Department for Science, Innovation & Technology

Governance of Engineering Biology: government response to the RHC

April 2025

Introduction

The applications of engineering biology-based technologies and techniques are many and varied, with innovation being demonstrated across a range of sectors including agriculture and food, health, low carbon fuels, chemicals and materials, waste and the environment. Engineering biology technologies are developing at a remarkable pace. As a nascent technology the rate of innovation will only increase, and with it the scope and scale of novel engineering biology products and services. Regulations and standards can help to support a pro-innovation environment for emerging technologies such as engineering biology, provide product quality and safety assurance, and enable the promotion of responsible innovation practices. It is of vital importance that the regulatory and standards ecosystem evolves to support and catalyse this creativity and innovation.

The importance of regulations and standards for engineering biology is laid out in several government strategies including the UK Biological Security Strategy (BSS) and the National Vision for Engineering Biology. The National Vision for Engineering Biology, published in December 2023, set out the government's priorities and vision for Engineering Biology in the UK. The government's vision is "for the UK to have a broad, rich engineering biology ecosystem that can safely develop and commercialise the many opportunities to come from the technology and the underlying science". Underpinning that Vision was a commitment to "work across government and with all relevant regulatory bodies to ensure that the UK's regulatory landscape will help engineering biology-derived products to reach the market".

The government welcomes this report from the Regulatory Horizons Council (RHC) which was commissioned by the Department for Science, Innovation and Technology (DSIT) in 2023, to build on existing work by analysing regulatory issues specific to engineering biology. The report was subsequently published in January 2025, and it provides timely recommendations across a range of regulatory issues from collaboration between the various parts of the regulatory landscape through to biosecurity and responsible innovation. The government broadly supports these recommendations to improve the UK regulatory environment for engineering biology companies, researchers and innovators and the following response reflects the government's commitment that the UK's regulatory landscape will help engineering biology-derived products reach the market.

There is work already taking place across government dedicated to addressing challenges with the regulatory and standards environment for engineering biology and regulatory innovation is high in this government's priorities. For instance, the Regulatory Innovation Office (RIO) was launched in October 2024 to help position the UK as the best place in the world to innovate by ensuring safety, speeding up regulatory decisions and providing clear direction in line with the Industrial Strategy.

Engineering biology has been identified as one of the RIO's four early priority areas, recognising its disruptive potential to deliver growth across wide-ranging sectors of the economy, from health to agriculture. As part of this, the government has announced support for the Food Standards Agency and Food Standards Scotland to build capability and capacity to support development of innovative products such as precision fermented foods. The Engineering Biology Sandbox Fund also aims to accelerate pro-innovation regulatory reform and encourage business innovation and investment. DSIT also runs a dedicated Engineering Biology Regulators Network (EBRN) that brings the regulatory ecosystem together to encourage collaboration and knowledge exchange.

The government understands that there are challenges to be overcome but is committed to driving forward improvements in the regulatory and standards environment for engineering biology in a responsible and secure way. To achieve this, the government, including the Regulatory Innovation Office, will continue to work closely with our stakeholders, including regulators, standards bodies, industry and academia.

Response to Recommendations

Recommendation 1

Engineering biology products should be governed from the earliest stages of development based on their properties as they emerge at different points along a value chain (including balancing potential benefits and hazards) and not based on the platform technology from which they originate.

Response: partially accept

The government acknowledges that regulatory processes that are based solely on the platform technology from which products originate could potentially stifle innovation and a blanket approach to governance based on platform is not suitable for all engineering biology products. However, due to the many applications of engineering biology across a range of sectors, from food and fuels to healthcare and the environment, governance processes necessarily differ across this spectrum. There also exists a wide range of applicable legislation, standards and guidance which makes a sweeping commitment to an overarching governance process unworkable. The government assesses that any changes to governance processes will need to be explored at an application level to explore the benefits and risks of governing engineering biology products on the basis of their properties, potential risks and benefits and not based on their platform technology. The government will

continue to work closely across departments and with regulators and standards bodies to determine the best approach to governance for engineering biology products.

