Centre for Science and Policy

Policy Workshop on Engineering Biology

Summary report of the discussion held on 19 June 2023

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Introduction

The Centre for Science and Policy (CSaP), University of Cambridge, organised a Policy Workshop on engineering biology in partnership with the Foreign, Commonwealth and Development Office (FCDO) and the Department for Science, Innovation and Technology (DSIT). The event brought together policy professionals, researchers, and other relevant experts.

The purpose of the Policy Workshop was to gain insights and expert opinions on the opportunities and risks linked to future science and technology developments in the field of engineering biology and to explore the policy implications of these developments. The workshop also sought to identify where the UK excels in relation to engineering biology and to better assess overseas capabilities to inform the UK's international engagement plan.

The key objectives of the Policy Workshop were to:

- Gain insights and expert opinions on opportunities and risks linked to anticipated future science and technology developments in engineering biology
- Explore the policy implications of these developments, including recommendations for international norms and standards
- Better understand areas where the UK excels and where the UK could lead the world in relation to engineering biology
- Better understand overseas strengths and capabilities to inform the UK's international engagement plan, including areas less explored in terms of collaborative potential
- Inform work on engineering biology policy across government
- Develop relevant networks and facilitate long-term knowledge exchange between researchers and policy makers in this area

The workshop addressed the following questions:

- What are the opportunities and mechanisms for research to inform the implementation of the UK government's principles set out in the Biological Security Strategy? How can we encourage and support responsible innovation?
- What are the key aspects of engineering biology that should be standardised?

- How do we promote global sharing and open technologies within this field? How and in which areas can the UK play a leading role internationally?
- How do we future-proof regulations, both on the domestic and international levels?
- What does the future of engineering biology mean for the UK international engagement? What are the key strengths and capabilities overseas that the UK should collaborate on?

Desired outcomes include:

- Productive knowledge exchange facilitated between researchers and policy makers around emerging research and policy priorities with improved understanding from both perspectives.
- Areas mapped where research evidence or advice can be used to inform policy making and enable policy implementation.
- Areas identified for further collaboration and potential partnerships.
- Developing links between the research community and policy makers within this field.

Overall, the workshop was designed to inform work on engineering biology across government and covered a wide range of topics including:

- The status of engineering biology in government plans
- Mechanisms for promoting collaboration in engineering biology
- Priority determination for engineering biology in the UK
- Biosecurity concerns emerging from developments in engineering biology
- The balance between support for fundamental science, applied science and commercialisation
- Challenges linked to regulating technology development and innovation from engineering biology

A Priority Technology for the UK Government

From the outset, workshop participants made it clear that engineering biology is a priority technology for the UK Government. Engineering biology is one of the five critical technologies referenced in both the UK's Science and Technology Framework and the Integrated Review Refresh. Engineering biology is included in FCDO's International Technology Strategy. It outlines how the UK will prioritise global leadership on responsible innovation shaping the global debate on norms and standards. As part of the work to refresh the UK's Biological Security Strategy, the government has been re-evaluating the risk landscape and considering the evolving rapid advances in science and technology. FCDO and DSIT participants pointed to a range of issues that they were interested in, such as the intersection between the bioeconomy and biosecurity, particularly in terms of trade-offs between growth and security. Engineering biology is listed as a priority technology in the International Technology Strategy and participants highlighted the importance, at this early stage, of identifying the UK's current strengths and gaps in relation to engineering biology. This could inform how the UK can establish international partnerships to promote shared solutions to problems and to co-ordinate responses to security concerns. In May 2023 the Council for Science and Technology released a Report on Engineering Biology: Opportunities for the UK Economy and National Goals with a series of recommendations related to engineering biology.

Participants noted that there is a need to regulate in a different way when it comes to engineering biology products, and it is useful that conversations are presently underway on this issue. One participant emphasised the importance of thinking in a holistic way about the levers that need to be brought together to give the engineering biology agenda coherency including developments in research, initiatives across governments, and funding.

