



SUPPORTING THE DELIVERY OF THE ENGINEERING BIOLOGY SECTOR

This policy brief was prepared as an advisory note for the EBLC

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Summary Recommendations

The UK Government has invested strongly in supporting basic research and early translation for transformative products of Engineering Biology (EB). In addition to economic benefits, these products have game-changing potential to deliver on Net Zero climate change, biodiversity and health-related UK policy objectives. The EB sectors are primed for major investment, and translational support from government and commercial sources is needed to accelerate exponential growth.

The recommendations outlined below are needed to safeguard this investment, to stimulate further commercial investment in UK EB sectors, and to ensure that its public and private benefits are retained within the UK to the extent that this aligns with effective translation.

Direct support for innovation in EB sectors and creating a supportive innovation environment are both equally important to safeguard the value of public investment and ensure that it leads to significant future commercial investment. The cost of these initiatives is relatively small compared to the scale of the previous investment being protected and of the expected benefits.

Direct support for innovation

Avoid barriers to entry to innovative technology sectors for small companies developing transformative products.

Set up an EB CATAPULT to act as a translational hub to support commercialisation of EB products.

Fill the gap in public support for innovation translation between the basic research stage and a project being 'investment-ready'.

Support expansion of a skilled technical and entrepreneurial workforce.

Support companies to undertake upscaling of manufacturing for EB products within the UK.

Creating a supportive innovation environment

Market-related incentives:

- sector-based targets and incentives to meet government policy objectives;
- a version of the US Bio-Preferred programme tailored to UK requirements and opportunities;
- positive labelling for EB products, informing consumers about societal/environmental benefits.

Opportunities for the UK to adapt its regulatory systems to meet national objectives and needs:

- urgently adapt the UK regulatory system for gene edited products and bring forward plans for UK regulation of all products of genetic technologies, building the confidence needed to support commercial investment;
- use standards and/or guidelines (soft law) to support market demand for EB-related products.

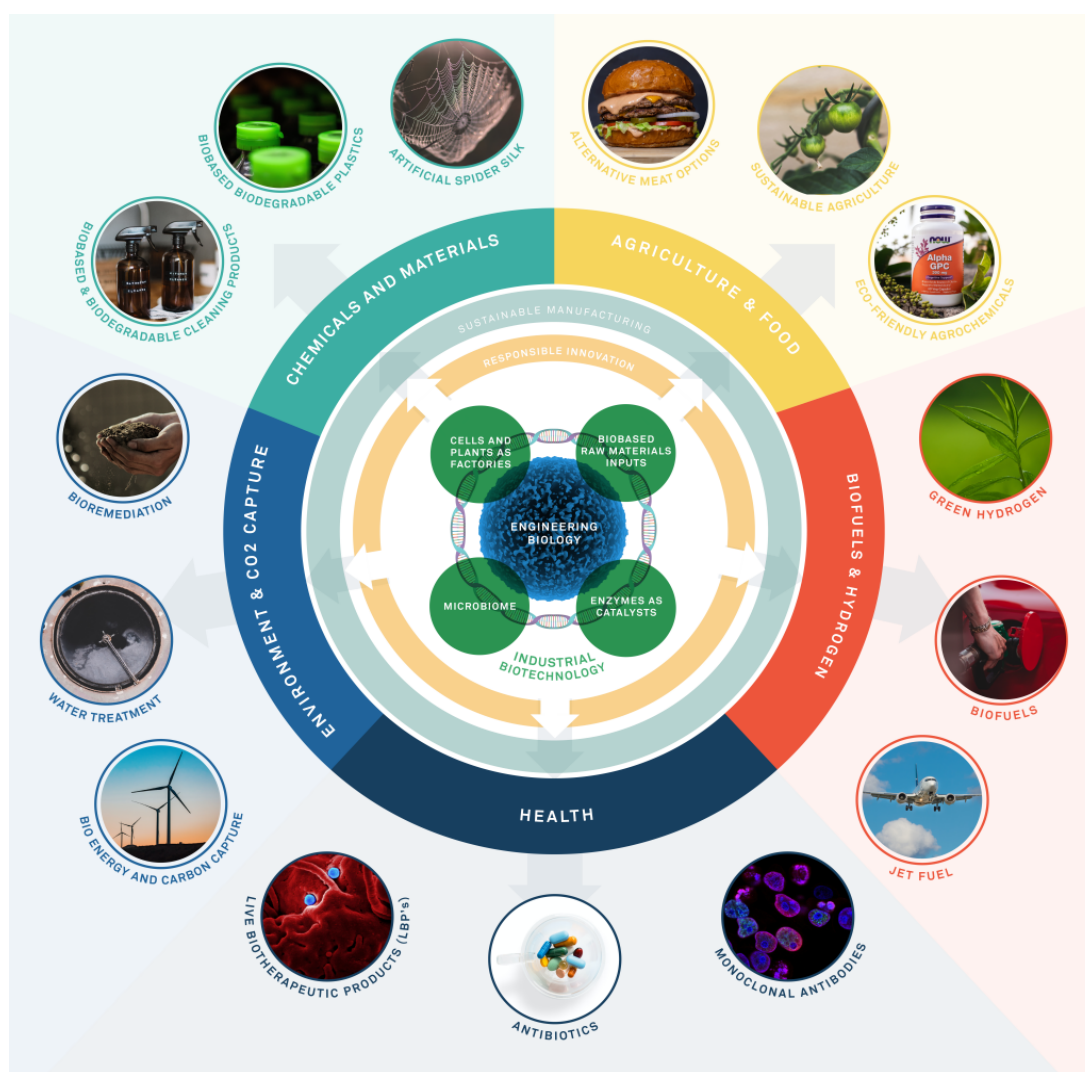
Stakeholder involvement and responsible innovation:

- involve all stakeholders equitably in discussions about innovative developments, their benefits and risks and how they should be regulated, ensuring high standards for the quality and breadth of evidence that is considered;
- encourage companies in EB sectors to adopt a standard for responsible innovation.

The Policy Context

The UK Government Innovation Strategy¹ will create an economy that excels at innovation, stimulating sustainable growth in seven key technology families, including engineering biology (EB). The EB technology family will drive transformative change across a broad range of subsectors with important contributions to other major UK technology families such as advanced materials and manufacture, energy and environmental technologies and bioinformatics and genomics. It will make essential contributions to tackling climate change and other environmental challenges and delivering food security, new health technologies and therapeutics, and healthier diets. The area is primed for major investment, and translational support from government and commercial sources is needed to accelerate exponential growth. Achieving this will require targeted policy and economic incentives and creative governance initiatives to ensure safe and effective delivery of the growth potential.

EB Technology Family and Subsectors/Clusters²



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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1009577/uk-innovation-strategy.pdf

² <https://ktn-uk.org/programme/industrial-biotechnology-leadership-forum/>

Benefits for the economy, the environment, health and society

EB-linked sectors will help to transform the UK economy, using gene editing and synthetic biology to develop cell, plant and animal-based products that are profitable, sustainable and contribute to climate-change and biodiversity-related policies by:

- reducing the use of fossil fuels for product manufacture and transport ;
- capturing and storing or recycling greenhouse gases (GHGs) (contributing to a circular economy);
- reducing the emission of GHGs in production and use of products;
- supporting the development of healthy diets that can reduce the demands on health services; and
- replacing products that damage biodiversity.

EB has the potential to transform the following sectors within the next 5-10 years, beyond that unlocking an estimated \$2-4 trillion in annual direct global economic impact by 2030 to 2040³. The following are just a few examples from a much wider array of innovations under development.

Chemicals and materials (Industrial Biotechnology)⁴

Using microbial fermentation processes to replace the use of petrochemicals in the production of detergents, plastics (bio-based and biodegradable), flavours, fragrances, fabrics and dyes.

Using fungal mycelia to create robust, biodegradable building materials;

Using spider silk to create fashion garments and bullet-proof vests.