The government does foresee occasions where a platform-focused approach might be required. The government is committed to responsible innovation as a key consideration in the governance processes for engineering biology products. For example, the government has considered requirements around synthetic nucleic acid – such as synthetic DNA – which is used by labs around the world and plays a fundamental role in a wide range of science and biotech advances. This enables academics and businesses to study and engineer biological systems to unlock new engineering biology products. However, increased access to synthetic nucleic acid resulting from new, more widely available technologies to produce it may present a small increase in biosecurity risk through accidental or deliberate misuse. That is why the UK published voluntary Guidance in October 2024 to promote the screening of synthetic nucleic acid consumers and sequences. Promoting screening guides the use of synthetic nucleic acid for legitimate purposes whilst also mitigating potential risks.

Advances in AI offers tremendous benefits for engineering biology by catalysing the design, scaling and commercialisation of biology-derived products and services. AI is already accelerating the ‘design-build-test-learn’ cycle through which advances in engineering biology are achieved. The government understands AI-Biology convergence holds promise for widespread and highly impactful societal benefits but also potential for risks owing to AI’s latent and unpredictable capabilities and the dual use nature of the interface of AI and biology. That is why the government is focused both on embracing the opportunities of these transformative technologies, whilst ensuring that unintended negative impacts are avoided. Governance may be required based on the platform technology from which engineering biology products are developed due to the potential holistic risks posed by AI-Biology convergence.

Recommendations 2 and 3

Recommendation 2

Innovators should ensure that regulators, standards bodies, metrology organisations and policy makers have a good systemic understanding of the innovative potential and properties of EB products and the uncertainties surrounding them at different development stages. The Department for Science Innovation and Technology (DSIT) should own the process of commissioning this information and disseminating it to the

wider EB regulatory landscape through, for example, the already-established Engineering Biology Regulators' Network (EBRN) or via a new broader, product/market focused Industrial Biotechnology Regulators' Network (IBRN). This could be coordinated by the most relevant trade body in each case, or where multiple trade bodies exist, by a nominated group. A direct 'in confidence' route could be established alongside this to enable businesses to share commercially sensitive information directly with regulators.

Recommendation 3

Regulators, standards bodies and policy makers should work together (via the Engineering Biology Regulators' Network or another route such as a product/market focused IBRN) to optimise EB governance decisions based on: (i) information provided based on recommendation 2; (ii) the principles of proportionality (to the benefits and hazards of EB products) and adaptation (to innovative governance requirements); and (iii) the creative use of standards and guidelines, in sequence or in parallel with legally-based regulations, depending on the circumstances.

Joint response to recommendations 2 and 3: accept in principle

There is notable complexity in the regulatory and broader governance environment for engineering biology due to the rapid pace of innovation and the breadth of applications that spans existing regulatory and governance bodies and functions. Government recognises the challenges for both innovators in navigating the regulatory ecosystem, and for regulators to keep pace with an evolving technology landscape. The report notes the important role of the EBRN, established in 2023 to share information and best practice, identify common challenges and collaborate on solutions. There are currently 12 regulators/agencies involved in the network, which is convened by DSIT. Government has made the list of regulators that attend the EBRN public with a contact email address so that innovators have a clearer sense of who to engage with for their products.

The following regulators/agencies are currently members of the EBRN:

- Food Standards Agency
- Office for Product Safety and Standards
- Medicines and Healthcare products Regulatory Agency
- Animal & Plant Health Agency
- Environment Agency
- Health and Safety Executive
- Department for Environment, Food & Rural Affairs

- Human Tissue Authority
- Information Commissioner's Office
- Veterinary Medicines Directorate
- UK Civil Aviation Authority
- Human Fertilisation and Embryology Authority

We regularly review the membership of the network and encourage UK regulators with an interest in engineering biology that are not already involved to contact engineeringbiology@dsit.gov.uk to be added to the network.