Sustaining Momentum for Engineering Biology

The United Kingdom has been at the forefront of promoting synthetic biology and creating a research community focused on engineering biology. This initiative has set the stage for international collaboration and the development of engineering systems for biological applications. While there is a shift towards application-driven technology and commercialization in engineering biology, the importance of maintaining a balance between foundational research and application-specific developments was stressed at the workshop.

One participant pointed out that there are growing concerns within research about the move from a synthetic biology model to engineering biology. There have been disruptions and delays in decision making during and after Brexit and the COVID-19 pandemic, while the mission-orientated nature of the UKRI engineering biology funding call lends itself towards application science, as foundational science is not explicitly part of the mission cause. As such, there are fears that the UK's leading role in the international synthetic biology space could be faltering and losing momentum in the shift towards engineering biology, particularly if foundational cross-cutting work is not properly supported.

Another participant pointed to the Strategic Roadmap for Synthetic Biology published in 2012, highlighting that many of the themes identified in this mapping exercise broadly resemble those that feature prominently today. They highlighted that care is needed to manage expectations about how quickly the transition to an engineering biology model will take place. One participant estimated that from the creation of the 2012 roadmap it would take thirty years to see major growth in the industry and commercial application. The risk, they suggested, is that the regulatory framework is not keeping pace with scientific developments, and this could decelerate development. Another participant pointed out that while many questions remain the same, bioengineering (and the issues associated with the industry) have grown in both scale and complexity.

It was suggested the 2012 roadmapping exercise was extremely valuable for convening and co-ordinating stakeholders (including academics, funders, and industry) and promoting a collaborative approach to the issue. Participants also noted that the roadmapping process provided a platform for constructive challenge and debate and, as different stakeholders came together, the hurdles became clearer. Various participants suggested that now might be an opportune time to revisit and update the 2012 roadmap and that such a process could provide a useful mechanism for bringing relevant stakeholders across academia, government, and industry together. Participants noted that such exercises should take place more frequently, with the aim of producing a rolling programme rather than a static document.

Changing Priorities and Technologies

Participants broadly agreed that while engineering biology has important applications in the areas of medicine and healthcare, it is important to think of this technology as an answer to questions across a range of areas such as chemicals, materials, agriculture, and defence. As part of its focus on transformative technologies, the UKRI has announced a £70 million funding call in its engineering biology missions which focus on 1) food systems; 2) biomedicine; 3) clean growth; 4) the environment, with projects due to start in February 2024. Greater acknowledgement of the varied applications of engineering biology technologies would be an important strategic shift within Government. The workshop discussed how policy makers across different departments need to be made aware of the potential applications of engineering biology to help solve the problems that they are facing.

However, the potential for manifold applications also raises the problem of focus and how to both identify and prioritise the issues that engineering biology could best contribute to. Participants pointed out that it is important that steps are taken to develop a foundational basis to support initiatives related to engineering biology across the board (for instance, by empowering supply chains around DNA synthesis and sequencing). By cultivating the underlying technologies, DSIT could help develop a rich ecosystem that would empower relevant departments to pursue emerging opportunities related to engineering biology in their specific areas. To identify priorities for application, it was suggested by one participant that the UK could look to international partners and their priorities to align and narrow down options.

The Wider Implications of Engineering Complex Biological Systems

The Importance of Systems Thinking

The Policy Workshop highlighted the importance of whole systems thinking in engineering biology in the UK. Participants discussed the ambitious idea of being able to engineer biological components like Lego pieces to build organisms that function seamlessly. While this approach has shown promise at smaller scales, the workshop emphasised the need for a cautious and holistic perspective when dealing with larger, complex biological systems, and emerging technologies with uncertain outcomes.