Agriculture and food

Using crop, animal or microbial innovation to increase food production efficiency;

Developing crops that are heat, drought and flood resilient, or pest and disease resistant;

Developing animals that are disease-resistant, heat tolerant and (in ruminants) produce less methane;

Developing alternative protein sources for human food and animal feed (single cell protein, insect- and plant-based), increasing production while reducing GHG emissions;

Developing crops, animals and micro-organisms for future healthier diets;

Using plants as factories for drugs, vaccines, dietary supplements, and complex molecules for future manufacturing value chains.

Health-related developments

Complex drug developments that are beyond the reach of chemical synthesis, including antibiotics, vaccines and monoclonal antibodies;

New, very short-lived products that need to be manufactured close to the point of care;

Novel, programmable, safe and effective cell and gene therapies;

Living medicines, e.g. engineering the microbiome;

New classes of sensors and diagnostics for disease states and testing of pharmaceuticals.

³ See note 1.

⁴ Industrial Biotechnology Leadership Forum, *National Industrial Biotechnology Strategy to 2030*, <https://www.bioindustry.org/uploads/assets/uploaded/d390c237-04b3-4f2d-be5e776124b3640e.pdf>

Orchestrating support for the EB sector

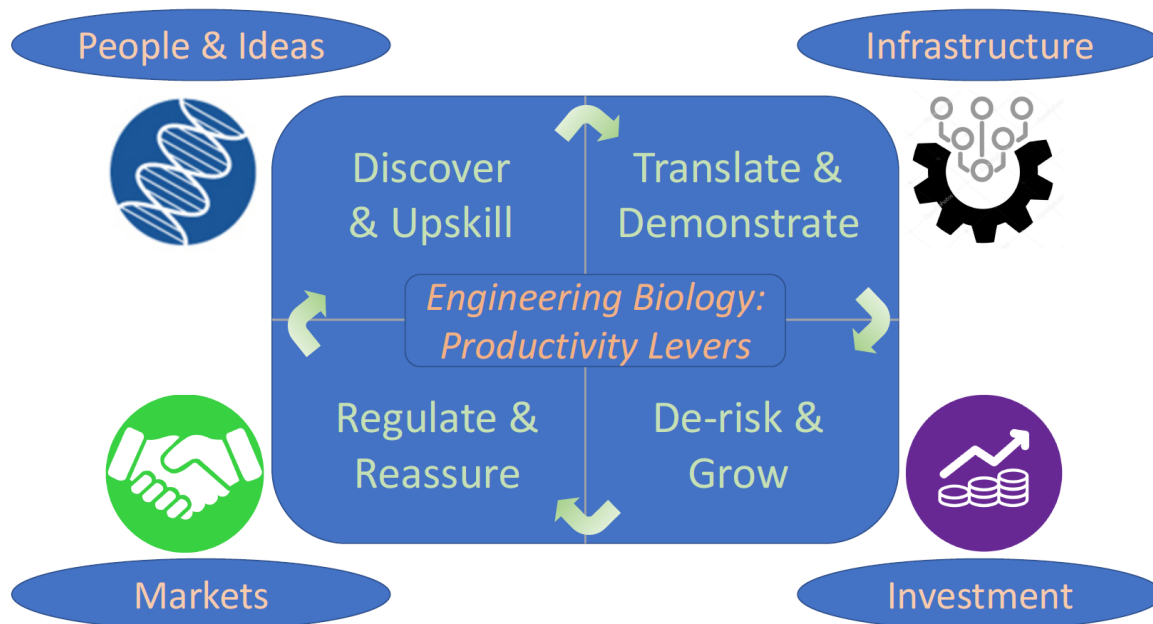
Past government investment in EB-related research has placed the UK in a leading position in terms of science and technology capabilities and it is important to ensure continued investment to retain this position. Support will be most needed for transformative technologies capable of disrupting the business models of incumbent companies, potentially leading to the formation of new and profitable sectors, building on this strong research and development base in the UK.

This direct support for research and innovation will not deliver the expected benefits without an equivalent focus on optimising the innovation environment, led by smart policy and regulatory initiatives, not necessarily involving large scale commercial investment. For example companies will actively seek to locate their future investment in the UK if our regulatory systems are proportionate and adaptive to the needs of these innovative products.

