Chapter 7

National policies for the development and application of synthetic biology

The lack of policy development reflects two things: synthetic biology is still very young, and it may still be too indistinct from genetic modification and recombinant DNA technology to warrant specific policy developments and interventions. Countries are taking different approaches to public funding of synthetic biology R&D. Educational initiatives are key to the future of the field, as the need for an interdisciplinary approach in higher education is a challenge to science education, owing to the need for sufficient depth and breadth in both the biological sciences and engineering. Public engagement to date has been limited and this requires serious consideration. A noticeable development is the spread of interest in competitions to countries outside of the United States. Some consider that the most pressing near-term need is to develop technology roadmaps for synthetic biology. There is even a feeling that a global roadmap might be enabling and a key element of policy. It is clear that a technology roadmap can also serve as a policy roadmap, with the inclusion of strategies for public engagement and educational priorities.

Introduction

Countries are taking different approaches to public funding of synthetic biology R&D. Because synthetic biology is still very young, many countries have not yet begun to address this issue. This chapter presents relevant efforts by several countries that have seen the need for public engagement. Some consider that the most pressing near-term need is to develop technology roadmaps for synthetic biology. It is clear that a technology roadmap can also serve as a policy roadmap, with the inclusion of strategies for public engagement and educational priorities.

Australia

Infrastructure

Infrastructure is being developed mainly through CSIRO[1] projects. These are mostly based on applications, especially platforms. A project on crop biofactories has been under way for eight years and may continue for another eight. The target is the production of novel oils and oleochemicals in plants (e.g. nutraceuticals, biodiesel, lubricants and polymers). One of the reasons for doing this work in plants is that it is scalable, constrained simply by the availability of land, and versatile. Compared to fermentation, however, it lacks a fine degree of process control. Sunflower is one of the target crops. It is not a major food crop in Australia, but it is suited to marginal land, which is abundant there.

An objective of the relatively new Molecular Machines project is making metabolic pathways outside cells. This offers several advantages, especially in specificity and noise reduction. Another major part of the work is the development of flow cells, which are intended to be modular and scalable and to operate in parallel fashion. If it achieves industry buy-in, this could be a 16-year project.

Regulation

The main legislation in force is the *Gene Technology Act* (2000).[2] Its objectives are to protect the health and safety of people and to protect the environment. It aims to do this by identifying risks posed by, or as a result of, gene technology, and by managing those risks through the regulation of certain utilisations of genetically modified organisms (GMOs). The Australian philosophy, as in other countries, is based on risk analysis and risk management.

The main message is that Australian regulators are aware of synthetic biology, are maintaining a watching brief on it, but in practical terms existing regulation adequately covers current activities. Regulation should be commensurate with risk and Australia's regulatory frameworks seek to ensure protection of human health and the environment while allowing application of technologies and products with the least impact on businesses and R&D.

The Office of Gene Technology and Regulation (OGTR) has disseminated information about Australia's regulatory system to individuals aligned with the DIY bio- movement, and also posted these on its website. The Gene Technology Ethics and Community Consultative Committee (GTECCC) has also considered the question of whether synthetic biology raises new ethical issues and concluded that issues are qualitatively similar to those raised by gene technology. GTECCC recommended maintaining a watching brief on developments in synthetic biology.

There was an independent review of the Gene Technology Act 2000 in 2011 which noted that scientific and technological advances in gene technology and biotechnology continue to be rapid. The 2013 All of Governments Response to the review agreed to undertaking further investigation of ways to ensure that the Act remains up to date with advances, including in relation to mechanisms to expeditiously amend legislative definitions and exclusions but also in relation to the scope of regulation. The review report and government response are available from the Department of Health website[3].

Ethics

GTECCC has also produced a guidance document – "National Framework of Ethical Principles in Gene Technology"[4] – which could also be applied to synthetic biology.

Public engagement

As in other countries, different applications of synthetic biology produce different reactions. People respond to the applications rather than to synthetic biology itself. Early results show that 60% of the Australian public have not heard of synthetic biology (OECD, 2012). Of those who have, there is strong support for synthetic biology to move forward. Results are largely comparable with those in the United States and the United Kingdom, which show "conditional" support for synthetic biology. As in most countries, there is very limited public attention to synthetic biology in Australia.

