

Written evidence from UK BioIndustry Association (ENB0023)

About the BIA

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation. Our members include start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR agencies. We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

BIA has been promoting the UK's health engineering biology sector for over a decade, and the non-health engineering biology (which we have termed 'deep biotech') sector since 2023. Our expert Engineering Biology Advisory Committee ([EBAC](#)) has been active since 2013, providing insights into engineering biology business and shaping our activities and publications, such as our 2018 [Engineering Biology Explained](#) report, our 2022 [Power of Biology](#) report, and our 2024 [Deep Biotech](#) report on engineering biology beyond health.

This submission contains responses to a few selected questions from the Committee's [inquiry](#). For further views of the BIA and our membership on engineering biology, please see our substantial [September 2023 submission to DSIT's consultation on engineering biology](#).

Summary of recommendations

- It is vital for the UK to ensure that innovative companies can access the necessary infrastructure and finance and have a clear regulatory pathway if the UK wants these companies to scale and succeed in the UK.
 - We need more cost-accessible pilot and scale-up facilities, especially for upstream and downstream bioprocessing, and availability of specialist equipment, noting that different sectors need different equipment.
 - The current and next government must continue to implement the Mansion House Reforms to unlock capital that is key to delivering long-term strength in the UK venture financing ecosystem that most

engineering biology companies rely on. We need proof-of-concept funding from Innovate UK, greater focus on engineering biology within British Patient Capital, and an internationally competitive and efficient R&D tax relief regime.

- We need regulators to have a pro-innovation, collaborative mindset and to be resourced appropriately, both in terms of funding and knowledge, to be able to horizon scan and deliver effective regulation, where it is required, and ensure companies can commercialise their products safe in the knowledge that they are acting within UK law, where it is not.
- Significant progress must be made in these three areas *in the first half* of the 10-year Vision in order to ensure innovative companies can succeed.

2. What are the key applications for engineering biology?

Are there innovative companies, start-ups, or spin-outs that you think are of particular promise or significance using engineering biology in the UK today?

and

Can you give examples of particularly exciting or interesting applications? In particular, applications which could be taken forward or are being worked on in the UK?

The UK is leading Europe in the number of biotech startups and funding for those companies over 2017 to 2023. Around 1,162 engineering biology companies exist in the UK across the breadth of engineering biology applications in various sectors. The BIA and UK Government's 2022 brochure on the Power of Biology lays out three broader areas of engineering biology, namely health, agriculture, and industrial, and includes a directory of engineering biology companies in those areas in the UK. Detailed applications and innovative companies in those areas are mentioned below.

All of the below applications are actively being worked on by innovative companies in the UK, and supported by UK's national and regional accelerators and incubators. It is vital for the UK to ensure that innovative companies can access the necessary infrastructure and finance and have a clear regulatory pathway if the UK wants these companies to scale and succeed in the UK.

The application areas and some example companies include:

Health

- London-based Prokarium design bacteria to deliver therapeutic cargo molecules to fight cancer.
- Stevenage-based Neobe Therapeutics design programmable microbial 'trojan horses' engineered to disrupt solid tumours and enable existing therapies in non-responding patients.
- Using AI, London-based Sixfold Biosciences develop RNA drug delivery nanotools for cancer.
- Oxford-based Ochre Bio use AI to deep phenotype livers at scale to design precision RNA therapies to regenerate human livers outside the body, tackling chronic liver disease.
- Cambridge-based bit.bio's platform creates any human cell type and manufactures it with consistency at scale.
- Nottingham-based CHAIN Biotech engineer bacteria to function as oral vaccines and immuno-therapies.
- Edinburgh-based Resolution Therapeutics engineer macrophages to leverage their regenerative potential to treat liver cirrhosis.

