Written evidence from National Measurement Laboratory (NML) (ENB0017)

Introduction:

- The National Measurement Laboratory (NML), hosted at LGC, has been the Designated Institute for 'Chemical & Biological Measurement' within the UK, since 1988. As a national laboratory and PSRE based in a private limited company, we interact across the research, development, and innovation ecosystem, bringing together diverse groups of stakeholders. The work of the NML focuses on providing high quality world-leading science, to solve measurement problems and provide the resilient measurement infrastructure needed to support government, healthcare, industry and protect consumers within the UK, as well as representing the UK's measurement interests internationally. We support businesses to innovate more effectively, faster and with less risk - through the application and translation of fit-for-purpose measurement solutions and the provision of standards that underpin complex measurements. The NML also supports the role of the 'Government Chemist' (GC), which has a statutory function as an independent referee analyst under a number of acts of Parliament focusing on public protection, value for money and consumer choice. In addition, the GC provides advice on areas including the quality of food and animal feed, medicines and chemicals.

1. What are the UK's key strengths in the area of engineering biology?

- The UK is considered as a global leader in Engineering biology with an excellent research base, boosted recently by funding for six new UKRI Engineering Biology Mission Hubs and 22 Mission Award projects to meet the goals of government's National Vision for Engineering Biology which was announced in December 2023 to address global challenges, drive economic growth, and increase national security, resilience, and preparedness. Future success and maintenance of this leading position will be determined by the UK's ability to translate the research into commercialised processes or products. Measurement science (metrology), standards and regulation all play an important role in this translation piece. They help to ensure that early research and development in engineering biology generates robust and reliable data, leading to faster translation, de-risking of the commercialisation stage, and improved confidence in the safety and performance of innovative

products and processes. The UK is currently world-leading in these areas, a position that can and should be leveraged and built on.

- The UK has a well-established infrastructure for measurement science (metrology) through the laboratories that make up the National Measurement System (NMS). Ensuring this system is embedded into the research, development and innovation sectors is key to the successful implementation of rigorous engineering principles.
    - The NML at LGC is leading the global measurement community through development of improved measurement tools and reference materials to support engineering biology and development of best practice guidance, measurement training and internationally accepted documentary standards through ISO to support development and ensure consistent evaluation of engineering biology products and processes.
- The UK plays a leading role in standardisation activities globally, ensuring innovative products and processes developed within the UK are accepted globally, and enhancing trade. Practical implementation and standardisation of testing methods is key to the development, scale up and successful uptake of engineering biology technologies and ensures they comply with relevant quality and safety standards.
    - Experts from the NML at LGC are active contributors on national and international committees – e.g., International Standard Organisation (ISO) Technical Committees (ISO/TC 276, ISO/TC 212), European Committee for Standardisation (CEN), BSI (BT/1) – and lead on standards development. This includes underpinning standards, e.g., ISO 20395:20191, made freely available during the pandemic due to its critical nature, as well as a variety of technical standards supporting areas critical to the success of engineering biology such as viral vector gene delivery, gene expression profiling of engineered cells, and cell counting.
    - The specific standards needs of UK engineering biology stakeholders are being addressed by the NML at LGC through collaboration with BBSRC. This collaboration will lead to the development of new technical standards to direct and support engineering biology globally. A new standard (applied to biosafety and reliability) has recently been proposed through the BSI "Standard Challenge Fund" Standards Challenge Fund | BSI (bsigroup.com).
- The UK also maintains a strong leadership in emerging regulation for the manufacturing of novel engineering biology products. Some initiatives are already underway to ensure flexible regulation whist guaranteeing safety, e.g. regulatory sandboxes led by DSIT, where the NML at LGC is providing a supporting role.

[1] ISO 20395:2019. Biotechnology — Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR.

- LGC is the UK National Reference Laboratory (NRL) for GMOs (EC retained legislation 2017/625) and authorisation (method validation services) for placement on the market of GMOs for food and feed use (GB). Experts from the NML at LGC sit on bespoke EU committees and working groups associated with genetically modified microbes (GMM) and products of genome editing (GE) that are beginning to gain additional traction. It is likely that applications for these GMO and precision bred (PB) products will be received in the UK soon.
- The NML at LGC is also represented on the BIA's Engineering Biology Advisory committee (EBAC) providing advice to the Bioindustry on the importance of sound measurement science and standards in support of emerging regulations and commercialisation of engineering biology products and processes.

