PatentSight data assessed the global landscape fin a slightly different way, looking at International Patent families rankings from 2010-2021[10]. Their analysis produced the same top 3 countries, and the same other top 10 countries but in a slightly different order.

Overall, several observations can be made:

- **United States**: Consistently leads in biotechnology and synthetic biology patent filings, reflecting strong research and development infrastructure.
- **China**: Rapid growth in biotechnology patents, indicating significant investment and focus on this sector.
- **Europe**: Countries like Germany, France, and the UK maintain strong positions but face challenges in international patent competitiveness.

Emerging players: Nations such as South Korea and the Netherlands show notable activity in biotechnology patenting, suggesting growing emphasis on innovation in these areas.

Economic activities and investments

Appendix Table 2 identifies a range of public and private funds supporting engineering biology in different countries. The scale of funding has been significant in leading countries such as the US, with public investment to date in the $ billions allied to a robust level of private investment. Similarly in the UK, public funding initiatives go back to 2014, with a substantial £2 Bn public investment committed in 2023, but with a lesser private investment portfolio. However, the National Vision for Engineering Biology identified that the UK ranks third globally in total private investment in Engineering Biology between 2017 to 2022. The recent House of Lords Science and Technology report “Don’t fail to scale: seizing the opportunity of engineering biology”[11] acknowledged strong early stage (low TRL) support, but described a gap in funding support for scale-up in the UK.

[10] Figure 4 in the UK National Vision for Engineering Biology

[11] https://publications.parliament.uk/pa/ld5901/ldselect/ldsctech/55/55.pdf

Estimating the direct contribution of engineering/synthetic biology to GDP across multiple countries is challenging due to varying definitions, overlapping sectors (biotech, industrial biotech, pharma), and limited public data. However, a 2020 report by McKinsey analysed around 400 potential applications of synthetic biology and estimated they could generate a global economic impact of $2 to $4 trillion annually within the next 10 to 20 years[12]. Additionally, research by the Boston Consulting Group suggested that synthetic biology could play a role in manufacturing sectors responsible for over 30% of global production by 2030—equating to approximately $30 trillion in value[13].

Closer to home, the Council for Science and Technology's 2023 report "Report on engineering biology: opportunities for the UK economy and national goals"[14] identified that there are over 1,800 businesses undertaking modern industrial biotechnology-related activity, which could in the near future benefit from Engineering Biology, employing 14,000 individuals, generating £3.7 billion in revenue and contributing £1.2 billion in gross value added.

Skills

The shortage of skilled workers in Science, Technology, Engineering, and Mathematics (STEM) fields is becoming an increasingly pressing issue for many countries worldwide, posing a significant threat to a country's future economic growth and competitiveness. For instance, the US is projected to face a shortage of up to 3.5 million STEM workers by 2025 (HR Forecast 2023)[15].

At the UK level, respondents to the UK government inquiry suggested that demand outstrips supply for skilled bioprocessing experts for industrial scale engineering biology. This was reiterated in the recent UK Government Office for Science Foresight report "Engineering Biology Aspirations"[16] and by the House of Lords Science and Technology Committee. There is a shortage of skilled individuals, and those who acquire these skills are hard to retain. The UK is in a global competition for talent in EngBio. However, restrictive visa policies, high visa fees, and a perceived hostile attitude to immigration are jeopardising the UK's ability to attract and retain the best talent.

More widely various national initiatives have been established focussing on skills and training. China has embedded skills development in its 14th Five-Year Plan for Bioeconomy Development and have issued Guidelines to Promote Biotech Cultivation (2024–2028) thereby offering opportunities for upskilling[17]. France has also developed a 2025 Biotechnology Skills Plan[18] with the aim of increasing domestic production of biotherapies from 5% to 20% by 2030.

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[12] The Bio Revolution: Innovations transforming economies, societies, and our lives, McKinsey (2020).

[13] Candelon, F. et al. (2022), Synthetic Biology Is About to Disrupt Your Industry, Boston Consulting Group

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

[15] https://hrforecast.com/the-stem-skills-gap-a-growing-challenge-for-countries-to-overcome

[16] https://www.gov.uk/government/publications/engineering-biology-aspirations-report/engineering-biology-aspirations

[17] Zhang et al. The roadmap of bioeconomy in China. Eng Biol. 2022 Nov 30;6(4):71-81. doi: 10.1049/enb2.12026

[18] https://frenchhealthcare.com/plan-competences-biotech-2025/

There are also several examples of national training support programmes such as the Biotechnology Industrial Training Programme in India, National Biologics Training Program and Training Programs for Biologics and Biomedical Industry in Australia and the Canadian Alliance for Skills and Training in Life Sciences and BioTalent Canada.

Infrastructure/Facilities

There is a diversity of facilities/infrastructure globally and within the UK and Scotland (**Appendix Table 3**). These can roughly be categorised into scale up fermentation (industrial biotechnology/bioprocessing), and genome/DNA/RNA foundries. The former are generally classic, albeit often state-of-the-art, fermentation facilities that allow for the scale up to near or actual commercial scale thereby allowing some of the issues of scale up to be addressed ahead of commercialisation. These issues can include proof of scalability to derisk subsequent investment, productivity optimisation, cost reduction and availability of the skills that scale up requires. The latter, foundry and/or genome hubs, focus more on the design, engineering and functional characterisation of synthetic DNA, organisms often with access to various genotyping, phenotyping and chemotyping facilities and services depending on the nature of the engineering biology undertaken.

At the global and EU level, **Global Biofoundry Alliance** is a community collective of publicly funded Biofoundries across the world. As part of this they have dedicated working groups (WGs) addressing issues such as software, business models outreach, with new WGs targeting standards/metrics and grand challenge projects to come online soon.

Pilots4U, is an evolving data base of fermentation and bioprocessing facilities at pilot and demonstration scales, with currently 451 entries and 104 organisations across the EU. The database also holds information on allied upstream/downstream technologies such as anaerobic digestion, chemical processing, material technologies, mechanical and/or physicochemical separations, pre-treatments etc.

At the national level, infrastructure and facilities scale and availability varies considerably across the academic and industrial sectors. The UK is reasonably well represented for the biofoundry aspects, but has limited translational scaling capability, with selected fermentation capacity identified up 300L and the possibility of scaling to 4000L via the GSK Biotechnology Pilot plant using mothballed-but-still-available-for-use infrastructure. Analogous national capabilities exist across the EU but crucially it has with greater scale up capabilities, e.g., ARD, France, and their 30L-180000L SIP fermenters and up to 350,000L sanitised reactors.

Access to scale up infrastructure and support is an issue identified at the UK level by the UK Government Science and Technology Committee and Government Office for Science. Allied issues identified in the National Vision for Engineering Biology include limitations with respect to:

- Food-grade facilities (e.g. fermenters/bioreactors >20,000l)
- Bioprocessing facilities below pharmaceutical grade (forced to use over-spec equipment which increases costs)

- Computational and robotics platforms to enable high-throughput production and automation
- Data infrastructure (high-quality, standardised data)
- Lack of accessible information on range of facilities and equipment

The combination of these is proposed to be an underpinning driver of the migration of UK SMEs to the EU and beyond.