Chemicals and materials

- Building on the rapidly evolving technology of biofabrication, London-based Modern Synthesis developed a microbial weaving process that uses bacteria, found in kombucha tea, trailing tiny fibres of nanocellulose to weave a novel biomaterial. The process allows clothing items to be precisely shaped, designing out waste.
- Norwich-based Colorifix aim to reduce the textile industry's environmental impact with a dyeing process that uses the DNA codes of colours found in nature and has microbes recreate them, removing the need to rely on harsh chemicals.
- Livingston-based Scotbio produces a range of natural ingredients, including blue food colourant and plant-based protein from spirulina algae.
- London-based Solena Materials creates biodegradable textiles from synthetic proteins using computational design.
- London-based Shellworks develops a novel material made by microorganisms found in marine and soil environments to make durable, fully compostable tubs or jars. The material's regenerative

nature means that once it is composted, the same microbes in the soil used to make the jar will consume it as a source of food, meaning the material biodegrades without generating microplastics.

- Oxford-based Spintex artificially spins high-performance silk fibres that are 1000x more energy efficient than synthetic plastic fibres, using no hazardous chemicals.

Agriculture & food

- Oxford-based Moa Technology can rapidly screen the microscopic behaviour of plants to develop novel and safe herbicide candidates by using high-content imaging, AI and machine learning techniques, allowing them to fight the rapid rise of herbicide-resistant weeds.
- Norwich-based Tropic Biosciences use CRISPR gene editing to develop improved varieties of tropical crops.
- Oxford-based Ivy Farm Technologies cultivate meat to create real mince beef, while London-based Hoxton Farms cultivate animal fats to combine with plant protein for meat alternatives. Edinburgh-based Roslin Technologies provide companies like these with immortalised cells to turn into the finished product.
- Edinburgh-based Green Bioactives develop and manufacture natural ingredients by extracting plant stem cells from whole plants that can be used in cosmetics, food and beverage, agriculture, and more.
- Nottingham-based Deep Branch recycles CO₂ and hydrogen into protein for animal feed.

Biofuels & hydrogen

- London-based Phycobloom develop microalgae to produce oil that can be used for fuel.
- Manchester-based C3 Biotech transform low-value waste streams into high-value chemical materials and fuels using natural biological processes.

Environment & CO₂ capture

- ABS breed bacteria that can consume waste, blockages, spills, pollutants or algae, replacing the need to use toxic chemicals.

- London-based Puraffinity develop a novel material that removes harmful pollutants such as Per- and Polyfluorinated Substances (PFAS) from water.
- London-based Cyanoskin develop a living photosynthetic paint that absorbs CO₂ by being painted on building surfaces in mid and high-rise cityscapes.
- London-based Epoch BioDesign design and scale enzymes capable of transforming plastics into low-carbon, circular chemicals.

Supportive technologies

- Cambridge-based Evonetix synthesize gene-length DNA on the surface of a silicone semiconductor chip and supply it for engineering biology research across sectors.
- London-based Touchlight develop a synthetic DNA vector with enzymatic production to make DNA to support the growth of genetic medicines.
- Cambridge-based Camena Bioscience's gene synthesis platform produces long and hard to synthesise DNA constructs.
- Cambridge-based Constructive Bio's platform writes synthetic genomes to make new molecules used in pharmaceuticals and biomaterials.
- Bristol-based Extracellular provide research, development and manufacturing capabilities for sustainable biotech, including cultivated meat and seafood and other non-human cell culture products, while Edinburgh-based Ingenza engineer biological systems to make therapeutics, enzymes and consumer products.
- Newcastle-based GitLife Biotech develop the first version control system for engineering biology and DNA-based biosecurity tools.
- Aberdeen-based NCIMB has built a diverse collection of microbes and developed a microbial platform to support precision fermentation and a broad range of industrial biotechnology applications.

Where does engineering biology have the potential to add value over processes that are currently used? What is the nature of this added value (e.g. throughput, sustainability, range of processes that are possible)? Which industries are most likely to be affected?