2. What are the key applications for engineering biology?

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

- We routinely observe first-hand how important it is to have the right players from across the RDI system around the table, from the beginning, to ensure the most effective and fit-for-purpose solutions can be found.
- Currently, systematic connections between innovators (academia, start-ups), scale up facilities, the wider regulatory system (including metrology), user groups, businesses and investors are lacking. Government has a crucial role to play to bring together the disparate parts of the RDI system and encourage greater interconnectivity. This would allow more effective and efficient translation from research (progression through TRL's 4-6) to better exploit the potential of engineering biology commercially. Care should however be taken across government not to replicate already existing expertise and national assets but rather use those that already exist more effectively.
    - The NML at LGC recently submitted a UKRI "Big Idea" proposal to begin to address this that is now being explored, i.e. creating an environment and appropriate frameworks to facilitate greater collaboration across the system to encourage more joined up thinking.

- The UKRI research councils (e.g. BBSRC, EPSRC) are well placed to support early research for academia.
    - The recently formed Engineering biology Mission Hubs (UKRI cross-council funding, BBSRC, EPSCR, IUK, MRC, NERC) are supporting mission-led solutions over a five-year horizon that allow for cross-system collaboration. There has been some positive engagement with the standards, metrology and regulatory sector in the areas of advanced therapeutics, circular economy and clean growth, although there is the potential for greater engagement and wider systems awareness. Seed Corn funding could help support this.
- However, increased accessibility to (longer-term) funds across government departments, regulators, and infrastructure organisations (e.g, DSIT, UKRI, NML at LGC, wider NMS, OPSS, DEFRA, FSA, MHRA, DESNZ, MOD) would be welcome to facilitate cross government opportunities for the benefit of the UK. Practical mechanisms are needed to facilitate cross-government collaboration and funding between departments This would help ensure that the infrastructure and highly skilled workforce that are required to develop and innovate are available to effectively support the sector.
- The National Vision clearly identifies the need and role for standards in commercialisation for supporting scale up and is an area where the UK is leading globally. This will need continued support as the sector develops and will benefit from joined up thinking and increased awareness and accessibility.
- Although standards are addressed, the underpinning role of measurement is not fully considered. A clear plan for leveraging the well-established and internationally well-regarded UK infrastructure and embedding it across the sector would benefit the UK.
- Within the National Vision, the plan to develop facilities to support lab scale and pilot scale innovation is welcome but thought should be given to include provisions and facilities to bridge the gap between pilot and large scale, addressing the challenge of equipment investment costs that can be a significant barrier for SMEs at this stage.
- Well-considered skills development for the sector will be crucial. A focal point here should be enabling researchers, innovators, and developers to get access to the most relevant training material, utilising the expertise and examples that already exists across the system. There is a particular regulatory skills gap that the Engineering Biology Regulatory Network should consider addressing.
    - Through collaboration between the NML at LGC and BBSRC, the UK is already beginning to successfully embed metrology into early research by developing and delivering a training programme in metrology for researchers in engineering biology. Further work has now started on applying metrology to environmental solutions (UKRI Engineering biology mission

awards). This collaboration with BBSRC, UKRI and the NMS provides a template for potential future expansion of the approach.

4. How can the UK maximise the economic potential of developments in engineering biology?

- Engineering biology has the potential to improve public services i.e. healthcare, environmental protection, food security and resource management. As potential users and beneficiaries of Engineering biology, the government departments responsible for those services/sectors should consider Engineering biology and procure innovation type projects/pilot studies to evaluate its benefits/applications. Cross-government initiatives should be considered where possible to ensure most impact for investment.
- Ensuring the accuracy, reliability and reproducibility of data generated by UK engineering biology stakeholders across the entire landscape, and therefore confidence in results that are globally recognised, will be fundamental in capitalising on maintaining global leadership, realising the opportunities for the UK, and exploiting the potential of engineering biology.
- De-risking commercialisation by ensuring prototypes and processes are reproducible, a key aim of measurement science, would help encourage investors.
    - The UKRI Innovate UK Analysis for Innovators2 programme provides access to existing measurement infrastructure for UK companies (micro/SMEs) with challenging technical problems. Funding over 450 projects to date, it has successfully created jobs, encouraged investment and encouraged spin outs. A similar approach targeted across the engineering biology could be highly impactful, potentially addressing testing and validation of: raw materials (ensure supply chain security), product (characteristics and properties), production processes (scale-up) for both SMEs and larger companies to ensure investor confidence.
- Independent assessment of the technologies (finished products and production process) would ensure trust and confidence for the investors and verification of reproducibility of claims.
- Ensuring a flexible and transparent regulatory framework that enables innovation whilst maintaining user safety is crucial.
- Developing an effective scale up infrastructure for engineering biology manufacturing that draws on all parts of the RDI system, its expertise, and capabilities, is critical to the successful commercialisation of