Appendix 1

Table 1. The regulatory approach for Engineering Biology (processes and products) in selected global countries and regions

Country/ Region	Policy/ Strategy	Summary of regulatory approaches	Regulatory/Legal Framework	Hyperlinks
United States	Under review	Product-based Focus on Engineering biology, & biomanufacturing Gene therapy is permitted but must be approved by the Department of Health and Human Services (DHHS).	Transgenic crops are product regulated in the US by the United States Department of Agriculture (USDA) under Biotechnology Regulations 7 CFR part 340 (plants) Gene edited animals are still strictly regulated, effectively treated as drugs under the federal 1938 Food, Drug and Cosmetic Act, by the Food and Drug Administration and the Environmental Protection Agency (varies by application)	https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340 (plants) Engineering Biology Research Consortium
European Union	EU bioeconomy strategy (2018) European Commission: "Building the Future with Nature: Boosting Biotechnology and Biomanufacturi	Process-based Strict regulation of GMOs and gene-edited organisms. Devolved down to national regulatory authorities for approval. New proposal to ease the regulatory constraints on plants for gene-edited crops in negotiations by European Parliament. Member states would be able to opt-out.	**Directive 2001/18/EC** on the deliberate release of GMOs into the environment **Directive (EU) 2015/412** allowing member States to restrict or prohibit the cultivation of GMOs in their territory **Directive 2009/41/EC** on contained use of genetically modified micro-organisms **Proposal** for a regulation of the European Parliament and of the	https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-legislation_en https://www.consilium.europa.eu/en/press/press-releases/2025/03/14/new-genomic-techniques-council-agrees-negotiating-mandate/ Proposal in full: https://eur-lex.europa.eu/legal-

	ng in the EU" (2024) EU level "Regional Innovation Valleys for Bioeconomy and Food Systems" initiative	Patent law and consumer labelling regulations still being debated. Gene therapies are permitted but require authorisation for marketing through the European Medicines Agency (EMA)	Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 Regulation (EC) No 1394/2007 on advanced therapy medicinal products (must also comply with must comply with Directive 2001/83/EC on medicinal products for human use)	content/EN/TXT/?uri=CELEX:52023PC0411 https://health.ec.europa.eu/medicinal-products/advanced-therapies_en
United Kingdom (and Scotland)	National vision for engineering biology Invest 2035: the UK's modern industrial strategy	Process-based Deregulates gene-edited crops & animals from GMOs Advisory committees and councils include Engineering Biology Advisory Panel & Regulatory Horizons Council	**Genetic Technology (Precision Breeding) Act 2023** The Advisory Committee on Releases to the Environment (ACRE) within DEFRA regulates the release of GMOs Advanced therapy medicinal products (ATMPs) are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).	https://bills.parliament.uk/bills/3167 https://www.gov.uk/government/news/world-leading-gene-editing-bill-becomes-law The Governance of Engineering Biology (Regulatory Horizons Council)
Norway	Norwegian Bioeconomy Strategy (2016)	Process-based Currently regulates gene-editing and GMOs in the same strict process-based way as the EU The Norwegian Gene Technology committee submitted a proposal to the	Classifies any modification to the plant or animal genome, including gene editing, as described under the **1993 Gene Technology Act** Contained use of GMOs is administered by the Ministry of Health and Care Services.	https://www.bioteknologiradet.no/english/norwegian-regulation/ https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/norway-crops-food/

		Norwegian government in 2023 for adopting a case-by-case product-risk based assessment for gene technologies, which is under consideration.	Deliberate release of GMOs is administered by the Ministry of Environment and the Norwegian Environment Agency. *At time of writing, one species of GMO ornamental purple carnation and one high Omega-3 GM rapeseed (for use as aquaculture feed) have been approved in Norway.*	
Switzerland	No National strategy specifically dedicated to Engineering Biology	Process-based Strict regulation of GMOs and gene editing, although reviewing regulations regarding new genomic techniques in plants. Likely to still favour stronger control mechanisms for approval than the EU proposal. A Moratorium on commercial cultivation of GMOs in agriculture was voted in 2005, extended on several occasions, most recently extended to the end of 2025.	**814.91 Federal Act on Non-Human Gene Technology** (Gene Technology Act, GTA) (2003) Importation and sale of GM food and feed are permitted, provided they meet safety standards, authorised by the Federal Food Safety and Veterinary Office (FSVO). Marketing of GM products authorised by Swiss Expert Committee for Biosafety (SECB)	Authorisation of genetically modified organisms Switzerland drafts new law on NBTs Switzerland in favour of more precaution and freedom of choice in new genetic engineering Marketing of genetically modified organisms

China	4th Five-Year Plan (2021-2025) & Long-Term Goals (2035) Bioeconomy 5-Year Plan	Approvals for gene-editing and genetic modification in plants are on a case-by-case basis. Gene-edited crops treated as GMOs unless exempt (updated guidelines 2022). Gene therapy is allowed and clinical trials only require approval by an ethics committee of a hospital. Intra-agency co-ordinating body "Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms" to established to coordinate biotech policies	**Ethical Guidelines for Human Embryo Research (2003)-** administered by Ministry of Science and Technology (MOST) **Regulations on Administration of Agricultural Genetically Modified Organisms Safety 2001**- administered by Ministry of Agriculture and Rural Affairs (MARA) **Updated Guidelines for Gene-Edited Crops (2022)** **Biotechnology Safety Law (2021)-** administered by Ministry of Ecology and Environment (MEE), State Council of China	Regulations on Administration of Agricultural Genetically Modified Organisms Safety [English version] China's regulatory change toward genome-edited crops Toward the effective implementation of the Biosafety Protocol: a Chinese regulatory capacity-building perspective
Brazil	CTNBio Regulatory Framework	Fast-tracks CRISPR crops for approval, pro-GMO agriculture	**Law 11,105/2005** (biosafety) GMOs regulated by Internal Biosafety Committees (CIBios), the National Biosafety Technical Commission (CTNBio), the National Biosafety Council (CNBS) and the Surveillance and Registration Bodies	https://www.gov.br/ctnbio/en
Canada	Canada's Biomanufacturing and Life	Product-based	Health Canada & Canadian Food Inspection Agency oversight e.g. novel foods approval process	https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/gene-

	Sciences Strategy (2021) Focus on precision medicines, including cell and gene therapies, RNA, and viral vectors, and monoclonal antibodies.	New guidelines were adopted in 2023 on crops developed through gene-editing and other NBTs, regulating them in the same limited way as conventional crops with no or limited labelling requirements. GMO crops will continue to require a pre-market safety evaluation based on restrictive regulations adopted in 2006 Gene therapy is permitted, but must be approved by Health Canada's Biologics and Genetic Therapies Directorate (BGTD), which is responsible for overseeing all clinical trials.	Gene edited or genetically engineered animals with novel traits are regulated under the **Canadian Environmental Protection Act (1999)** *Six GMO crops have been approved for sale: herbicide-tolerant canola, non-browning apples and potatoes, less bitter mustard-greens, improved alfalfa and more digestible corn. A faster growing GMO salmon was approved for sale as food and animal feed in 2016, but there is no commercial production in Canada yet.* Assisted Human Reproduction Act (AHRA) (S.C. 2004, c. 2)- strictly prohibits germline gene editing even for research purposes.	editing/eng/1563375469804/1563375470111 Engineering Biology: A platform technology to fuel multi-sector economic recovery and modernise Biomanufacturing in Canada
Australia	Advanced Engineering Biology Future Science Platform (AEB FSP) The Commonwealt	Gene drives are considered GMOs and subject to GMO regulations Gene-edited crops, animals and human cell lines with no foreign DNA are no longer classified as GMOs	Office of the Gene Technology Regulator (OGTR) oversees and implements The National Gene Technology Scheme based on the **Gene Technology Act 2000** 2019 Amendments to the Gene Technology Regulations 2001	https://www.ogtr.gov.au/ https://www.ogtr.gov.au/about-ogtr/australias-gene-technology-regulatory-system

	h Scientific and Industrial Research Organisation (CSIRO) National Synthetic Biology Roadmap (2021)	Gene therapy is permitted but must comply with clinical trial regulations from the Australian Therapeutic Goods Administration (TGA).	Prohibition of Human Cloning for Reproduction Act 2002 (PHCR) Many products including food, agricultural chemicals, and therapeutic products need to comply with additional industry specific standards and mandatory regulation e.g. Food Standards Australia New Zealand (FASNZ), Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Australian Therapeutic Goods Administration (TGA).	
Japan	Japan Integrated Innovation Strategy 2020 Japanese Bioeconomy strategy 2022 - with specific Engineering Biology support	Product-based Transgenic crops and animals are product regulated. Gene-edited products with no external DNA/RNA were clarified to be exempted from additional safety evaluation since 2019. Unique accelerated approval system for gene and stem cell therapies since 2014.	**The Cartagena Act**: The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97, 2003)- Gene and stem cell therapies regulated by The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). *As of 2019, three stem cell treatments have earned conditional approval through the accelerated system*	https://www.maff.go.jp/j/kanbo/bioeconomy/pdf/seisaku_keikaku_en.pdf https://doi.org/10.3389/fgeed.2022.899154 Japanese Pharmaceutical Regulations of Engineered Viral Vectors for Medical Use Compared With Those in the United States and the European Union

