

SYNTHETIC BIOLOGY LEADERSHIP COUNCIL (SBLC)
TERMS OF REFERENCE FOR THE GOVERNANCE SUB-GROUP (GSG), 2019

A balanced, adaptive and consultative approach

The role of the Governance Sub-Group will be to support the safe delivery of the benefits of synthetic biology and related technologies¹, along with maximum value for money from the UK's investment in the basic science. It will adopt an approach that is open, adaptive and supportive of innovation to deliver public benefits in medicines and healthcare, fine and specialty chemicals, energy, environment, sensors, agriculture and food^{2, 3}. This will involve understanding, and balancing the interactions among: scientists and innovators; policy makers and regulators; and citizens and stakeholders. The GSG will respond to the needs of all three constituencies to the extent that they are involved in future synthetic biology and related developments, building on the outcomes of the synthetic biology dialogue⁴. The terms of reference set out here will guide GSG members in addressing these issues.

The following principles will guide the GSG approach:

- A responsible approach to innovation, regulation and engagement;
- Balancing the interests and values of all relevant stakeholders and communicating effectively with them;
- An understanding of risk issues and how they are perceived by different communities;
- An approach that is tailored to the needs of different sectoral applications of synthetic biology; and
- Commitment to decision making based on a balanced assessment of the quality of the available evidence.

The GSG will focus on interactions that can shape the future of the industry sectors involved in synthetic biology and related technologies, and the range of products and processes that may arise from them, to support the delivery of benefits to human health, the environment and the economy.

GSG Scope and Mode of Operation

GSG members will represent relevant academic disciplines; government policy, regulatory and funding bodies; companies developing innovations based on synthetic biology, and stakeholders with interests relevant to synthetic biology innovation and its governance.

The scope of the GSG will thus cover governance, policy and regulation, citizen and stakeholder engagement, and communication, as they relate to science and innovation in SB. Three meetings will be held each year, timed to input to subsequent SBLC meetings. The GSG will advise the SBLC, through minutes of its meetings, a report presented at SBLC meetings and conclusions arising from

¹ We will use the term 'synthetic biology' to cover the full range of genomics-related tools and platforms that are becoming the foundation of the future bioeconomy, including all forms of gene editing.

² UK Synthetic Biology Roadmap Coordination Group (2012) *A Synthetic Biology Roadmap for the UK*. <http://www.rcuk.ac.uk/documents/publications/SyntheticBiologyRoadmap.pdf>

³ UK Synthetic Biology Strategic Plan, 2016. *Biodesign for the Bioeconomy*. <https://admin.ktn-uk.co.uk/app/uploads/2017/10/UKSyntheticBiologyStrategicPlan16.pdf>

⁴ See <http://www.bbsrc.ac.uk/society/dialogue/activities/synthetic-biology/findings-recommendations.aspx>

discussions at GSG meetings. It will also comment and take action between meetings where necessary related to issues arising that are relevant to its remit.

Meetings will be conducted under the Chatham House Rule.

The GSG will:

- 1. Be well-informed on relevant aspects of current issues;**
- 2. Comment on national and international (EU and UN) aspects of governance, policy development and regulation with a view to considering how SBLC can best support decision making in these contexts; and**
- 3. Contribute through stakeholder engagement and communication to building a consensus for safe delivery of the benefits of synthetic biology and related technologies, along with maximum value for money from the UK investment in the basic science.**

These roles will support delivery of a governance approach that is adaptive, consultative and balances responsible research and innovation with equivalent responsible approaches to regulation and engagement.

The following modes of operation are proposed for these roles.

1. Circulation of relevant documents, and presentations/discussion at GSG meetings.
2. For innovations emerging from synthetic biology and related technologies, consider what are the most appropriate innovation support policies and regulatory approaches and what are their strengths and defects. Through SBLC, we will advise policy makers and regulators based on our collective experience.
3. We will inform ourselves about, and build on, engagement initiatives conducted by others and, where additional engagement initiatives are proposed, we will work to ensure attention to the following considerations:
 - different approaches will be needed for scientific research and for products and processes in development; for different industry sectors; and for innovation that is disruptive of current industry business models and markets;
 - discussions will be open, fair, and accommodate the range of relevant opinions from citizens, scientists, industry, users of the technology and consumers, fostering a willingness among participants to reach a consensus;
 - where consensus is not attainable, to ensure a balanced approach to benefits and risks;
 - maintaining a high standard for the quality and breadth of evidence that is brought to discussions about innovative synthetic biology and related technologies and their governance.