One participant explained that biological engineering, particularly when applied to crop systems, pharmaceutical production, and other vital areas, involves much more than manipulating individual DNA components. The living organisms interact with their environment, undergo growth and maintenance, and have broader social and ecological impacts. They proposed that biological systems should be considered as hierarchical and social entities, like economic, religious, or political systems.

Participants acknowledged the challenges of integrating engineering biology into dynamic social systems and achieving desired outcomes, and that a broader systems approach can reveal unforeseen consequences and potential backlash. Simply introducing new biological products or solutions is not enough; the entire system must be considered, including aspects of growth, human impact, agronomy, diversity, and environmental implications. Policy makers need to understand the demands, needs of industries, and consider the consequences of sourcing the necessary resources. The engineering of biology should not lead to unsustainable resource usage or further environmental degradation.

Engineering biology is a fast-moving technology, and a key concern is promoting responsible innovation and growing the sector in a way that is safe and sustainable. One participant pointed to biofuels as a cautionary tale of industry led priority determination. A sector like aviation has an industry need to reduce emissions and one means of achieving this is to use waste feedstocks to produce fuel. However, there is simply not enough waste to meet the sector's demand, which could result in the diversion of feedstocks from other sources, having a devastating impact on nature and biodiversity. Another participant explained that many companies are not actually using waste feedstock in their processes and that purpose-grown feedstocks can pose a greater risk to land-use-change and environmental degradation than waste feedstocks. While the participant acknowledged general shortages, they emphasised the importance of a transition away from purpose-grown feedstocks and the promoting a range of other sources, including agricultural and carbon waste. Ultimately, there is a risk that without understanding the scale that industries moving from current systems to engineering biology-based systems need to operate at and the resources needed to facilitate this, engineering biology could be applied in a harmful way.

Leading on from this, the concept of responsible research and innovation was discussed, emphasising the importance of a culture where responsible innovation and self-governing are encouraged and practiced in both academia and companies, without relying solely on restrictive regulations. Participants stressed that building a culture of responsibility and oversight early on can prevent misuse and negative impacts, drawing a comparison with how nuclear physicists have carefully managed their field since 1945. Considering the broader implications, impacts, and scale of biological engineering applications will be essential to achieve sustainable and socially beneficial outcomes. Policy makers and researchers should work together to navigate the complexities and uncertainties of this emerging technology responsibly.

Biosecurity Concerns

Participants discussed the diverse ways that we need to be thinking about biosecurity in relation to engineering biology:

1. **Malicious actors:** can these technologies be weaponised by bad actors to harm the UK.
2. **Accidental risks:** due to the complexity of these technologies it is feasible that biosecurity risks will arise through accident.
3. **Supply chains:** What vulnerabilities emerge due to dependence on new supply chains that support the bioeconomy and is the UK taking steps to insulate itself against such vulnerabilities.
4. **Conservation:** how facilitating the bioeconomy may pose risks to conservation and to biodiversity.

Government is in the initial stages of thinking about the implications of engineering biology for security, and participants emphasised the need to consider these issues from a variety of angles. For instance, malicious actors could range from terrorists who could use engineering biology technology to weaponise pathogens, to state actors that could be interested in producing super soldiers. It is important to make departments across government aware of the positive potential of engineering biology technologies, but it is also important to educate policy makers of the risks and to build a community across government that promotes forward-facing resilience building measures. In terms of economic security, one participant pointed to the desire within the UK government to foster sovereign capability; it is important to think about supply chains and what parts of these supply chains are critical for the UK's resilience.

Another participant recommended that the government must be realistic about the levers that can be put in place to combat different threats to biosecurity. For instance, a regulatory approach is going to have a minimal impact on restricting malicious actors as they are not concerned with abiding by the law. It was also noted that most of what is being done in the engineering biology space is harmless, but there is already quite a lot of regulation: it is important to get the balance right. When thinking broadly about the unknowns related to engineering biology, one participant envisaged a role for the Arts. They pointed to science fiction as a genre that imagines the possibilities to better understand potential threats, noting that the dystopian sci-fi of the 1970s and 1980s predicted things that have (in a broad sense) become a reality.