To directly support regulators in innovating their approach, Government launched the Engineering Biology Sandbox Fund to support regulators to design, test and implement innovative regulatory behaviours. The aim of this fund is to accelerate regulatory reforms for engineering biology-derived products, improve the quality of decision-making when assessing these products and encourage business innovation and investment. The concept of a 'sandbox' is intentionally flexible to allow innovative approaches, but all sandboxes facilitate extensive dialogue between industry and a regulator to inform regulatory actions that strike the right balance between facilitating innovation and mitigating risk. This fund is a clear example of government enabling innovators to ensure that regulators and policy makers have a good systemic understanding of the innovative potential and properties of engineering biology products. The next round of the Engineering Biology Sandbox Fund will open in April 2025.

The government agrees that collaborative working across the ecosystem will be essential, particularly given the wide range of applications and sectors impacted by engineering biology. DSIT will work with the EBRN and the RIO to pilot further innovative ways of ensuring the pipeline of innovations in engineering biology are able to inform standards and regulation to ensure the governance ecosystem keeps pace with the rapid advances in this technology. However, any further solutions in this space will have to take into account any increases in burdens on regulators or the innovators providing information and balance this against the potential benefits. At this time, the government does not intend to set up a further regulatory network for engineering biology, beyond the existing EBRN.

Recommendation 4.1

In addition to planned biosecurity-related communications among those involved in policy making, research and development of EB products, there needs to be a linked, parallel, public-facing strategy and narrative, designed to communicate the

background and reasons for biosecurity-related governance to a general, non-specialist audience.

Response: accept in principle

The government agrees with the need to proportionately communicate risks around emerging technologies, including engineering biology. The UK BSS acknowledges that “Public communication of risk is an essential part of building trust and facilitating public and private sector partnerships, as it ensures a common understanding of potential threats, threat indicators and the impact of policy interventions.” The government is developing a coordinated communication campaign to improve public understanding and awareness of natural, deliberate and accidental biological risks with support from behavioural scientists and communications experts.

Under the BSS, the government committed to exploring how additional objective data sources can be used to understand and interpret public behaviour - providing more accurate feedback loops to inform communications strategies during a response to a biological incident.

Under the BSS’s commitment to make the UK a world leader in responsible innovation, DSIT is responsible for maintaining a positive and transparent dialogue between government and the public and developing robust insights into public attitudes towards engineering biology. This dialogue will help society make informed decisions about their uses of engineering biology-derived products and foster public confidence in the technology.

DSIT surveyed 3,000 UK adults in August 2024 to gain insight into their understanding and perceptions of engineering biology. This was the first dedicated survey of the UK public on their perceptions of engineering biology across five application areas; health, agriculture and food, low carbon fuels, chemicals and materials, and waste and environment. The results, published on GOV.UK, highlight that there is limited public awareness of engineering biology, but that people are likely to be optimistic about using the technology to solve societal challenges. DSIT will continue to build public awareness of the potential of engineering biology and use public attitudes to guide its work.

Recommendation 4.2

The Biosecurity Leadership Council should consider the need to ensure that the latest government thinking on pro-innovation regulation, as implemented through the Regulatory Innovation Office (RIO), and as embodied in Recommendations 2 and 3, is considered and integrated into future plans for biosecurity governance.

Response: accept

The government agrees with the need for careful consideration of responsible innovation and pro-innovation regulation in its approach to biosecurity. The government created the UK Biosecurity Leadership Council in September 2023 to provide formal advice on best practice in responsible innovation. This group was re-named the Responsible Innovation Advisory Panel (RIAP) in January 2025 to reflect the government's commitment to responsible innovation in its approach to engineering biology. The government continues to work closely with the RIAP and other key stakeholders to ensure a responsible approach to innovation is informed by the innovation pipeline where appropriate.

As noted, the RIO was established to champion a pro-innovation approach across government and it has three core pillars of activity: knowledge, strategy and capability building. The government will ensure activities undertaken and supported by the RIO will inform policy and governance across the spectrum of engineering biology interests including, where appropriate, biosecurity.