China

As there are few private investors in China, the government plays an important role in fostering new areas of science and technology, such as synthetic biology. In 2008, a dedicated research funding scheme for synthetic biology was proposed to encourage research on the development of new biofuels and biomaterials and to find novel approaches to bioremediation and medical applications. However, it has been delayed (Pei et al., 2011a).

Long-term support for industrial biotechnology is reflected in China's 11th Five-Year Plan (Wang et al., 2009), with planned spending on biofuels and renewable energy in the billions of US dollars. China is the world's third largest producer of ethanol. Existing bio-based production includes vitamin C and citric acid. The Chinese chemicals industry makes increasing use of industrial biotechnology, particularly in biopolymers. Pei et al. (2011a) describe many synthetic biology applications and numerous institutions involved in research. In the 12th Five-Year Plan, China will spend USD 308.5 billion on science and technology, with biotechnology a major priority,[5] specifically biopharmacy, bio-engineering, bio-agriculture and bio-manufacturing.

A draft roadmap for China

China is developing its synthetic biology strategy through a roadmap that sets out targets over 5, 10 and 20 years (Zhang, 2012). The five-year targets concentrate on technologies and industrial, medical and agricultural applications. By the 20-year stage, the technology targets are: databases of full ranges of parts and devices for chassis organisms; and integrated technology platforms for design, modelling and validation of biosystems.

The products envisaged at the 20-year stage include: commercial production of a range of natural compounds, drugs, chemicals and biofuels; clinical applications of devices and biosystems for surveillance, control and treatment of selected major diseases; commercial plants and crops with high tolerances and improved photosynthesis, and engineered microbes with improved nitrogen fixation capabilities; microorganisms with enhanced capabilities for the bioremediation of environmental pollutants; and artificial microbial life forms. China is currently developing synthetic biology capabilities through a number of projects (Table 7.1).

Table 7.1. Current synthetic biology research projects in China, 2010

Project	Cost (million RMB)
Artificial cell factory	80
Photosynthesis and the artificial leaf	50
High-yield production of microbial drugs	30
New functional biodevices	40
New pathways for biological materials	2.5
Standardisation of biological components (under review)	30-40
Industrial, agricultural or medicine applications (under review)	20-40

Source: Zhang, X.-E. (2012), "Synthetic biology: China's perspective", Presentation at the Six-Party Joint Symposium on Synthetic Biology for the Next Generation, under the auspices of the NAS/NAE, Washington DC, 12-13 June.

Regulation

Like other countries, China currently regulates synthetic biology through genetic modification regulations, e.g. Order No. 304 (2001), The State Council of the People's Republic of China, Safety regulations for agricultural genetically modified organisms.[6] For the majority of the Chinese population, synthetic biology is an unknown concept, and discussions of the social issues are for the moment confined to the scientific community (Pei et al., 2011b). Most researchers believe that regulation is sufficient to cope with the current status of synthetic biology. According to a series of interviews with researchers (Pei et al., 2011b):

- Four interviewees out of 20 considered that the current institutional review of research regulation was sufficient.
- Seven out of 20 thought that regulations at a national level would be better, whereas three preferred an international framework.
- Four suggested that regulation should be either targeted at risk prevention or based on research objectives.
- One considered that the current regulation on recombinant DNA was sufficient.
- Two were worried that further regulation specific to synthetic biology would harm the development of the field.

Denmark

Denmark has identified synthetic biology as a field with enormous potential to create innovation and growth. Research in synthetic biology began around 2005 with some small projects. In 2008, funding of EUR 16 million was given to the UNIK Synthetic Biology Research Centre by the Danish Ministry of Science, Technology and Innovation. In 2010, the Novo Nordisk Foundation provided EUR 100 million for the establishment of the Novo Nordisk Foundation Centre for Biosustainability, a basic research centre with a focus on synthetic biology. Today, research in synthetic biology is taking place at most Danish universities and in a number of Danish companies (ERASynBio, 2012).

The Danish Council for Strategic Research has prioritised synthetic biology and will encourage scientists to work in international networks in order to pool competences and resources. In addition to supporting research in synthetic biology, an education programme at the undergraduate, postgraduate and doctoral levels is to be developed.