Several participants stressed the need to build appropriate cultures within universities and companies that have safeguarding built in. It was noted that those best placed to judge the level of risk is the community itself and that a culture, like in nuclear research, which can assess risk and self-police is necessary. There remain open questions on how best to establish effective horizon scanning so that potential threats can be mapped and categorised. This is made more difficult by the interdisciplinary nature of engineering biology. It is difficult to establish norms and conventions when people are coming into the field from different starting points: when individuals cross disciplinary boundaries their ideas of what is 'dangerous' may not match up. As students and practitioners from different disciplinary contexts come to work on fields related to engineering biology, it is important to acknowledge that they come from their own contexts with their own standards and norms. As such, it is important consider how to incorporate questions related to ethics and governance into education across the range of disciplines relevant for engineering biology early on.

Public Perceptions

Another crucial aspect that the workshop participants addressed is public perception. They recognised the importance of ensuring engineering biology is accepted positively by the public. It was noted that there is a fear factor attached to engineering biology even though alternative technologies have the potential to do more harm. It was also noted how art can play a role in influencing public perceptions (for better or worse); alarmist discourses around Artificial Intelligence are framed around ideas of an AI takeover that has been fermented in popular culture. One participant emphasised that building a positive culture around engineering biology and around biosecurity should start with educating the public, especially younger audiences, and making engineering biology less abstract.

One participant pointed to the public reaction to Genetically Modified Organisms (GMO) as a cautionary tale, noting that the backlash experienced by GMO is part of the reason engineering biology is called as such. It is important that initial experiences of engineering biology are reassuring and exciting, and an education setting could provide an importance space to shape perception of these technologies. Another participant suggested that users and publics should be brought into the agenda-setting process and that funding mechanisms and structures should provide space for such views when making decisions.

Moreover, public perceptions of engineering biology need to be carefully managed to ensure positive initial experiences and widespread acceptance. If the development of engineering biology is approached in a gradual and inclusive manner, it can become a technology that seamlessly integrates into society, avoiding any potential concerns associated with a sudden and disruptive introduction. To achieve this, engaging with problem owners and incorporating public voices, particularly patients and end-users, becomes crucial. By involving these stakeholders, a comprehensive narrative can be created, highlighting the benefits of engineering biology and addressing any potential concerns. It is also important to broaden the focus of engineering biology beyond healthcare and consider its applications in areas such as plant science, agriculture, and new materials. Funding mechanisms and infrastructures should be developed to support research agendas aligned with the priorities and needs of different user communities.

International Collaboration

International collaboration was emphasised as a critical area of focus, given that biological engineering is a priority technology within the International Technology Strategy. Collaboration and partnering with other nations were considered by the participants to be important for setting global standards, coordinating responses to security concerns, and finding solutions to shared challenges. They agreed that the UK should aim to provide leadership in regulation, aligning norms and regulations with the country's democratic values.

Furthermore, while there are some core aspects of the supply chain that the UK should maintain or develop sovereign capability in, there was an acknowledgement that the UK could not do everything alone and that it is necessary to establish who the potential overseas partners are and how to work with them. As one participant noted, the list of potential partners that have good capabilities in areas of engineering biology today is not necessarily the same as the list of partners who will be important in the future, as new challenges and opportunities present themselves. When strategically planning collaborations, it is important to identify where the UK’s strengths lie and where there are gaps that need to be filled through international collaborations or by capacity building at home.

This is not an easy task, as the UK must juggle current supply chain deficiencies with gaps that could open in the future. To be able to judge these questions with certainty the supply chains should be mapped out. One participant indicated that a major barrier to building local capacity is that there is a lack of transparency about the inputs that go into the production process: companies are reluctant to share what their inputs are and where they obtain them from. Investing in talent exchanges, research infrastructure, and policy discussions could foster a robust and resilient ecosystem. The exchange of knowledge and the establishment of standards and interoperability facilitate the growth of the field on a global scale.