Africa (AU)	AUDA-NEPAD Gene Editing Policy Framework AUDA-NEPAD Flagship Biosafety framework	Varying degrees of biosafety and biotech regulations. Many countries have no specific regulatory framework. The African Union Development Agency-NEPAD (AUDA-NEPAD) supports the use of gene - editing for crop improvement and elimination of hunger and supports the development of regulatory frameworks in countries currently lacking them e.g. Zimbabwe	Countries such as Ghana, Nigeria, Togo, Senegal, Zambia, Malawi and Kenya have some framework for regulation of GMOs and/or gene-edited organisms.	https://www.nepad.org/publication/map-of-biotechnology-regulatory-status-africa
India	Various research initiatives recognising synthetic biology as an important technology (e.g the National Biopharma Mission and the National Biofuel Policy), but no national	Process-based Case-by-case approval for GMOs by the Genetic Engineering Appraisal Committee (GEAC). Regulation revised in 2022 to make gene-edited crops without foreign DNA exempt from GMO restrictions, subject to approval by the Institutional Bio-Safety Committee (IBSC).	GMOs including GM crops are regulated under “Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989” under the **Environment (Protection) Act, 1986** **Draft Biotechnology Regulatory Authority Bill.** For crops developed by site directed nuclease the approval by the has been reassigned to India's Seeds Act,	Guidelines for the Safety Assessment of Genome Edited Plants https://dbtindia.gov.in/sites/default/files/Final_%2011052022_Annexure-I%2C%20Genome_Edited_Plants_2022_Hyperlink.pdf https://www.spglobal.com/commodity-insights/en/research-analytics/india-eases-gene-editing-regulations

	strategy specifically dedicated to Engineering Biology.	Gene therapy is allowed but requires approval from the Central Drugs Standard Control Organisation (CDSCO). India has banned the commercial use of stem cell therapy	in lieu of the Environment Protection Act. Regulatory framework includes Recombinant DNA Advisory Committee (RDAC), Regulating and Approval Committees, and Post Monitoring Committees *Insect-resistant Bt cotton, approved for in 2002, is the only GMO crop currently allowed for cultivation. India is the largest producer of Bt cotton in the world.*	
South Korea	Development and Dissemination Strategy of Core Technologies in Synthetic Biology. Synthetic Biology Act is targeted at Biopharma development	Gene-edited organisms currently regulated under GMO laws. Gene-edited products are not currently distinguished, but the act is in amendment. Gene therapies are classified as drugs under the **Pharmaceutical Affairs Act**, subjecting them to approval by the Ministry of Food and Drug Safety. The new **Regenerative Medicine Law** will allow some patients to receive cell and gene therapies that do	**Synthetic Biology Promotion Act** (proposed 2025) **Living Modified Organism (LMO) Act (2012)** **Bioethics and Biosafety Act (2005, amended 2017)** **Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products** (Act No. 16556, 2019)	Korea to announce the National Synthetic Biology Initiative https://embryo.asu.edu/pages/south-koreas-bioethics-and-biosafety-act-2005 https://parentsguidecordblood.org/en/news/south-korea-expands-access-regenerative-medicine-serious-illnesses

		not yet have market approval.		
Singapore	No formal strategy/roadmap and but a focus for research support via the Singapore Consortium for Synthetic Biology (SINERGY)	Process-based Gene-edited crops without foreign DNA are exempt from pre-market safety assessments but must notify Singapore Food agency (SFA) First country to approve lab-grown meat Advisory body - Genetic Modification Advisory Committee (GMAC)	Biological Agents and Toxins Act (BATA) (2005)- regulated by the Ministry of Health. Cell, tissue or gene therapy products are regulated under the Health Products Act (HPA) as a higher risk product	https://sinergy.sg/ https://www.sfa.gov.sg/regulatory-standards-frameworks-guidelines/genetically-engineered-food-and-feed/regulatory-framework-for-the-use-of-genome-edited-crops-in-food-and-or-animal-feed https://biosafety.moh.gov.sg/infohub/genetically-modified-organisms
Argentina	National Advisory Commission on Agricultural Biotechnology (CONABIA) Resolution 124/91 (and rolling updates since then)	Plants and animals	Crop based gene-edited products regulated by National Advisory Commission for Agricultural Biotechnology (CONABIA)	https://www.argentina.gob.ar/agricultura/bioeconomia/biotecnologia/conabia Resolution 124-91 - https://www.magyp.gob.ar/sitio/areas/biotecnologia/conabia/_archivos//000000_Resoluci%C3%B3n%20124-91.pdf

				For a summary of South America at 2023, see https://doi.org/10.3389/fbioe.2023.1069628

Table 2. Global Engineering Biology support and Economic Activity by Country.

Country	Engineering Biology support and Economic Activity
United States	**Public:** Committed $2 billion (£1.57 billion) for biotechnology and biomanufacturing in 2022, including $1 billion (£0.8 billion) in domestic biomanufacturing infrastructure over 5 years. Now revoked by the Trump administration. Funding has previously been through three major routes: National Science Foundation (NSF) • Systems and Synthetic Biology Program: Supported research employing systems biology or synthetic biology approaches to address compelling questions in molecular and cellular biology • NSF Global Centers 2024 programme • Emerging Frontiers in Research and Innovation (EFRI): In 2024, NSF invested $14 million in bioengineered systems and ethical biocomputing research, fostering fundamental and ethically responsible research and development of organoid intelligence systems. Department of Energy (DOE) • The DOE has been a significant funder of synthetic biology research, particularly focusing on biofuels. Between 2005 and 2010, the U.S. government spent around $430 million on synthetic biology research, with the DOE funding a majority of this research. Department of Defense (DoD) and DARPA • Between 2008 and 2014, the U.S. invested approximately $820 million in synthetic biology research. The DoD became a key funder, with DARPA's investments increasing from near zero in 2010 to more than $100 million in 2014, surpassing NSF's spending. • DARPA's focus includes developing synthetic biology applications for national security, such as engineered organisms for sensing and responding to environmental threats. **Private:**

	US synthetic biology startups have attracted significant venture capital. Several VC firms have been instrumental in funding synthetic biology ventures e.g. Atlas Venture, Arch Venture Partners
United Kingdom	**Public**: • UKRI's Synthetic Biology for Growth programme invested over £100 million in the field between 2014-2022 • In 2023, the UK government released £2 billion of public investment into engineering biology over 10 years (Dec 2023) • There are many other non-specific sources of funding for science and innovation e.g. the Faraday Discovery Fellowship scheme run by the Royal Society aims to fund and support emerging top talent in all areas of science and technology, including Engineering Biology. It was supported by a £250 million fund from the Department of Science Innovation and Technology (DSIT). • More recently ARIA, a UK R&D funding agency built to unlock scientific and technological breakthroughs and over seen by DSIT, was established in 2023. Within their funding programmes synthetic/engineering biology is features as part of, for example, Programmable Plants (£64.2M) **Private**: • The UK ranks third globally in total private investment in Engineering Biology between 2017 to 2022, behind the US and China • SynBioVen (SBV) was launched in mid-2022 with a £20 million investment from Winton Capital as a new investment vehicle focused on supporting the next generation of UK synthetic biology scientists, founders and start-ups with proof of concept, pre-seed and seed funding, in strategic partnership with SynbiCITE. So far it has supported 8 UK synthetic biology SMEs at different stages of investment (but no Scottish companies)

EU	**Public:**
	
	1. Horizon Europe
	
	Horizon Europe is the EU's primary research and innovation program, running from 2021 to 2027 with a budget of €95.5 billion. It supports various projects, including those in synthetic biology, through different pillars:
	
	• European Innovation Ecosystems (EIE) Programme: This program funds initiatives like the SYNBEE project, which aims to cultivate entrepreneurial ecosystems centred around synthetic biology. SYNBEE brings together stakeholders from 25 European countries to support synthetic biology entrepreneurship.
	• European Innovation Council (EIC): With a budget of €10.1 billion, the EIC supports high-risk, high-impact technologies, including synthetic biology, through various funding schemes
	  ○ EIC Pathfinder: Funds early-stage research for radically new technologies. Particular foci include:
	  ▪ "Biotech for Climate Resilient Crops and Plant-Based Biomanufacturing"
	  ▪ "Waste-to-value devices: Circular production of renewable fuels, chemicals and materials"
	  ○ EIC Transition: Supports the maturation and validation of novel technologies and the development of business cases.
	  ○ EIC Accelerator: Provides substantial financial support to SMEs, including grants up to €2.5 million and equity investments up to €15 million, to develop and scale up innovations.
	