Please see the BIA's recently published Deep Biotech report, showcasing the wide-ranging impact of UK engineering biology companies.

The potential of engineering biology to help us design targeted cures for untreatable diseases, reach our net zero and sustainability goals, and to create a truly sustainable bioeconomy, is enormous. Its cross-cutting nature means that it can provide solutions that support as many as 10 out of 17 Sustainable Development Goals (SDGs). It is estimated that more than half of the economic impact from applications of biotechnology overall will lie outside healthcare, with the most significant proportion being in agriculture, aquaculture and food (\$0.8–1.2 trillion globally by 2030–40), followed by consumer products and services (\$0.2–0.7 trillion globally by 2030–40) and materials and energy production (\$0.2–0.3 trillion globally by 2030–40)'. The impact of many non-health applications of biotechnology will, in addition, ultimately have a positive impact on the healthcare sector, for example by reducing healthcare costs due to decreased air pollution, expanding the total economic and social value even further. However, the realisation of this impact relies to a large part on consumer, societal and regulatory acceptance. The role of private investment as well as Government support should also not be underestimated.

The UK has innovative companies active in all of the below mentioned areas of impact, as exemplified above.

Health

The positive impact of deploying advances in modern biotechnology has been demonstrated in the UK's thriving health life sciences sector. The use of engineering biology enables us to insert corrected copies of defective or missing genes into patients with certain genetic diseases, tweak immune system cells to accurately detect and kill cancerous cells, harness gut bacteria to deliver targeted therapeutics and vaccines, and genetically reprogramme mosquitoes that limit the spread of diseases such as dengue fever. Engineering biology is industrialising DNA sequencing, manufacturing and editing, making it cheaper and more accessible. Scientists are already able to insert edited copies of defective or missing genes, and gene editing techniques now allow scientists to accurately and rapidly cut out and replace specific DNA sequences. Engineering biology can help reduce reliance on animal testing, by creating human cells that may be used to test medicines in vitro ahead of in-person clinical trials. These are only a few examples of engineering

biology applications which can have a real impact in the lives of patients, and will further lead to reductions in healthcare costs and palliative care with significant economic impact.

Agriculture & food

Engineering biology enables us to produce real proteins through processes like precision fermentation and cell cultivation. Cell cultivation involves growing animal cells in large bioreactors to create real meat. These techniques remove the need for emission- and resource-heavy farming, and are well on the way to becoming price competitive. The process of cellular agriculture and the cultivation of meat in labs instead of fields has the potential to reduce greenhouse gas emissions. Livestock represents a total of 14.5% of all greenhouse gas emissions globally, with cattle being the largest contributor. By contrast, cultivated meat production may cause up to 92% less global warming, 93% less air pollution and use up to 78% less water. In addition, moving the production of meat away from land frees up valuable agricultural land by using up to 95% less land, and helps fight deforestation and biodiversity loss. Further, the use of engineering biology techniques such as gene editing and genetic modification can enhance the nutritional benefits of foods and feed, and create more resilient crops.

Materials & chemicals.

The fashion industry is estimated to be causing 10% of global carbon emissions. Polyester, largely derived from petroleum, dominates 54% of the global market due to the competitively low price of fossil fuels. Novel biomaterials have the potential to reduce our reliance on animal- and petrochemical-derived materials in the future, and prevent the pollution of water through microfibre shedding. Globally, 16% and 35% of microplastics released into our environment are from the laundering of synthetic textiles which can end up in the food chain and, ultimately, the human body. Other novel biomaterials can remove such pollutants from water and soil to decontaminate them. Similarly, chemicals in most everyday household and consumer items are derived from fossil fuels. Using biological processes and products helps established industries become more sustainable in their manufacturing processes and reach their net zero targets.