Finland

As in most countries, synthetic biology is in its infancy in Finland and synergies are being sought through the pooling of researchers' resources in the various -omics technologies, bioinformatics and systems biology. Networking will be a key feature of the development of synthetic biology and may be fostered by public policy.

To capture the multidisciplinarity of synthetic biology, Finland has created FinSynBio, a national research programme in synthetic biology (Academy of Finland, 2012). The stated aims of the programme are to: support high-level synthetic biology research in Finland; promote co-operation among scientists and researchers based in Finland and working in different fields to facilitate the achievement of critical mass in the research community and international competitiveness in the synthetic biology field; increase international collaboration to support the achievement of other programme objectives; foster dialogue between the research community and the rest of society on socio-cultural concerns and issues related to synthetic biology; and promote public understanding of synthetic biology research. The programme is to run from 2013 to 2017.

France

Educational initiatives

The European Master in Systems and Synthetic Biology (University of Evry-Val-d'Essonne) aims to provide students from the life sciences, mathematics, engineering and physical sciences with a means to engage fruitfully in collaborative work across disciplinary boundaries, with applications in systems and synthetic biology. Students undertaking the course gain hands-on experience in experimental biology, modelling and design.

Infrastructure

Synthetic biology currently has two main centres in France, one in Evry (Paris area) around Genopole,[7] Evry University and the Centre National de la Recherche Scientifique (CNRS),[8] and one in Toulouse around INSA,[9] INRA[10] and the CNRS. The CNRS is the largest basic research organisation in Europe. It encourages multidisciplinarity and the opening up of new fields of enquiry to meet social and economic needs. One of the stated aims of CNRS multi-disciplinary programmes is to support the emergence of new research themes at the interface of traditional fields relevant to synthetic biology.

Five strategic recommendations have been made to support the development of synthetic biology in France (*Ministére de l'Enseignement Supérieur et de la Recherche*, 2011):

1. promotion of dialogue between science and all relevant stakeholders to enable the involvement of society in the direction of synthetic biology in France;
2. facilitation of the emergence of multidisciplinary centres of excellence and creation of a national forum on synthetic biology to facilitate exchanges of best practice;
3. mobilisation of public-private institutions in a co-ordinated fashion;
4. development of a strategy to reach critical mass for synthetic biology not seen elsewhere in Europe;
5. harmonisation of political aspects internationally and control of risks.

Commercialisation and venture capital

The only well-known European enterprise working on biofuel production by a synthetic biology route is Global Bioenergies[11] in Evry, France. In February 2009, the company raised EUR 3.2 million from Masseran Gestion, the venture capital subsidiary of *Caisse d'Epargne* (now BPCE), one of the three largest banks in France. In March 2012, Global Bioenergies announced that they would be receiving EUR 740 000 of financing from OSEO, a French state SME-funding agency, in the form of an interest-free loan to be reimbursed from 2016 onwards. The loan will be used to support the creation of an isobutene production strain compatible with industrial pilot testing. This brings OSEO's financing of various development stages of Global Bioenergies' isobutene programme to a total of EUR 2 million since 2009.[12]

India

India is including plans for developing synthetic biology in its 12th Five-Year Plan. The following recommendations were made by the Task Force on Synthetic and Systems Biology Resource Network:[13] augment capacity in India through the creation of institutions; augment human resource development; build translational capabilities; evolve multi-modal and fast-track funding options; build international linkages; create training centres, network centres, dedicated seminar circuits for synthetic and systems biology research; create fellowships and facilities for micro-fluidics, high-throughput genome sequencing, and engineering and "-omics"-scale data generation; and create plug-and-play facilities and creation of open knowledge-ware. The indicative budget for this in the 12th Five Year Plan (2012-17) is INR 19 700 million (approximately EUR 277 million).

Japan

Competitions

RoboCon is a well-known robot contest in which individually developed robots compete on the basis of excellence in certain skills. GenoCon is the life science version, and expects researchers to compete on the basis of their skills in the rational design of genome-based sequences. The competition also hopes to attract researchers familiar with bioinformatics who may lack the experimental resources to build what they design.