	Scottish/UK-based researchers can in theory access the funding if collaborating with at least one EU member state.
	
	2. European Institute of Innovation and Technology (EIT)
	
	The EIT, with a budget of €3 billion for 2021–2027, aims to strengthen Europe's innovation capacity. It supports entrepreneurial education, business creation, and innovation-driven research projects, including those in synthetic biology.
	
	3. Bio-based Industries Consortium (BIC)

	The Circular Bio-based Europe Joint Undertaking is a €2 billion public-private partnership between the EU and the Bio-based Industries Consortium established under Horizon Europe (2021-2031). The CBE-JU invests in innovative technologies and biorefineries that transform biological residue waste streams into green products, supporting the bioeconomy and synthetic biology sectors, with a strong focus on supporting companies in scaling up technologies. **Private:** While public funding plays a significant role, private investment in EU synthetic biology is growing: • Venture Capital: Europe hosts a dynamic ecosystem of venture capital (VC) firms actively investing in engineering biology and synthetic biology. These firms support startups across various stages, from early research to commercial scaling, focusing on applications in therapeutics, sustainable materials, agriculture, and industrial biotech. Examples include Sofinnova Partners, AdBio Partners, High-Tech Gründerfonds (HTGF), HealthCap. Biogube Ventures, etc • Investment Funds: Funds like eureKARE and Nucleus Capital have been established in Europe to support synthetic biology ventures, indicating a positive trend in private investment.
China	**Public:** National Initiatives National Fund for Technology Transfer and Commercialisation (NFTTC) is a state-backed fund focusing on China's high-tech sectors, including biotechnology. By the end of 2022, it had established 36 sub-funds, investing nearly 36 billion yuan into 616 enterprises, leading to the commercialisation of 974 scientific and technological achievements e.g. • National High-tech R&D Program (863 Program) • National Basic Research Program of China (973 program)

	Municipal initiatives • Shanghai's 2030 Biomanufacturing Plan: The Shanghai government has set a goal to become a global biomanufacturing hub by 2030. The plan includes building industrial bases, promoting international collaborations, and supporting businesses in synthetic biology e.g. through the new Shanghai Synthetic Biology Innovation Centre (Opened 2024) • Shenzhen's Guangming Science City: Shenzhen has established a comprehensive innovation chain to support synthetic biology enterprises. The Guangming Science City, along with the Industrial Innovation Center for Engineering Biology, provides infrastructure, funding, and support for startups to transition from research to commercialisation. For instance, Synceres Biosciences, a startup in this ecosystem, has grown significantly with nearly 300 million yuan in funding. **Private:** Venture Capital Investments 1. Sinovation Ventures: Founded by former Google China head Kai-Fu Lee, Sinovation Ventures has raised multiple funds, including a $500 million fund in 2018. The firm invests in various high-tech sectors, including synthetic biology, and has backed companies like Insilico Medicine. 2. CBC Group: South East Asia (including China) based Investment group. Largely targeting healthcare they hit their first close on China's largest healthcare buyout fund $980 Million) 3. Eight Roads Ventures: Broad investor with multiple global bases including China. Targets include healthcare, pharma etc.
India	**Public:** 1. Department of Biotechnology (DBT) Established in 1986 under the Ministry of Science and Technology, the DBT is the central body overseeing biotechnology development in India. It funds research, infrastructure, and commercialisation efforts in synthetic biology. Key initiatives include: • Biotechnology Industry Research Assistance Council (BIRAC): A public sector enterprise under DBT, BIRAC supports startups and SMEs through funding, mentorship, and incubation. It has established 31

incubators across India to foster innovation in areas like CRISPR, enzyme engineering, and microbial engineering.

- National Biotechnology Development Strategy (2020–2025): This strategy emphasises funding in emerging areas such as precision medicine, gene editing, and synthetic biology, aiming to position India as a global leader in biotechnology.
- BioE3 Policy: A transformative initiative focusing on high-performance biomanufacturing, innovative research, and the development of strategic sectors like specialty chemicals and climate-smart agriculture.

2. Collaborative International Funding

India collaborates internationally to bolster its synthetic biology research:

- DBT-NSF Joint Funding: An agreement between India's DBT and the US National Science Foundation (NSF) facilitates joint research projects, allowing Indian researchers to receive funding from DBT for collaborative work with US counterparts.

Private:

1. Venture Capital Investments

Between 2013 and 2023, Indian deep science biotechnology startups attracted over $900 million in investments, indicating growing investor confidence in the sector.

Notable venture capital firms investing in Indian biotech include:

- Ankur Capital: Focuses on early-stage investments in sectors like agriculture, health, and education, supporting startups leveraging synthetic biology.
- Omnivore Partners: Invests in startups at the intersection of agriculture and technology, including those utilizing synthetic biology for sustainable solutions.

A comprehensive list of biotech venture capital funds active in India can be found here

Germany	**Public:** 1. Federal Ministry of Education and Research (BMBF) The BMBF is a primary source of public funding for biotechnology in Germany. It supports research through institutional funding and project-based grants. Notably, the BMBF initiated the German Network for Bioinformatics Infrastructure (de.NBI) in 2015, providing bioinformatics services and training to life sciences researchers across Germany and Europe. From 2022, de.NBI has been integrated into Forschungszentrum Jülich, a major research center with an annual budget of approximately €948 million in 2022, of which 48% was institutional funding from the federal and state governments. Their latest (2022) review on the bioeconomy in Germany can be found here. 2. The German Research Foundation (Deutsche Forschungsgemeinschaft, DFG) The DFG is the central self-governing research funding organisation in Germany and has an annual budget over €3.9 billion to fund research fellowships, projects, collaborative research centres, clusters of excellence, infrastructure etc. It distinguishes between four scientific disciplines: humanities and social sciences, life sciences, natural sciences and engineering sciences, subdivided into research areas, review boards and subject areas. There is no categorisation for Engineering Biology. **Private:** Germany is the fastest growing regional market in Europe for synthetic biology, projected to reach $2658 million by 2030 [Grand View Research]. 1. Venture Capital Investments Germany has a vibrant venture capital scene supporting biotech and synthetic biology startups. Notable VC funds include: • High-Tech Gründerfonds (HTGF): Invests in early-stage high-tech startups, including biotech ventures. • Wellington Partners: Focuses on life sciences investments across Europe.

	• Boehringer Ingelheim Venture Fund: With an investment volume of 250 million euro, the Venture Fund invests in biotech and start-up companies with innovative concepts and technologies in the therapeutic platform sector A comprehensive list of biotech VC funds active in Germany can be found here: Top 50 Biotech VC Funds in Germany.
Australia	**Public:** • National research grant schemes • Between 2021-2024, (e.g. Australian Research Council (ARC) and National Health and Medical Research Council (NHMRC)), have awarded A$29.7 million (£14 million) in grants for discrete research projects directly related to synthetic biology. An additional A$14.8 million (£7 million) of grant funding supported broader biotechnology research projects and could indirectly support the development of national synthetic biology capabilities • Centre of Excellence in Synthetic Biology (CoESB): Established in 2020, CoESB received A$35 million from the ARC, A$1 million from the New South Wales Government, and A$13.1 million from partner organisations. The Centre focuses on engineering synthetic microbes to create a sustainable advanced biomanufacturing industry and has attracted an additional A$23 million in competitive grants. 1. CSIRO and Main Sequence Ventures • The Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australia's national science agency, along with its venture arm, Main Sequence Ventures, projects that synthetic biology could underpin an industry worth up to A$30 billion per year and create over 50,000 new jobs by 2040. 2. State-Level Investments • New South Wales Government: In 2022, the NSW Government invested A$6 million in a synthetic biology and biomanufacturing development program aimed at improving access to manufacturing and production facilities across the state.