A New Roadmap for UK Bioengineering

A Balance between Foundational and Applied Science

Foundational science plays a crucial role in the field of engineering biology, as discussed extensively by participants. The recognition of the importance of foundational science has emerged over the past two decades, with a growing consensus that understanding biology is essential for rational design approaches in engineering biological systems. This recognition is particularly significant considering the pressing challenges faced by humanity, such as the shift towards circular economies and sustainable practices, which require the modification and engineering of biological materials.

One participant explained that the unique nature of biological systems presents challenges in engineering them due to their non-linear interactions and distributed cause-and-effect relationships. Unlike conventional engineering, biological systems are based on networks and interactions, requiring a deeper understanding and ability to program them. This is where foundational science becomes critical, as it provides the necessary knowledge and insights to comprehend and manipulate biological systems effectively. Foundational science is intrinsic to the nature of engineering living systems and cannot be overlooked. Foundational science forms the basis for technological advancements and innovation.

Furthermore, participants highlighted the need to address the challenges posed by the climate crisis. Fundamental research is essential to tackle the scale of these challenges, but there is also a need for translational science to bridge the gap between lab-scale experiments and large-scale applications. Building pilot facilities and scaling up biological processes require both foundational research and practical implementation expertise. Other countries like the United States and China have also recognised the significance of engineering biology and have initiated various programmes and significant investments in this field which are equal to investments in applied technologies.

Bringing Industry and Academia Together

The Policy Workshop also focused on the critical importance of bridging the gap between academia and industry in the field of engineering biology in the UK. Promoting collaboration was a theme that ran throughout the discussion, and participants highlighted the need for efforts between these two spheres to drive innovation, create market pull, and develop a skilled workforce capable of sustaining the biotechnology industry.

One participant highlighted that coordination, collaboration and healthy debate were a key part of the 2012 Strategic Roadmap for Synthetic Biology, although they acknowledged that it was a more straightforward process at the time, as less government departments and funding agencies were involved. Several key strategies were proposed to facilitate integration between academia and industry moving forward, including workshops to foster dialogue, funding mechanisms to support feasibility studies, and reimagining education systems to meet the demands of a growing biotechnology sector.

Workshops emerged as a valuable tool to bring together professionals from academia and industry in a small, interactive setting. These gatherings facilitate discussions that match people's interests, leading to a better understanding of the practical applications and needs of the industry. By engaging researchers, clinicians, and industry representatives in collaborative brainstorming sessions, the workshops promote rethinking and reframing of research ideas to align with real-world demands. Another participant highlighted that workshops could also help overcome silos which can hinder academic research and innovation. While interdisciplinary research centres have broken down barriers, academia is still structured across departments that do not always talk to one another.

Participants recalled successful experiences of past collaborations between academia and industry, particularly through initiatives supported by Innovate UK. By aligning problem owners (industry) with solution providers (academia), these collaborations resulted in feasible solutions and opportunities for further funding. Revisiting and refining such models could be beneficial for fostering new partnerships and driving market pull.

Education and workforce development emerged as crucial components of the successful integration of academia and industry in engineering biology. Creating an educated and skilled workforce is essential to fuel the growth of the biotechnology sector in the UK. However, if the bioeconomy is successful, it could displace jobs. Therefore, particularly in certain sectors like agriculture, workers need to be retrained so that, as one participant pointed out, "engineering biology does not become the enemy of job creation." Like China's approach, which reorganised its university system to support biotechnology, the UK should invest significantly in education to produce a knowledgeable workforce capable of scaling up and driving innovation in the field.

The conversation expanded to consider the diverse interests and challenges within the biotechnology industry. There are distinct cohorts of industry players, including big players in industry such as agriculture, pharmaceutical companies, and other large corporations, as well as emerging startups working on ground-breaking new products. The dialogue focused on how to engage both types of industry, as each has unique needs and can contribute to creating market pull in diverse ways.