GenoCon expects small-scale business groups and academics with patented DNA sequences to use the platform to find optimised versions of the sequences claimed in the patents. Results will normally be made public, but participating companies will have the option to keep sequences secret if they are negotiating joint patent or licensing agreements with other businesses, a strategy that has been coined open-optimisation research. Like the annual international Genetically Engineered Machine (iGEM)[14] competition (see Chapter 1), the organisers hope that GenoCon will attract budding scientists through a separate category for high-school students. Currently, the GenoCon2[15] biannual international competition focuses on modifying the genome of the thale cress plant *Arabidopsis thaliana*.

Infrastructure

A comprehensive approach to building synthetic biology infrastructure is being taken at the RIKEN BASE (Bioinformatics and Systems Engineering) division.[16] The following activities and projects are being developed: international cyber-infrastructure standards; database integration; common platform uniting projects; RIKEN SciNeS: life science networking system; scalable platform incubating databases; strengthening bioinformatics; and genome design.

United Kingdom

Roadmap

The United Kingdom Technology Strategy Board published their roadmap in July 2012 (UK Synthetic Biology Coordination Group, 2012). It maps to 2030 the timeframe for the development of a bioeconomy. It has five core themes: foundational science and engineering: the need for sufficient capabilities for the United Kingdom to maintain a leading edge; continuing responsible research and innovation: including the need for awareness, training and adherence to regulatory frameworks; developing technology for commercial use; applications and markets: identifying growth markets and developing applications; and international co-operation.

A crucial element of the roadmap proposal is the establishment of a leadership council. The range of potential synthetic biology applications and the corresponding number of bodies involved in different aspects of synthetic biology show the need for one body to be a visible point of co-ordination. The government has proposed that this leadership council would own and oversee the development and delivery of the vision and roadmap. A recommendation in the UK Synthetic Biology Roadmap is the creation of a network of multidisciplinary centres, including a dedicated innovation and knowledge centre. An announcement to this effect was made on 11 September 2012 (EPSRC, 2012).

Innovation and knowledge centres were established by the Engineering and Physical Sciences Research Council (EPSRC) as centres of excellence with five years' funding to accelerate and promote business exploitation of an emerging research and technology field. Educational initiatives

Synthetic Biology, Imperial College, London: A final-year option in synthetic biology is available to undergraduates wishing to study for a BSc in Biochemistry or Biology or a BEng or MEng in Biomedical Engineering. In the undergraduate synthetic biology course, students learn about the foundational technologies and theory behind engineering biology and real-world situations in which synthetic biology is being applied. The course contains an introduction to the moral and ethical issues associated with synthetic biology, as well as practical sessions on experimental molecular biology and biological modelling. The course culminates with a "mini iGEM" project, a two-week task to develop a synthetic biology idea and outline the design, modelling, experimental work and data analysis required to bring this to reality.

MRes at Imperial College, London: The Master in Research course, at the Institute of Systems and Synthetic Biology, consists of an eight-month multidisciplinary research project, as well as case studies, practicums and taught courses in advanced molecular biology, genetics, synthetic biology, biophysics, bioengineering, systems biology, physiological systems, advanced imaging technology and data analysis. The degree is designed to prepare students for doctoral course work or for a career in research, by placing emphasis on a significant dissertation.

Infrastructure

The cross-cutting nature of synthetic biology is exemplified by a joint initiative between four UK research funding councils – the Biotechnology and Biological Sciences Research Council, the Engineering and Physical Sciences Research Council, the Arts and Humanities Research Council and the Economic and Social Research Council. Together, they have provided funding totalling GBP 970 000 to finance seven networks in synthetic biology (Table 7.2). Annex B presents individual synthetic biology research projects funded by two UK research councils. They cover a diversity of types of projects and university departments.