Guidelines should be developed, providing criteria to help investors and policy makers to identify (i) which are the potentially transformative future developments, (ii) for which companies in the product value chain they will be most transformative, and (iii) what barriers to their future development will need to be addressed⁵.

These guidelines would support decision making about investment in product development from the public and private sectors and identify where new policy and/or regulatory initiatives are needed.

The EBLC 2021 report⁶ recommends four areas of intervention to leverage the value of UK Engineering Biology.



'Discover and Upskill', 'Translate and Demonstrate', and 'De-risk and Grow' all relate to direct support for transformative innovation. This is the investment that is at risk unless we also address the fourth factor, 'Regulate and Reassure', addressing the need for supportive governance related policies to ensure that public and commercial investment in innovation promotion does deliver the expected benefits.

⁵ Tait, J and Wield, D. (2019) Policy Support for Disruptive Innovation in the Life Sciences. *Technology Analysis and Strategic Management*. <https://doi.org/10.1080/09537325.2019.1631449>

⁶ EBLC (2021) *Engineering Biology for the UK: a resource to help Build Back Better*. https://ktn-uk.org/wp-content/uploads/2021/07/EBLC-Building-back-better-with-Engineering-Biology_upload.pdf

Direct support for innovation

The most powerful transformative innovations are most likely to come from small companies and to be challenging for larger incumbent companies and this should be taken into account in innovation promotion. The initiatives suggested here could have a powerful impact on the future of the EB sectors in the UK with suitably targeted, but relatively modest amounts of funding.

Innovation support policies should ensure equitable participation of small and medium sized enterprises (SMEs) in innovation systems, for example by avoiding barriers to entry for small companies.

Small and large companies will benefit from access to an infrastructure to provide incubation and other resources, e.g. an EB CATAPULT that could channel expertise, resources and funding, acting as a translational hub to support commercialisation of EB products.

Based on interviews with innovators, there is evidence of an important gap in the provision of public support after the end of the basic research stage and before a project is 'investment-ready'. **There is a need to provide the relatively small amounts of funding needed to fill this gap, opening up many more opportunities for major private investment to follow.**

Delivering the expected growth in EB-related sectors will require continued expansion of a skilled multi-disciplinary workforce, particularly technical and entrepreneurial.

Too many companies, often with public funding from UK sources, are moving to other countries to undertake the up-scaling stage of development, increasing the probability that later translational stages and location of commercial production will also take place out with the UK. **Ensuring that it is attractive for all companies to undertake upscaling of manufacturing processes in the UK will pay dividends through commercial investment in later development stages, and encourage innovators in other countries to locate their future investment in translation of innovative products in the UK.**

Creating a supportive innovation environment

Investing public money in direct support for innovation requires equivalent attention to delivering a supportive innovation environment. Key elements of the innovation environment that are amenable to government policy influence include market-related incentives, regulation of products and manufacturing systems, stakeholder engagement and responsible innovation.

Market-related incentives

Transformative innovations are generally more expensive than competing products when they first enter the market, but become competitive as their uptake increases, e.g. solar panels and wind turbines. Governments can have a role in creating market-related incentives (market-pull) for companies to develop transformative products, particularly if they will help to meet important policy objectives such as Net Zero GHG emissions, supporting biodiversity and contributing to a circular economy. Policy options in this area include:

Where appropriate, set sector-based targets and incentives to meet government policy objectives, guiding companies and customers to develop and use products with the relevant properties.

Consider a version of the US Bio-Preferred programme⁷, tailored to UK requirements and opportunities. This could include mandatory purchasing requirements for government bodies and their contractors.

Set up a positive labelling initiative for EB-related products, informing consumers about their societal and environmental benefits.

⁷ <https://www.biopreferred.gov/BioPreferred/faces/pages/AboutBioPreferred.xhtml>

Regulations and standards

The EU regulatory system for EB-related products has directly and indirectly inhibited innovation in EB sectors and Brexit has created an opportunity for the UK to adapt its regulatory system to be more in line with those of non-EU countries with a long history of innovating in these areas, opening up new markets for UK-based companies. Initiatives that make regulatory systems more agile and adaptive to the needs of innovative technologies, particularly bringing down their cost and timescale, would also enable the rebalancing of the contributions of large and small companies in the innovation economy, as has already been the case in Argentina⁸.