Private:

1. Venture Capital Investments

- Between 2021-2024, Australian synthetic biology start-ups attracted over A$363 million in capital investments, with agriculture and food applications receiving the largest share. The report on this can be found here.
- Notable Venture Capital Firms:
  - Main Sequence Ventures: The venture arm of CSIRO, investing in deep-tech start-ups, including synthetic biology ventures.
  - Mandalay Venture Partners: Focuses on ag-tech investments, supporting companies like Loam Bio and Cauldron.
  - SparkLabs Group: An international accelerator and venture capital firm that has invested in Australian ag-tech start-ups.
- A comprehensive list of biotech venture capital funds active in Australia can be found here.

2. Start-Up Ecosystem

- Proto Axiom: An Australian biotech investment incubator that supports early-stage companies in synthetic biology and related fields.
- **Jumar Bioincubator** ($65m)- funded by Innovation investor Breakthrough Victoria and managed by Cicada Innovations (Australia's leading deep-tech incubator) focusing on early-stage and scaling biotech ventures.
- **UNSW Founders Program Bio10x**- established in 2022 to bridge gap from research to start-up creation specifically for SynBio, provide funding and opportunities for further investment, plus free access to university. Has supported 9 companies over 2 years
- **Bioplatforms Australia (BPA)**- partner with UNSW Founders program to offer university facilities and space to SynBio start-ups. Part funded the IDEA Bio Biofoundry.

Japan	**Public**: 1. National Bioeconomy Strategy and Government Initiatives Japan has designated biotechnology as a strategic sector for national investment. The Basic Policy on Economic and Fiscal Management and Reform 2023 emphasises biotechnology's role in economic security and innovation. An executive order issued in September 2022 aims to bolster the domestic biotech industry. The Bioeconomy strategy 2022 aimed for 50% increase of market size by 2030, with a total 92T yen investment (~£480 million), specifically supporting biofoundries and biorefineries, genome editing technology-based breeding, biologics/vaccine development & production, and large-scale genome databases. 2. Japan Science and Technology Agency (JST) JST supports collaborative research in engineering biology through programs like ASPIRE. Joint initiatives with international partners, such as the UK, focus on foundational research and cross-cutting technologies in engineering biology. 3. Japan Agency for Medical Research and Development (AMED) AMED co-funds research collaborations in engineering biology, particularly targeting novel therapies and diagnostics. 4. RIKEN As Japan's largest national research institute, RIKEN conducts extensive research in various scientific fields, including synthetic biology. With an annual budget of approximately ¥100 billion (US$750 million) in FY2023, RIKEN supports both basic and applied research across multiple campuses. 5. New Energy and Industrial Technology Development Organisation (NEDO) A national initiative called the NEDO Smart cell project was launched in 2016. It was intended to be used for automated gene-editing tools and synthetic biology research technologies to increase development and commercialisation of these technologies. It funded the biofoundry at Kobe University, among other projects.

	Private: 1. Venture Capital Investments Japan's biotech sector has seen increased venture capital activity. Notable firms include: • Saisei Ventures: Focuses on growing the Japanese biotech ecosystem by supporting dynamic entrepreneurs and bridging technical, operational, and financial gaps. • AN Ventures: Builds biotech companies leveraging Japanese scientific innovations. • Mpower Partners: Invests in growth-stage, scalable Japanese companies, emphasizing tech-enabled sustainable living industries. A comprehensive list of biotech venture capital funds active in Japan can be found here. 2. Corporate Venture Capital Established pharmaceutical companies are also investing in biotech startups: • Eisai Co., Ltd.: Engages in corporate venture capital activities to invest in startups with innovative technologies and business models . • Taiho Ventures: Focuses on strategic investments in biotech companies, leveraging its expertise in venture capital and executive management. 3. International Collaborations Japanese corporations are forming partnerships to advance synthetic biology applications: • Sojitz Corporation and Ginkgo Bioworks: Announced plans to utilise synthetic biology R&D services to accelerate sustainable manufacturing in Japan.
Canada	**Public:**

	1. Genome Canada and Regional Genomics Centers Genome Canada, a federally funded non-profit organisation, has invested over C$1.5 billion in genomics research since 2000. This investment has attracted an additional C$2.1 billion from partners in the private, public, and non-profit sectors. Genome Canada supports six regional centers, including Ontario Genomics, which has secured over C$375 million in federal funds and C$180 million in direct industry investments for genomics research programs. 2. Strategic Innovation Fund (SIF) The Strategic Innovation Fund has allocated significant funding to biomanufacturing projects. Notably, it invested approximately C$768 million in COVID-19-related vaccines, therapies, and biomanufacturing initiatives, including substantial contributions to companies like AbCellera Biologics Inc. and Medicago Inc. 3. Biomanufacturing and Life Sciences Strategy $2.2 billion (£1.2 million) was investment pledged in 2021 Budget towards implementing the Biomanufacturing and Life Sciences strategy, including C$1.2 billion to rebuild the country's vaccine, therapeutics, and biomanufacturing capacity and $45 million (£25 million) to support stem cell and regenerative medicine research. 4. Regional Development Programs • BioCreate Program: FedDev Ontario invested over C$5.6 million in Ontario Genomics to deliver the BioCreate program, providing seed funding and support to genomics SMEs in health, food and agriculture, and cleantech sectors. • Western Diversification Program: Through this program, the government provided C$1.1 million to support the purchase of state-of-the-art equipment for a synthetic biology maker space at the University of Lethbridge, facilitating research commercialisation. 5. Immuno-Engineering and Biomanufacturing Hub (CIEBH)

	In May 2024, the government announced a C$140 million investment in projects associated with the CIEBH, a national research hub led by the University of British Columbia, focusing on advanced therapeutics manufacturing and biomanufacturing research. **Private:** 1. Venture Capital Investments Canada's biotech sector has seen significant venture capital activity. Prominent venture capital firms investing in Canadian biotech include: • Genesys Capital: Focuses on building companies in biotechnology, pharmaceuticals, and medical technology. • Amplitude Ventures: Invests in healthcare innovations, aiming to bring the best healthcare solutions to market. • Forest City SynBio: Offers investors equity in a VC fund, diversifying portfolios through investments in synthetic biology companies. A comprehensive list of biotech venture capital funds active in Canada can be found here. 2. Emerging Investment Firms Firms like Juniper VC plan to invest between US$100,000 and US$500,000 in early-stage synthetic biology startups, particularly those working on sustainable solutions.

Israel	**Public:** The Israeli government has promoted a national initiative of “bio-convergence”, which is similar to the term Engineering Biology and refers to the integration of tools from the fields of bioengineering (such as SynBio) and micro and nano-scale engineering to solve problems in multiple sectors (e.g. medicine and healthcare, agriculture, food, energy, environment, defence, and homeland security), with a particular focus on economic growth and defence. 1. The First public funding was from the Department of Defence 2. Israel Innovation Authority (IIA) • Synthetic Biology R&D Infrastructure: In 2021, the IIA established Israel's first synthetic biology applied R&D infrastructure in collaboration with Chai Laboratories and the Herzliya Interdisciplinary Center. The initiative received an initial NIS 18 million ($12 million) upon meeting predefined milestones. • Bio-Convergence Program: Recognizing the interdisciplinary nature of synthetic biology, the IIA launched the Bio-Convergence program, investing approximately $30 million to promote the integration of biology with fields like engineering, nanotechnology, and data science. 3. Academic Research Grants • Israel Science Foundation (ISF): The ISF provides competitive grants to researchers in synthetic biology and related fields. In 2023, several faculty members from the Technion's Faculty of Biology received ISF grants, underscoring the foundation's commitment to advancing life sciences research. **Private:** 1. Venture Capital Investment- there has been a growing interest in SynBio from VCs in Israel since 2018 • Israel Biotech Fund (IBF): Established in 2015, IBF focuses on investing in Israeli and Israeli-related biotech companies at all development stages. The fund has a portfolio of over 16 companies and has formed significant partnerships with key market players.