[2] Innovate UK Analysis for Innovators - Innovate UK Business Connect (ktn-uk.org)

engineering biology products. Scaling up is sensitive to small changes which have direct impacts on the quality, efficacy, and costs of end products. Early consideration of metrology and standards are essential to the successful development of scaling up and require a mechanism for their early consideration that would de-risk innovation.
    - The Council for Science and Technology recommended that a hub designated for developing scale up technologies be established3. Ensuring metrology and standards are embedded into such scale up hubs would facilitate their success and impact for the UK.
- The UK must continue to be an open and supportive environment for attracting talent (universities and industry) to ensure the UK remains a place to invest in. Careful consideration is required of the impacts that changes to the Minimum Salary, Shortage Occupation List and Graduate Visa requirements will have on the sector and its future.

5. What are the risks posed to society by engineering biology?

- Engineered organisms might have unforeseen effects on ecosystems. Systems to simulate the effect of Engineered organisms on ecosystems in the lab before real-life applications will be essential for assessing safety and the NML at LGC is part of such initiatives under UKRI Engineering biology mission awards on derisking environmentally focussed engineering biology and ultimately support its future deployment.

- Spread of engineered traits: Engineered genes could escape from organisms and spread to wild populations, potentially disrupting ecosystems. This is especially concerning for microorganisms. The NML at LGC is also part of a BSI Standard Challenge Fund to develop a standard for barcoding engineered biological assets.

- Engineered organisms could also generate unintended allergens or toxins, harming human health, so robust procedures are needed to assess safety.

[3] *Report on engineering biology: opportunities for the UK economy and national goals*

6. How should engineering biology be regulated?

- The infrastructure already exists with the UK RDI landscape (e.g. PSRE's) to provide the necessary support for engineering biology to develop the regulatory landscape and support innovation and entrepreneurship. However, the ability for these institutes to collaborate is hindered by current funding mechanisms which restrict cross-government programmes.
- Ease of access to metrology, standards and regulatory expertise at an early stage would help in de-risking innovation and supporting the early consideration of any potential regulatory challenges.
- Guidance is needed especially to help SMEs navigate the regulatory system, in terms of robustly demonstrating safety and performance of new engineering biology products and processes. Roadmaps signposting them to appropriate methods, materials and standards would de-risk the initial stages of developing new products or services.
    - The regulatory sandbox initiatives being developed by DSIT will go part way to addressing these challenges. Greater clarity of purpose, scope for engagement, and time to develop effective and well-thought-out proposals with the stakeholder community would support this activity.
- The UK already holds a globally recognised leadership position within the standards and regulatory space. Greater long-term support for the UK standards and metrology community to continue to represent the UK on the international stage over the required time frames will ensure the needs of UK stakeholders are addressed. Leadership in this space will ensure the standards and regulations that are developed support and align with UK interests and innovation and ensure global recognition of UK products and processes to underpin trade.
    - Precision breeding regulation is an example where the UK has a strong presence, leading on the development of genetically modified organisms (GMO) testing strategies and associated international regulations for the correct detection, identification, and quantification of GMOs. Experts from the NML at LGC authored the EC guidance document on measurement uncertainty testing for GMO testing labs and, through the NML at LGC, the UK also holds an honorary member position of the European Network of GMO Laboratories (ENGL) that are responsible for enforcement in the EU-Member States.
- Government could facilitate the collaboration of researchers and industry experts, with the support of existing infrastructure for standards and metrology, in identifying, prioritising, and developing key standards, by providing specific funding opportunities for this type

of activity. Leadership in this area will help ensure global recognition, acceptance of, and trust in, UK innovation.
- There is an opportunity to build on the existing infrastructure (PSREs, regulators, accreditation bodies) to support the practical implementation and provision of standards, reference materials and schemes for engineering biology to support External Quality Assurance, ensuring the safety of and trust in engineering biology products and processes across sectors.

7. What are the possible barriers and limitations to good and effective use of engineering biology?

- Lack of standardisation in engineering biology can lead to challenges in ensuring the accuracy, reliability and reproducibility of data generated by UK engineering biology manufacturers for new products and processes is consistent, and confidence in results can be globally recognised.
- Support for independent assessment of the technologies (finished products and production process) would ensure trust and confidence for the investors and verification of reproducibility of claims.
- Well-supported skills development for the sector will be crucial. A focal point here should be enabling researchers, innovators, and developers to get access to the most relevant training material, utilising the expertise and examples that already exists across the system. There is a particular regulatory skills gap that the Engineering Biology Regulatory Network should consider addressing.

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