Table 7.2. Synthetic biology research networks in the United Kingdom funded by public money

Network title	Lead university
Synthetic components network: towards synthetic biology from the bottom up	Bristol
Standards for the design and engineering of modular biological devices	Edinburgh
A synthetic biology network for modelling and programming cell-cell interactions	Nottingham
From robust synthetic biological parts to whole systems: theoretical, practical and ethical challenges	Oxford
SPPI-NET: A network for synthetic plant products for industry	Durham
The UCL network in synthetic biology	University College London, Birkbeck
MATEs – microbial applications to tissue engineering: an exemplar of synthetic biology.	Sheffield

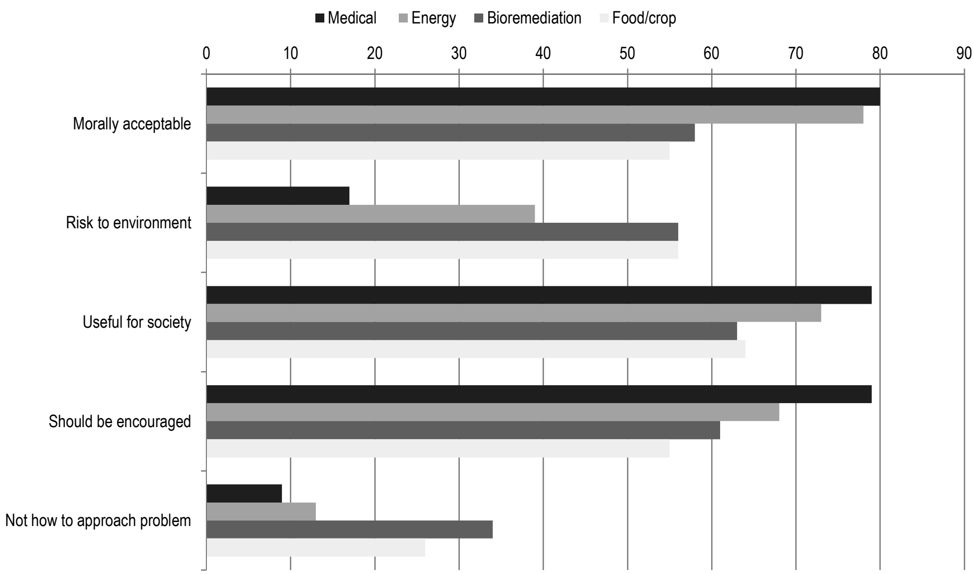
Source: Royal Academy of Engineering (2009), "Synthetic Biology: scope, applications and implications", ISBN: 1-903496-44-6.

Public opinion and engagement

Findings from a UK public dialogue showed conditional support for synthetic biology (Bhattachary et al., 2010). While there was great enthusiasm for the possibilities of the science, there were also fears about control, who benefits, health or environmental impacts, misuse, and how to govern the science under uncertainty. There was broadly greater support for medical applications (Figure 7.1) than for food/crop applications, with a perception of greater risk to the environment associated with the latter, combined with relatively lower societal benefit.

Figure 7.1. Public attitudes in the United Kingdom to synthetic biology in different applications

Percentage of responses



Source: Bhattachary, D., J.P. Calitz and A. Hunter (2010), "Synthetic biology dialogue", for the BBSRC, United Kingdom.

United States

Educational initiatives

The United States has synthetic biology education programmes ranging from high school to postgraduate. A few representative initiatives are:

- Massachusetts Institute of Technology (MIT) high-school enrichment programme: The course, intended for 12th grade, demonstrates the process of cloning a gene from start to finish, including use of polymerase chain reaction (PCR) to amplify a gene of interest, BioBrick assembly of DNA fragments, transformation of DNA into a host bacterium strain, and controlled expression through a variety of expression systems.[17] MIT is also developing integrated, interdisciplinary graduate courses that are accessible to students from different backgrounds. MIT synthetic biology education is discussed in detail by Tadmor and Tidor (2005).