	• Tech-bio (one of the first VCs focussing on SynBio) was founded in 2018 and focusses on pre-seed investments in Israel and US. • Several VC firms have now added the SynBio vertical to their investment thesis, including: NFX, Viola Ventures, MoreVC, aMoon, Deep Insight, Meron Capital, Aleph VC, A16Z (Andreesen Horowitz), Entree Capital, Team8, Arkin Holdings, Lionbird, Innovation Endeavours, Sapir Ventures, and many more 2. Corporate and International Collaborations • Aleph Farms: A pioneer in cultured meat, Aleph Farms raised $105 million in a Series B investment round led by L Catterton's Growth Fund and DisruptAD, with participation from Temasek, Thai Union, BRF, and CJ CheilJedang. In January 2024, the company received approval from the Israeli Ministry of Health to sell lab-grown steaks in Israel. • Nevo Labs: A new research institute focusing on artificial intelligence, quantum computing, and synthetic biology, Nevo Labs is raising $800 million to support its interdisciplinary research initiatives.
Singapore	**Public:** • National Research Foundation (NRF) and Research, Innovation and Enterprise (RIE) Plans • In 2018, Singapore launched a national Synthetic Biology Research and Development Programme with an initial investment of SGD 25 million (£13.6 million) over five years, focusing on areas like bio-manufacturing and bio-based chemicals. • RIE2025 Plan: Continues to prioritise engineering biology, with funding directed towards sustainable biomanufacturing and bio-based solutions • **Singapore Consortium for Synthetic Biology (SINERGY)**- connects nine academic and 27 industry partners, supported by the National Research Foundation. • National Centre for Engineering Biology (NCEB) Established as a national research institute, NCEB serves as a hub for synthetic biology research and development. It collaborates with international partners, such as the UK, to advance specialty chemical production through engineering biology.

- Agency for Science, Technology and Research (A*STAR)

A*STAR plays a pivotal role in advancing engineering biology in Singapore:

- Sustainable Biomanufacturing Technology Platform (SBTP): In collaboration with MojiaBio, A*STAR is developing a SGD 44.8 million platform integrating synthetic biology and bioprocessing innovations to position Singapore as a leader in sustainable biomanufacturing.
- Collaborations with Academic Institutions: A*STAR partners with universities like the National University of Singapore (NUS) and Nanyang Technological University (NTU) to foster research and innovation in engineering biology.

- The National University of Singapore (NUS)

NUS is championing synthetic biology with a SGD 120 million (£70 million) investment to advance sustainable manufacturing and global innovation (National SynBio Initiative for Green Manufacturing)

Private:

1. Venture Capital Firms

Singapore hosts several venture capital firms investing in engineering biology:

- iGlobe Partners: Invests in technology startups in Singapore and Southeast Asia, with a portfolio including companies like Ginkgo Bioworks and Twist Bioscience.
- ClavystBio: Invests in early-stage ventures in biotech, medtech, and digital health, with a portfolio including companies like MediSix Therapeutics.

2. Corporate Investments

Multinational corporations are establishing research centres in Singapore:

	• Eli Lilly: Set up a systems biology R&D centre in Singapore, supported by the Economic Development Board's SGD 600 million R&D Fund, to promote private R&D investment. • WIL@NUS Corporate Laboratory- a partnership with Wilmar International. Focuses on translating academic SynBio research into practical applications, particularly in biomanufacturing
Denmark	**Public:** 1. National Research Foundations • Independent Research Fund Denmark (IRFD): Support for independent research across all scientific disciplines, including engineering biology, to benefit society as a whole. • Danish National Research Foundation (DNRF): Funds research centres of excellence, fostering high-impact research in various scientific fields e.g. In 2008, the Danish government allocated 120 million DKK (approximately £13.2 million) to establish the Centre for Synthetic Biology at the University of Copenhagen • Innovation Fund Denmark (IFD): Invests in innovative projects with high potential for commercialisation, including those in synthetic biology and biotechnology. • Innovation Centre Denmark (ICDK) currently has innovation centres in South Korea, India, China, Israel, Germany and the United States, and helps to implement Denmark's bilateral cooperation on research, technology and innovation **Private:** 1. Novo Nordisk Foundation The Novo Nordisk Foundation is a significant player in Denmark's life sciences sector investing in stem cell-based therapy research and other biomedical sciences. The Novo Nordisk Foundation Center for Biosustainability was established in 2010, which hosts the DTU Biofoundry. It was the world's first interdisciplinary research centre within sustainability, with main research focus on Natural Products, Microbial Foods and Sustainable Chemicals. They have also have established global research centres across the world, including in the US, China, UK and India.

	2. Venture Capital and Private Equity • Venture Capital Firms: A list of 50 VC funds investing in biotechnology startups based in Denmark is available here. • Lighthouse Zealand is a public-private business consortium for biosolutions
Sweden	**Public:** 1. Vinnova – Sweden's Innovation Agency. Is at the forefront of supporting synthetic biology in Sweden: • Moonshots through Synthetic Biology: In 2024, Vinnova launched a call to fund ambitious projects aiming to tackle large, seemingly insurmountable problems using synthetic biology. • Everyday Innovators in Biotech and Synthetic Biology: This initiative provides up to SEK 300,000 for capacity-building activities, including hackathons and workshops, to engage the public and foster innovation in synthetic biology. 2. SwedenBIO – National Life Sciences Strategy SwedenBIO outlines the nation's strategy to become a leading life sciences nation, emphasizing the importance of synthetic biology in addressing societal challenges. 3. Swedish Research Council (Vetenskapsrådet) The Swedish Research Council supports fundamental research in synthetic biology, providing grants to academic institutions and researchers to advance knowledge in the field. 4. International Collaborations Sweden actively participates in international research collaborations, such as the project grant for research collaboration between Korea and Sweden, focusing on advanced biotechnology, including synthetic biology. **Private:**

	1. Venture Capital and Private Equity Sweden boasts a robust venture capital ecosystem supporting biotech startups: • OMX Ventures: A venture capital firm that adopts a technology-first approach, focusing on growing groundbreaking discoveries into scalable biotech companies. • A list of 50 angel investors and VC funds that invest in biotech startups based in Sweden can be found here. 2. Public-private partnerships • **RISE** is Sweden's research institute and innovation partner. It has funded multiple projects in alternative proteins in particular, through public-private partnerships • **Biotech Heights**: A public-private partnership established in 2023 through a collaboration between Lund University, Tetra Pak, and Vinnova, serving as an interdisciplinary research and innovation hub. It focuses on bioprocess technology and scale-up, aiming to advance protein diversification and sustainable food production.
Norway	**Public:** 1. Research Council of Norway (RCN) The RCN is a central governmental agency that funds research and innovation projects across various disciplines, including engineering biology. In 2022, the RCN allocated NOK 11.7 billion to support research activities. It manages several funding schemes, such as Centres for Research-Driven Innovation (SFI) and Centres of Excellence (SFF), which support collaborative research in synthetic biology and related fields. 2. SINTEF SINTEF is an independent, non-profit research organisation that conducts contract research and development projects. It has a nationally leading research laboratory for the development of microbial and cell-based

	production processes, including synthetic biology applications. SINTEF collaborates with various academic institutions and industries to advance research in biotechnology and nanomedicine. 3. NordForsk NordForsk is an organisation under the Nordic Council of Ministers that promotes and supports research collaboration between Nordic countries. It funds joint research projects in areas like synthetic biology, with funding models that include pooled resources from participating countries. **Private:** 1. SINTEF Technology Transfer Office (TTO): SINTEF's TTO is responsible for commercializing research results through the licensing and development of new companies, patenting, and licensing of technology. It has been instrumental in spinning out several biotech startups, such as Biosergen, which focuses on antifungal treatments. 2. Sarsia Innovation: Sarsia Innovation is a technology transfer company based in Bergen, established to finance innovative projects from proof of concept up to seed-stage. It has been involved in funding biotech ventures and facilitating the commercialisation of research in synthetic biology. 3. Argentum: Argentum is a Norwegian fund-of-funds that invests in private equity and venture capital funds. It has indirectly supported biotech firms by investing in life science funds like Teknoinvest VIII, which in turn invested in companies such as SantoSolve, a pain management company.
Finland	**Public:** 1. Academy of Finland – FinSynBio Programme: The Academy of Finland launched the FinSynBio Academy Programme to support high-quality research in synthetic biology and elevate Finnish synthetic biology research to an internationally competitive level. The programme concluded in 2019, having funded various projects in drug development, industrial processes, and biomaterial manufacturing.