Biofuels & Hydrogen, Environment & CO2 capture

Biomass, such as crops or biowastes like residues from whiskey production, can be used to produce liquid and gaseous biofuels, replacing our dependence on fossil fuels. At 24% of the UK's total emissions, the

transport sector emits the largest amount of greenhouse gases of any sector in the UK. Biofuels play a significant part in helping us reach net zero by decarbonising our transport sector. Algae are well known as natural 'decarbonisers' through their ability to absorb carbon emissions from the biosphere. Applying the engineering biology toolkit allows us to increase algae's absorbing capabilities, turning them into highly efficient producers of algae oils – a sustainable source of fuel more powerful than solar, wind, and lithium. Like algae, certain species of bacteria use carbon as a source of food. Bioreactors containing these bacteria can be retrofitted into carbon emitting industrial plants and used to upcycle carbon gases into valuable chemicals like ethanol.

Biomanufacturing

Engineering biology processes can make the UK manufacturing sector cleaner and greener. The Boston Consulting Group reported in 2022 that by the end of the decade, engineering biology could be used extensively in manufacturing industries that account for more than a third of global output, or just under \$30 trillion in terms of value. In addition, investing in biomanufacturing for medicines can make engineered (e.g. bacterial) therapeutics cost effective, leading to a cost reduction of currently expensive treatments such as immunotherapies (up to £200,000 per patient).

3. How can Government policy support the development of engineering biology?

Does the Government's "National Vision for Engineering Biology" set out the right priorities for government to develop the engineering biology field in the UK? Was there anything missing from the strategy that should have been included?

and

The Government has committed to spend £2 billion over the next 10 years on engineering biology. Is this scale of subsidy sufficient to be competitive? Where should this funding be focused to best support engineering biology in the UK?

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Is there a danger that engineering biology advances developed in the UK are exploited overseas?

The Vision was received well by industry, and it is important that Government continue to work closely with industry to implement it, and uphold and expand its spending commitment. The Vision provides a

strong signal of intent from Government, showing the sector that it is a priority. This sends a powerful message to global investors, too.

The priority areas to focus on and deliver swiftly are infrastructure, regulation, and finance. Significant progress must be made in these areas in the first half of the 10-year Vision in order to ensure innovative companies can succeed and future start-ups are welcomed by a supportive, globally competitive UK ecosystem in which they can thrive. If we fail to deliver on this now, innovators' efforts to commercialise will be stymied, private investors will be deterred to invest, and companies will be unable to stay in the UK, leading to a drain of great industrial potential away from the UK.

On Infrastructure, we would like to see more cost-accessible pilot (early-stage) and scale-up facilities, especially bioprocessing, and availability of specialist equipment and high-throughput lab equipment, noting that different sectors need different equipment.

- For example, there is no UK Good Manufacturing Practice (GMP) facility for companies developing microbiome therapeutics based on engineered bacteria, forcing them to look abroad.
- Companies in the agriculture & food space require large-scale food-grade fermentation facilities. Some currently use pharmaceutical-grade equipment which are more available in the UK but drive-up costs.
- Highly skilled staff are essential to run and maintain this equipment. We need to ensure that there is a sustainable pipeline of talent with technical skills, including through sustainable immigration policies.

On regulation, we need regulators to have a pro-innovation, collaborative mindset and to be resourced appropriately, both in terms of funding and knowledge, to be able to horizon scan and deliver effective regulation so engineering biology companies can bring their products to market. While for some companies the regulatory pathway and/or regulator is clear, this is not the case across engineering biology applications. Working together, with public research funders and with industry, regulators must ensure that where regulation is required for innovative products, it is provided, and where it is not, it is clear that companies can commercialise their products safe in the knowledge that they are acting within UK law.

- For example, a UK company developing bio-based plastics to eliminate the use of petrochemicals are still being taxed as plastics, meaning they are not price competitive.
- A company using biological products rather than chemicals to clean up spills, blockages, or pollutants, does not have a clear regulatory pathway and regulator.
- A company engineering microbes for health applications currently does not have clear guidelines for regulatory approval of their products.