- Brown University 1 BIOL 1940T (CRN 14871) Synthetic Biological Systems: This course builds on recent work in systems biology involving the modelling of biological systems, but goes further in that it involves the construction and standardisation of biological parts that fit together to form more complex systems. It covers fundamental principles of engineering such as abstraction, modularity, standardisation and composition and how these are being applied to biology.
- Harvard University Systems Biology 204: Biomolecular Engineering and Synthetic Biology: This is a course focusing on the rational design, construction and applications of nucleic acid and protein-based synthetic molecular and cellular machinery and systems. Students are mentored to produce substantial term projects. It is intended for graduate students in Systems Biology, Biophysics, Engineering, Biology and related disciplines.
- University of California Berkeley Implications and Applications of Synthetic Biology: This is different from other courses in that, not only does it have scientific and engineering aspects, it also covers aspects of policy making (e.g. policy recommendations) and business (e.g. market trends, intellectual property, hypothetical balance sheets for projects).
- Genome Consortium for Active Teaching (GCAT): Davidson College uses the MIT iGEM competition to expose undergraduates to complex research questions at the interface of mathematics, computer science and biology (Haynes et al., 2008). The course, which combines lectures in the theoretical foundations of biology and mathematics with intensive laboratory work, was recently awarded a multi-year NSF grant to develop the programme as the Genome Consortium for Active Teaching.[18] GCAT aims to make genomics education and research opportunities available to undergraduates, to provide a summer synthetic biology workshop for pairs of interdisciplinary faculty from colleges and universities around the United States and to introduce faculty members to the field of synthetic biology research.
- SynBERC: The Synthetic Biology Engineering Research Centre[19] sponsors a number of educational programmes. One of their sponsored projects is BioBuilder, a website filled with interactive and animated educational resources. Though it is geared towards students, the animations, which provide an introduction to the mechanics of engineering biology, are for any audience. There are also resources for teachers, a synthetic biology glossary and walkthroughs for a number of laboratory activities to introduce students to synthetic biology.

Roadmap

A comprehensive technical roadmap process has been proposed in the United States that would address key technological challenges, the development of common measurements and standards, and shared foundational elements such as tools, techniques, and platforms. The American synthetic biology research community, the National Academies and the business community have all expressed strong interest in a technical, pre-competitive roadmap focused on key challenges to be overcome in synthetic biology. Planning processes are under way at the National Academy of Sciences, the BioBricks Foundation and several industry-university coalitions.

The roadmap will likely represent a multi-year effort focused on overcoming the major technological, measurement, standards and scientific barriers. It is likely to take a very different form from that of the UK roadmap and others. It will not be an overview of the field or a strategy planning document but is much more likely to resemble the Semiconductor Roadmap, an on-going and comprehensive technical and scientific process involving working groups, measurements, technical challenges and benchmarks to drive progress in the field. Also, it is likely to focus more on the key building blocks for synthetic biology (tools, technology platforms, data, metrology) than on applications.

Research

Between 2005 and 2010, the US government spent approximately USD 430 million on research related to synthetic biology, with the Department of Energy funding the majority of this research.