Recommendation 5

In the context of the Convention on Biological Diversity (CBD) Nagoya Protocol and the new DSI multilateral benefit sharing mechanism, including the Cali Fund, ensure that the implementation of Access and Benefit Sharing Agreements aligns with the needs of the sector. The Regulatory Horizons Council can work closely with Defra and the Department for Business and Trade to support the design and delivery of industry engagement over the first quarter of 2025. This will be to ensure, as far as possible, that the implementation of the Nagoya Protocol and the DSI benefit sharing mechanism is compatible with, and supports, the overall governance approach recommended in this report.

Response: accept in principle

The government recognises the importance of access to and utilisation of genetic resources to the engineering biology sector and that benefit sharing from the sector will help conserve nature as a provider of genetic resources.

The Nagoya Protocol, which is a supplementary agreement to the Convention on Biological Diversity (CBD), provides a framework for access to, and the fair and equitable sharing of benefits arising out of the utilisation of, physical genetic resources. As a Party to the Protocol, the UK has established a compliance mechanism, the UK ABS (Access and Benefit Sharing) Regulations, which require users of genetic resources, including those in the engineering biology sector, to demonstrate that they have conducted due diligence in accessing genetic resources from outside the UK, and have shared benefits accordingly. The Office for Product

Safety and Standards, within the Department for Business and Trade is responsible for the enforcement of the Regulations.

Where digital genetic sequence code is used from open access databases, in place of physical genetic resources, users of that information can choose to share benefits through the multilateral benefit sharing mechanism including through the “Cali Fund”. The Fund was agreed by Parties at CBD COP16 and officially launched in February 2025. The Fund can now receive payments from the private sector, recognising their use of nature in the development of products and services. The benefits shared will be directed to achieving the objectives of the CBD, including the Global Biodiversity Framework, to halt and reverse global biodiversity loss.

In the UK, the mechanism will be voluntary, and the UK Government is working with a range of sectors to support their participation. The Department for Environment, Food and Rural Affairs, the Department for Business and Trade and the Department for Science, Innovation and Technology will collaborate to engage the engineering biology sector on access and Benefit Sharing issues, including the Nagoya Protocol and the Digital Sequence Information (DSI) multilateral benefit sharing mechanism, and deliver awareness raising and training sessions to support compliance and participation. The RHC will be invited to support the development of these activities to ensure they are aligned with the needs of the sector.

Recommendation 6

Across all sectors of the economy, including IB, as part of the implementation of a pro-innovation governance approach, companies should be encouraged to undertake a formal commitment to responsible innovation.

Response: reject

The government is committed to championing a responsible approach to innovation in engineering biology. To achieve this commitment, the government is working closely with UK industry, academia and international partners to create a safe, secure and resilient environment in which the biotechnology and life sciences sectors can flourish. This includes engaging with industry and other stakeholders through the RIAP and the Engineering Biology Advisory Panel to provide a continuous two-way feedback loop to support responsible innovation policy development and implementation.

The government will continue to monitor the changing technological landscape to determine a proportionate approach to mitigating risks whilst ensuring the UK can harness the benefits offered by the technology. With the development of engineering biology technologies, the biosecurity risks are also likely to evolve, which can bring both benefits and challenges. To prevent unnecessary burdens on innovators,

voluntary guidance can be the best approach in some instances, however government will continue to consider the full suite of options available, including regulation, to maintain biosecurity and biosafety practices and protect the safety of the UK.

The adoption of responsible innovation practices is encouraged through a wide variety of guidance, including the Responsible Innovation Guide (PAS 440) and the UK's Screening Guidance for providers and users of synthetic nucleic acid. Publishing voluntary guidance supports providers and users in adopting responsible innovation practices and allows us to test the strength of proposed guardrails.

The government also supports the adoption of responsible innovation practices through the UK's research funding system. For example, UK Research and Innovation (UKRI) terms and conditions for research grants require recipients of UKRI funding to ensure that appropriate due diligence is undertaken on their collaborative activities. UKRI has published trusted research and innovation principles to support recipients when considering their approaches to ensuring trusted research and innovation.

The government will continue to work collaboratively to explore further ways to encourage and support a responsible approach to innovation.