The UK is one of the leading nations internationally in supporting moves to make regulatory systems more agile and proportionate to the needs of today's innovative technologies and has begun the process of regulatory adaptation for EB technologies. The UK's future regulatory system should be flexible but robust, well aligned with those of future trading partners, leading to a regulatory approach that addresses the hazards posed by the products concerned rather than, as is currently the case, the process/technology used to develop them.

Three areas of regulatory focus are important:

- (i) For living products (crops, animals and micro-organisms), designed to be used in an open environment, the UK could benefit, economically and as an international leader in regulatory adaptation, by proceeding with urgency with its current plans to adapt its regulatory system for gene edited products and by bringing forward as rapidly as possible its plans for regulation of all products of genetic technologies⁹.**
- (ii) For products developed in contained conditions (e.g. industrial biotechnology), reaffirm the government's intention to retain the current regulatory approach which is well-adapted to the needs of companies and the risks and benefits of the products.**
- (iii) Use standards and/or guidelines to support market demand for EB-related products, for example, in relevant markets, requiring products to contribute to Net Zero and biodiversity policies.**

Stakeholder involvement and responsible innovation

Major regulatory decisions should involve inputs from all relevant stakeholders, including members of the public, and approaches to stakeholder engagement have been evolving based on EB-related experience¹⁰, for example:

- **There should be equitable treatment across all stakeholders;**
- **Participants should accept that consensus may not be attainable and expectations should be managed accordingly;**
- **The engagement process should ensure that stakeholders are well-informed about the nature of the innovation, regulatory processes and how they work;**
- **The engagement process should ensure a balanced consideration of benefits and risks associated with the innovation and where its impacts will emerge;**
- **Standards are needed for the quality and breadth of evidence that is considered as a basis for discussion and decision making on regulatory processes.**

⁸ Whelan AI, Gutti P and Lema MA (2020) Gene Editing Regulation and Innovation Economics. *Front. Bioeng. Biotechnol.* 8:303. doi: 10.3389/fbioe.2020.00303

⁹ Regulatory Horizons Council (2021) *Report on Genetic Technologies*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014151/rhc-genetic-technologies.pdf

¹⁰ See note 9, pp28-29

Unnecessarily demanding regulation, including ‘gold-plating’ of regulatory standards, can have the effect of amplifying stakeholder perceptions of the risks of EB products. Likewise, vested interests can have a role in further amplifying risk perceptions or alternatively in minimising potential hazards.

To achieve democratically sound stakeholder engagement there is a need for an independent communication initiative to ensure an evidence-based understanding across all stakeholders of the benefits and hazards of EB-related products and how they are regulated.

Across all innovative sectors of the economy there are increasing demands for companies to demonstrate that they are innovating responsibly. Where significant regulatory adaptation is being considered, this will be an important contribution to reassuring stakeholders that product safety will continue to be maintained.

Companies should be encouraged to adopt the British Standards Institution Guidance on Responsible Innovation¹¹ or an equivalent standard.

Seeing the big picture

The UK Government has invested heavily in supporting basic research and early translation for transformative products of EB sectors. The initiatives proposed here are needed to safeguard this investment and to ensure that its public and private benefits are retained within the UK to the extent that this aligns with effective translation. These initiatives are designed to stimulate further commercial investment in UK EB sectors, but failure to take them on board could put the other investments at risk.

The best outcomes will be achieved where the government enables an integrated, systemic approach that can recognise where and when specific initiatives outlined above will have maximum impact on the performance of the system as a whole and how they will interact with one another.

Government could develop advisory guidelines for this integrated approach to policy support for innovation.

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¹¹ British Standards Institution (2020) *Responsible Innovation – Guide PAS 440*.
https://pages.bsigroup.com/l/35972/2020-03-17/2cgcnc1?utm_source=pardot&utm_medium=email&utm_campaign=SM-STAN-LAU-PAS-PAS440-2003