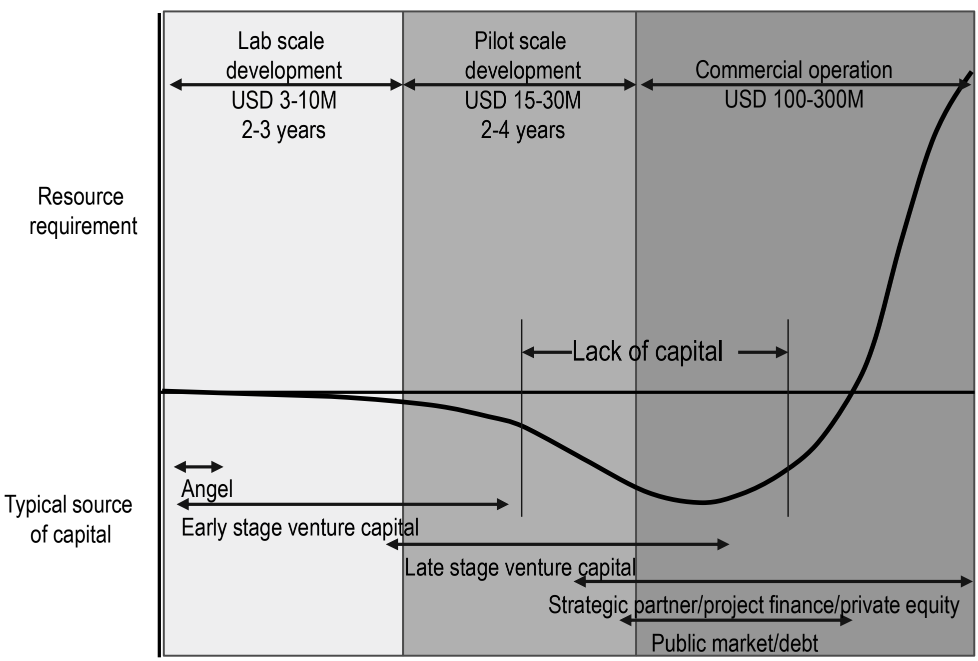
Intellectual property

The BioBrick Public Agreement is a free standardised legal contract that allows individuals, companies and institutions to use their standardised biological parts for free. According to the BioBrick Foundation,[20] "the BioBrick Public Agreement was developed for sharing the uses of standardised genetically encoded functions (e.g. BioBrick parts) but, in practice, can be used to make free the sharing of any genetically encoded function that you might already own or make anew". The BioBrick Public Agreement attempts to minimise legal uncertainty and to avoid disputes arising over ownership, intellectual property rights and attributions, like open source and free software licensing. According to Torrance (2010), this agreement could be seen as an "initial effort to draft a legal constitution to guide the beneficial development of the field of synthetic biology".

Commercialisation and venture capital

In the United States, a new wave of university funding may further stimulate synthetic biology through the commercialisation of near-market research. While MIT, Stanford and Caltech have long provided infrastructure to nurture new companies, other universities are now seeking to do the same. New York University, for example, announced a new USD 20 million venture fund to commercialise internal research (Belz, 2010). For university professors, access to internal sources of funds, instead of external venture capital, is attractive as it is likely to be accompanied by institutional support. University administrators can retain faculty members with the promise of funding their future enterprises. However, experience in the United States has shown that such spin-outs are resource-intensive, can take years to achieve sales and typically require financial support at levels beyond university funds. Figure 7.2 shows typical cash requirements for a young high-technology company in the United States.

Figure 7.2. Typical capital requirements for a biotechnology company



Source: Wyse, R. (2011), "Challenges to financing a global bio-based economy: opportunities for emerging economies", Presented at the European Forum for Industrial Biotechnology, 19 October 2011, Amsterdam.

In the United States, some synthetic biology companies with flexible platform technologies have seen significant investment. Among the biofuels processing technologies, synthetic biology start-ups have attracted increased funding since 2004.[21]

Lab-scale R&D is the least expensive phase of the development of a spin-out. Pilot-scale development has been lacking, but this is now being addressed. For example, the US biofuels industry is currently relying on pilot plants to develop efficient processes to produce cellulosic biofuel and verify its economic viability (An et al., 2011).

Regulation

The United States' approach to regulation of synthetic biology is premised on the assumption that regulation should focus not on the production process *per se* but on the properties of products as regulated under existing statutes. Consequently, synthetic biology products are currently covered by three different US agencies operating under four separate statutes (Bar-Yam et al., 2012).

Until recently, the role of governmental institutions in controlling synthetic DNA trade and production has been relatively marginal. However, this has changed slightly since US administrative bodies such as the National Science Advisory Board for Biosecurity (NSABB) have started to take a proactive role in promoting security standards in gene synthesis companies.

Documents such as the NSABB's Addressing Bio-security Concerns Related to the Synthesis of Select Agents[22] or the National Institutes of Health's Guidelines for Research Involving Recombinant DNA Molecules[23] represent government efforts to address the security aspect at the institutional level. Nevertheless, the involvement of government at this stage is limited to making recommendations.

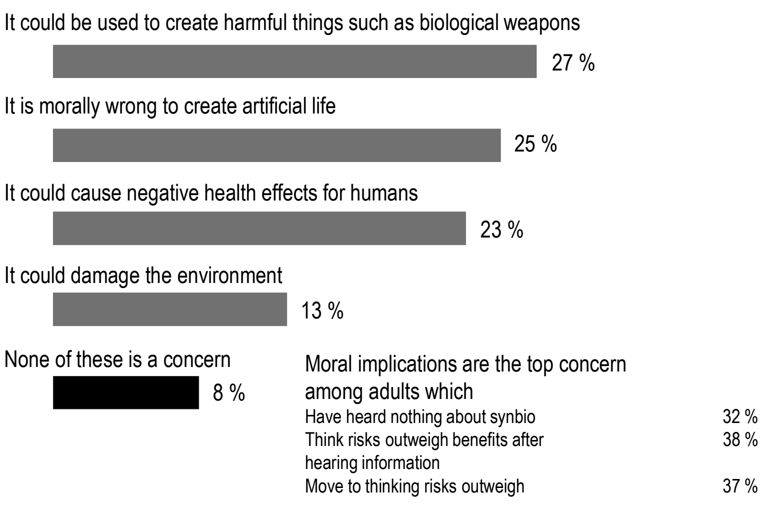
The engagement of US governmental agencies could represent a step towards a more global approach to synthetic biology security. This goal is also shared by the US Department of Health and Human Services. In explaining the objectives of its *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA,*[24] it pointed out that "the Guidance was composed so that fundamental goals, provider responsibilities, and the screening framework could be considered for application by the international community".