Classic industries can pivot their operations to embrace engineering biology, providing substantial market pull due to their prominent position in the market. Additionally, involving big players, such as those in the chemical sector or multinational corporations, is vital for creating momentum and leveraging their existing market presence to drive the adoption of engineering biology technologies.

In the biotechnology sector, there are unique challenges faced by start-ups. One participant expressed concerns about the sustainability of foundational companies – the first generation of start-ups – which are service-orientated. The first generation of companies, while pioneering in their efforts, may struggle to succeed in the same way as the second generation of companies that focus more on sustained product development. The participant highlighted conflicts of interest that can arise when spinning off assets or collaborating with competitors for first generation companies.

Regulation and Standards

Several key challenges and future considerations for the regulation of biological engineering in the UK were highlighted during the workshop. One of the main challenges discussed was the need for shared infrastructure to support the regulatory process, providing clarity for regulators, fostering greater market pull for novel applications, and ensuring access to talent. With the emergence of various technologies competing for attention, securing sufficient levels of UK finance for engineering biology was also identified as a pressing concern.

Participants discussed the GCSA (Government Chief Scientific Advisor) review on regulation in life sciences, which proposes the establishment of an Engineering Biology Regulators Network. This network would be responsible for defining the taxonomy of products within its jurisdiction and exploring innovative regulatory tools such as engineering biology sandboxes. During the workshop, participants highlighted the need to break down silos between different government departments and funding agencies, ensuring that all relevant sectors engage in the regulatory process. By fostering conversations and active engagement, maximum opportunities can be realised from various developments.

Regulatory complexity is a significant challenge. With the rapid advancement of engineering biology, existing regulations may not be sufficient to address novel applications. A more intelligent and adaptive approach is required to balance responsible regulation while enabling innovation. One participant raised the issue of first mover disadvantage, wherein regulatory hurdles and public perception barriers may hinder the progress of engineering biology technologies. This prompts the consideration of establishing more modularised arrangements for IP negotiations in universities, creating a streamlined process for spin-out start-ups.

Throughout the discussion, participants stressed the importance of continuous review and update of the regulatory framework. This dynamic approach ensures that regulatory measures keep up with the evolving science and applications, avoiding unnecessary hurdles while maintaining appropriate safety standards. By fostering collaboration among different stakeholders, promoting a gradual and positive public perception, and updating the regulatory framework to align with technological advancements, the future of regulation in engineering biology holds the promise of responsible innovation and growth in the UK.

The current regulations in place for engineering biology in the UK have created a first mover disadvantage due to their limited scope. The existing regulations were primarily designed for regulating plants or contained laboratory settings, but they do not adequately address the broader applications and complexities of the field. This has led to challenges in regulating innovative technologies, such as environmental biosensors, which do not fit into the available regulatory categories.

The lack of appropriate regulatory categories for emerging applications has resulted in significant struggles and uncertainties for researchers and developers in the field. Some have even opted to develop applications that are easier to regulate, using similar technologies, rather than pushing the boundaries of innovation. It is important to address these regulatory gaps and provide clear guidelines and standards to ensure responsible innovation and maintain public trust.

Furthermore, participants deliberated that as the field of engineering biology expands to encompass not only individual circuits but entire ecosystems, there is a need to strike a balance between intelligible regulation and understanding the complexity of these ecosystems. It is crucial to gain a better understanding of how these ecosystems function to establish effective regulatory measures. Simply advocating for cutting red tape without considering the intricate dynamics of ecosystems would be inadequate, one participant stressed. The workshop made clear that responsible regulation should aim to provide good standards while fostering innovation and maintaining public confidence in the technology. Several participants discussed how a more knowledgeable and iterative process for designing regulations is needed to enable good research, and to feed into a future set of actions.