On finance, engineering biology companies can struggle to receive the large amounts of funding necessary to scale up in the UK. The current and next government must continue to implement the Mansion House Reforms to unlock capital that is key to delivering long-term strength in the UK venture financing ecosystem that most engineering biology companies rely on. We need proof-of-concept funding from Innovate UK and an internationally competitive and efficient R&D tax relief regime.

- For example, Green Biologics (later known as Biocleave) was unable to raise the necessary funds to scale their proprietary fermentation process for bio-based acetone and 1-butanol in the UK. Instead, the company was able to utilise existing infrastructure and raise finance in the US to build manufacturing capability.
- For example, engineering biology companies developing therapeutics struggle to access larger amounts of funding in the UK (£20 million +) that is needed to get to market through clinical trials, leading them to access investment abroad.

British Patient Capital (BPC) should focus on R&D intensive businesses, fund companies to establish manufacturing, and assess their expertise in engineering biology, as this currently falls between their life sciences and technology teams.

Unless the ambitions of international policy initiatives such as the US' National Biotechnology and Biomanufacturing Initiative, the EU's Biotech and Biomanufacturing Initiative are matched in the UK, there is a danger that engineering biology companies move abroad, as such initiatives have a crowding-in effect, signalling to companies and investors alike to stay and grow there. Equally, more advanced regulatory systems abroad, such as in novel foods, attract companies to launch their products there.

While the Vision sets out £2 billion of investment into engineering biology over 10 years, BIA are aware this is not new money but reflects the approximate spend on UK engineering biology across all departments and areas of the last 10 years. It therefore is not ambitious enough, especially given the breadth and impact of engineering biology, and the rising costs associated with research and attracting talent. For comparison, £500 million was given to AI through UKRI for two years alone, on top of £300 million announced previously. The 10-year National Quantum Strategy is investing £2.5 billion in quantum over the next ten years.

Which Government departments, and non-departmental public bodies, are engaged or should be engaged with engineering biology?

We welcome DSIT, DBT, GO-Science, and DHSC who actively engage in the engineering biology agenda and support the [S&T Framework's 2024 progress update](#) that restated engineering biology as a priority for the UK. We would welcome more engagement from DEFRA and DNZES, as the impact of engineering biology in their sectors could be significant. Their active engagement is vital to the success of engineering biology companies.

6. How should engineering biology be regulated?

Please also refer to comments made under question 3 above.

While for some companies the regulatory pathway and/or regulator is clear, this is not the case across the range of engineering biology products. For example, while lab-grown meat companies know the FSA is their regulator, members working in the bioremediation area, where they are using biological products to replace traditionally used chemicals, the regulatory pathway and responsible regulator is unclear. Rather than follow the precautionary principle to regulation, the UK should continue to follow a science-led approach, as exemplified by the approach to the Precision Breeding (Genetic Technologies) Act 2023.

We welcome central Government's pro-innovation approach to regulation, which needs to extend to regulators themselves. Regulators are under-resourced both in terms of funding and knowledge and therefore struggle to deliver current regulation and respond to new innovative products. Government funding is needed in addition to a collaborative approach with industry to address the resource gaps. We welcome the Regulatory

Sandbox Fund, but more effort is needed to actively encourage regulators to apply to it, as companies themselves lack the resources and knowledge of the right pathway into regulators to urge them to apply.

International governance of genetic resources

Almost all biotech companies and researchers rely heavily on DSI to conduct research. The increasing international focus on governing (and sharing the benefits of) the use of genetic resources and Digital Sequence Information (DSI) in research, including the discussions under the WHO pandemic preparedness accord and the Convention on Biological Diversity, are of great concern to the biotech industry. Overly burdensome regulations of this kind run the risk of stifling innovation and commercialisation that could benefit society, health, the environment, and the economy.

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