	2. Business Finland – Bioeconomy Research and Development: Business Finland has granted a total of €10 million in R&D funding for two Finnish projects engaged in international bioeconomy research cooperation. These projects are part of the NSF Global Centers research program, aiming to develop breakthrough solutions to global challenges. 3. FIN-BioFoundry: FIN-BioFoundry is a national research infrastructure included in Finland's roadmap for 2025–2028, receiving part of a €130 million investment in selected infrastructures. Its goal is to advance research and education in synthetic biology and biomanufacturing, supporting Finland's transition toward a circular bioeconomy and contributing to both national and international scientific collaboration. 4. Synbio Powerhouse: Synbio Powerhouse is a project building a synthetic biology and circular economy network in Finland. It offers companies and researchers opportunities to pilot synthetic biology applications in the circular economy through seminars, company-specific development projects, and research and product development initiatives. **Private:** 1. MetGen Oy: MetGen Oy is a Finnish biotechnology company that has received over €10 million in grants from the EU Horizon 2020 instrument for 11 different projects. The company combines synthetic biology with chemistry and process engineering to create industrial solutions utilising more sustainable bio-based raw materials .
France	**Public:** France 2030 Plan: The French government committed €7.5 billion to the France 2030 Plan, aiming to position France as a leader in hydrogen, decarbonised industry, and biopharmaceuticals by 2030. This initiative includes significant investments in synthetic biology and biotechnology. 1. National Research Agency (ANR): The ANR manages the France 2030 plan budget for higher education and research with a total budget of €54 billion (£45 billion) over 10 years. This included £230 million for advanced therapies (e.g. CAR-T cells, gene therapy, monoclonal antibodies) and £125-210 million for industrialisation of bioproduction projects.

	It funds collaborative research efforts and infrastructure development to advance scientific knowledge and technological capabilities in the country. 2. France-BioImaging: France-BioImaging, a national research infrastructure, received €9.2 million in funding to upgrade its technology offerings. This investment aims to enhance biological imaging capabilities, which are crucial for advancements in synthetic biology. 3. France Génomique: France Génomique, a national infrastructure for genomic research, was awarded €7.28 million to support its activities. This funding facilitates research in genomics, a field closely related to synthetic biology, enabling advancements in understanding and manipulating genetic material. 4. Bio-IMP (2024-2027): EU-funded project to optimize the manufacturing of innovative biopharmaceuticals (£14.9 million) with the ambition to produce 20 domestically made biomedicines by 2030 (increase from 5% to 20%). **Private**: 1. Venture Capital and Private Equity France hosts a vibrant biotech ecosystem with numerous venture capital (VC) firms and private equity investors actively funding startups in the synthetic biology sector. A list of 50 angel investors and VC funds that invest in biotech startups based in France can be found here. 2. Corporate Investments Large corporations in France are increasingly investing in synthetic biology through partnerships, acquisitions, and internal research and development. These investments aim to integrate synthetic biology innovations into their product lines and services, enhancing competitiveness and addressing emerging market needs e.g. Sanofi planned to invest €935 million (£780 million) over five years (supported by French govt) to provide France with a complete and autonomous value chain for mRNA technology (March 2022).

Netherlands	**Public:** The Netherlands Organisation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek, NWO) is the main funding body for scientific research in the Netherlands. NWO, mainly endorsed by the Dutch Ministry of Education, Culture and Science (OCW, Dutch: *Onderwijs, Cultuur en Wetenschappe*n), allocates nearly €1 billion annually for research (0.125% of GDP in 2020) (Bhatt et al, 2022). **Private:** e.g. Cradle (formerly known as Cradle Biotech): Cradle, a biotech software startup based in Delft, Netherlands, has secured €22 million in funding to develop a proprietary generative AI model aimed at improving protein engineering. This investment underscores the growing interest in applying artificial intelligence to synthetic biology. **Research and Community Initiatives** SynBioNL - SynBioNL is a community initiative that brings together researchers, policymakers, and industry stakeholders to advance synthetic biology in the Netherlands. The community focuses on fostering collaboration and innovation in the field. SynBioNL plays a pivotal role in bridging the gap between public research and private industry.
Saudia Arabia	**Public:** The Kingdom has committed to investing 2.5% of its Gross Domestic Product (GDP) in research and development by 2040, aiming to add $16 billion to its economy. This investment is expected to drive innovation in biotechnology and genomics sectors. 1. National Biotechnology Strategy (NBS): The NBS aims to establish Saudi Arabia as a global leader in biotechnology by focusing on self-sufficiency in vaccines, biomanufacturing, and genomics. The strategy outlines plans to localise the entire biologics development value chain, from research and development to manufacturing and distribution. They recently launched a large Life Sciences cluster called HELM (Health, Endurance, Longevity, and Medicine) in the capital Abu Dhabi.

	2. Vision 2030 Investments: Under Vision 2030, Saudi Arabia plans to invest USD 65 billion to improve the healthcare system and encourage domestic manufacturing. This includes agreements with the Saudi National Unified Procurement Company (NUPCO) to transition pharmaceutical imports to domestic production, thereby reducing reliance on foreign suppliers. 3. Research Development and Innovation Authority - RDIA: Established in 2021 and has administrative and financial autonomy and targets research supporting Health and Wellness, Sustainability and Essential Needs, Energy and Industrials, and Economies of the Future, with synthetic/engineering biology nested in some of these.
Russia	**Public:** A. Federal Programs & Government Initiatives 1. Federal Scientific & Technical Program for Genetic Technologies Development (2019–2027) a. Budget: ₽127 billion, managed by the Ministry of Science and Higher Education b. Focus Areas: i. Gene editing (CRISPR) ii. Synthetic biology for medicine & agriculture iii. Biosecurity & bioengineering 2. National Project "Science" (2019–2030) a. Total Budget: ~₽1.6 trillion (~$18 billion) for all scientific fields b. Includes funding for biotechnology, synthetic biology, and genetic research. 3. Russian Academy of Sciences (RAS) & State Research Institutes a. Institute of Bioorganic Chemistry (IBCh RAS) – Synthetic biology & genetic engineering b. Kurchatov Institute – National Research Center for Biotechnology c. Engelhardt Institute of Molecular Biology (EIMB RAS) – Gene editing & synthetic biology B. State-Owned Enterprises & Corporations 1. Rostec (State Corporation for Biotechnology & Pharma) a. Invests in biotech through R-Pharm (leading biopharma company) 2. Rosatom (Nuclear & Biotech Initiatives)

	a. Develops synthetic biology applications for industrial biotech 3. RUSNANO (Former State Nanotech Fund) a. Previously funded biotech startups, now less active C. Government Grants & Competitions 1. Russian Foundation for Basic Research (RFBR) a. Small grants (~₽5–10M) for synthetic biology research 2. Russian Science Foundation (RSF) a. Larger grants (~₽20–50M) for genetic engineering 3. Skolkovo Foundation (Innovation Hub) a. Grants for biotech startups (~₽5–30M) **Private:** A. Venture Capital & Startups • VC Firms: RVC (Russian Venture Company) – State-backed VC with biotech investments B. Corporate R&D (Pharma & Industrial Biotech) • R-Pharm: Invest in biologics but limited synthetic biology focus (R-Pharm Website) • Sibur (Petrochemical Giant): Exploring bio-based materials (Source: Sibur)

Table 3. Global, EU and selected national Engineering Biology related facilities and infrastructure

Country	Infrastructure/Facilities
Global	Global Biofoundry Alliance: a community collective of publicly funded Biofoundries across the world

EU	Pilots4U: databases of European open access bio-economy pilot- and multipurpose demo facilities. Examples include:
	
	• Belgium:
	  ○ BioBase Europe- scale-up infrastructure for biotech companies from lab-scale to multi-ton scale
	  ○ Mycelia - solid state fermentation scale-up up to 5000 kg
	• Denmark:
	  ○ Aarhus University has bioreactor scale-up facilities from 800 – 10,000L scale
	  ○ DTU Biosustain Biofoundry and Pre-Pilot Plant -brings projects from Technology Readiness Level (TRL) 0 to 2/3, which are then advanced and scaled-up to TRL 6 at the Pre-Pilot plant.
	  ○ 21st.BIO's Pilot Plant Facility: a precision fermentation launchpad offering services ranging from strain construction to industrial production upscaling (up to 1200 L), supported by Novo Holdings.
	• France:
	  ○ CRITT Bio-industries (Toulouse)- up to 300 L scale
	  ○ BioRea- scale-up from L/kg to industrial scale
	  ○ ARD: 30L- 180000L SIP fermenters and up to 350,000L sanitised reactors
	  ○ CEA: algae specific scale-up, one of the leading Research and Technology Organisations (RTO) in Europe
	• Germany:
	  ○ Phytowelt GreenTechnologies GmbH
	  ○ Fraunhofer Center for Chemical-Biotechnological Processes CBP- up to 10,000L scale-up
	  ○ Leibniz Institute for agricultural engineering and Bioeconomy- pilot plant 0.5 – 1000L scale

	• Netherlands:
	  ○ Bioprocess pilot facility- Food certified FSSC 22000 Fermentation and DSP plant
	  ○ Wageningen University- lab and semi-pilot scale bioprocessing facilities
	• Norway:
	  ○ SINTEF Industry Reactors up to 300L
	• Finland:
	  ○ VTT- semi-pilot and pilot scale facilities for biomass processing, biohydrometallurgy, and industrial biotechnology (up to 1200L)

UK	• Biofoundries:
	  ○ Edinburgh Genome foundry (University of Edinburgh)
	  ○ London Biofoundry (Imperial College, London)
	  ○ Earlham DNA Foundry (Norwich)
	  ○ GeneMill (Liverpool)
	  ○ NPL reference Biofoundry (London)
	• Six dedicated Synthetic Biology Research Centres (Bristol, Edinburgh, Manchester, Nottingham, Warwick, Norwich)
	• Centre for Process Innovation (CPI) National centres:
	  ○ Medicines Manufacturing Innovation Centre (Renfrewshire)
	  ○ National Biologics Manufacturing centre (Darlington)
	  ○ RNA Centre of Excellence (Darlington)
	  ○ Novel Food Innovation Centre (Tees Valley)
	  ○ National Industrial Biotechnology Facility (Wilton, Redcar)
	• Industrial biotechnology scale-up facilities:
	  ○ IBioIC FlexBio Bio-processing Scale-up Centre, Edinburgh (up to 300L scale)
	  ○ BEACON Biorefining Facility, Aberystwyth (30-200L scale)
	  ○ Biorenewables Development Centre, University of York (up to 30L scale)
	  ○ GSK Biotechnology Pilot Plant, Worthing (up to 4000L scale but 100-4000L capability is mothballed but available for use)

USA	• Agile Biofoundry (Emeryville) • BIOFAB (University of Washington)

	• Colorado Cyberbiofoundry (Colorado) • DAMP lab (Boston University) • iBioFAB (Illinois Biological foundry for Advanced Biomanufacturing) • Living Measurement Systems foundry (NIST, Maryland) Bio-manufacturing and scale-up: • US companies commonly carry out pilot-scale testing in Europe due to more abundant facilities. • The Department of Defence introduced **BioMADE** as one of its Manufacturing Innovation Institutes in 2020, with the aim to generate and coordinate industrial-scale biomanufacturing in the US. It is also a member of Manufacturing USA®, a national network created to secure US global leadership in advanced manufacturing through large-scale public-private collaboration on technology, supply chain, and education and workforce development.
Canada	• The Biofoundry at UBC (Vancouver) • Biofactorial (Vancouver) • Concordia Genome Foundry (Concordia, Montreal) • Biologics Manufacturing Centre at the National Research Council
China	• SJTU Synbio Biofoundry (Shanghai) • SIAT Biofoundry (Shenzen Institute of Synthetic Biology) • Tianjin Biofoundry (Tianjin Institute of Industrial Biotechnology, Tianjin) • Tianjin University Biofoundry (Tianjin) • Zhejiang University (Zhejiang)
Japan	• Kobe Biofoundry (Kobe)- a member of the Global Biofoundries alliance
South Korea	• K-Biofoundry (Korea Advanced Institute of Science and Technology, Daejeon) • K-Biofoundry KRIBB (Korea Research Institute of Bioscience & Biotechnology)

	• Sky Biofoundry (Sungkyunkwan University, Seoul)
India	• Biofoundry India (New Delhi)- a member of the Global Biofoundry Alliance
Singapore	• Synthetic Biology for Clinical and Technological Innovation (SynCTI)- biofoundry established in 2014 and a member of the Global Biofoundries alliance.

Australia	• Australian Genome Foundry (at Macquarie University CoESB)
	  ○ State-of-the-art genomic facilities, technology and expertise, including genotyping, gene expression, bioinformatics and DNA extraction.
	• Australian Institute for Bioengineering and nanotechnology (Brisbane)
	  ○ An integrated multi-disciplinary research institute offering research infrastructure capabilities and expertise to accelerate industrial outcomes for advanced biomanufacturing applications, including biofuels, chemicals, biologics and novel bio-inspired devices.
	• CSIRO Biofoundry (Brisbane)
	  ○ Integrated Design Environment for Advanced Biomanufacturing (IDEA Bio)- CSIRO/University of Queensland bio-foundry. Specialises in deep molecular characterisation of strains within instrumented bioreactors. Collaborates with national and international companies.
	
	Scale-up Facilities:
	
	“Lack of suitable biomanufacturing infrastructure in Australia related to translation and commercial activities to support demonstration and scale-up of synthetic biology applications represents a major challenge.” [ref]
	
	• Cauldron- a company in NSW, provides specialised bioproduction and fermentation as a service to other companies, up to 10,000 and 100,000L scale
	• Future Foods BioHub facility in Mackay – Received funding from the Queensland government to conduct a feasibility study for developing a world-leading biohub, focused on the production of alternative foods, protein products and plant extractives

	• Mackay Renewable Biocommodities Pilot Plant- pilot-scale Research and Development integrated biorefinery for the conversion of cellulosic biomass into bioethanol and high-value biocommodities with capacity of up to 10,000 litres (pending). Part of the QUT Centre for Agriculture and the Bioeconomy Other allied facilities: • Phenomics Australia: a national research infrastructure provider enabling research discovery and high-impact healthcare outcomes in precision medicine • National Biologics Facility- a network of facilities, platform technologies and subject matter experts for all stages of biotherapeutic development, from discovery through to scale-up and manufacturing. Three main nodes in Victoria, New South Wales and Queensland. • BASE mRNA facility (The University of Queensland) • RNA Research and Pilot Manufacturing Facility- Sydney. Operated by Myeloid Therapeutics. • Samara Eco Infinite Recycling Facility and Research and Development Hub: plastics recycling through enzyme design and production
Israel	• FutuRx biotech Accelerator. An industry supported accelerator offering access to facilities for growth
Saudi Arabia	• SAUDIBIO – Saudi Biotechnology Manufacturing Co.: SAUDIBIO is the first and only biotechnology manufacturing facility in Saudi Arabia, focusing on drug security and utilizing advanced technologies for biomanufacturing. • Liberation Labs & NEOM Precision Fermentation Hub: In partnership with NEOM, Liberation Labs is establishing a precision fermentation facility aimed at producing dairy alternatives without traditional livestock, advancing sustainable food technologies.