Public opinion and engagement

During 2010, Hart Research Associates conducted a nationwide survey of 1 000 American adults about attitudes towards nanotechnology, and awareness of, and attitudes towards, synthetic biology. Awareness of synthetic biology grew significantly over three years from 9% in 2008 to 26 %. Figure 7.3 may be revealing if these opinions are widespread. It would appear that, in the United States at least, the negative association of synthetic biology with agriculture is not yet a concern. In a presentation to the European Commission, Michele Garfinkel stated that the five key societal concerns regarding synthetic biology in the United States are: bioterrorism; laboratory safety; harm to the environment; distribution of benefits; and ethical and religious concerns.

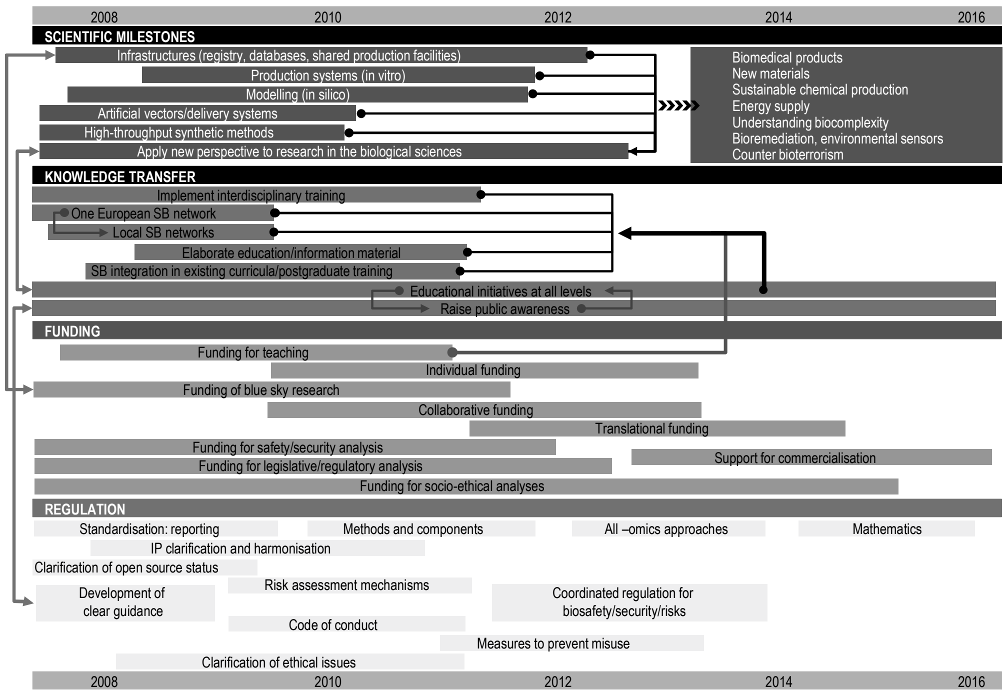
Interestingly, there was no concern about synthetic DNA itself; rather there was concern about whether specific engineered organisms pose risks to the environment; this is a link to concerns surrounding agriculture and forestry. In this regard, the debate has been on-going since the 1970s and is far from a new issue. The concerns over the distribution of benefits revolve around intellectual property and the concentration of benefits in a small number of companies. This is a concern for any new technology and is not specific to synthetic biology. Less tractable, however, are moral and ethical concerns over the changing relationship of humans to nature.

Figure 7.3. Top concerns about synthetic biology among US adults



Source: Hart Research Associates (2010), "Awareness and impressions of synthetic biology: a report of findings based on a national survey among adults", Hart Research Associates, Washington, DC.

Figure 7.4. A vision of an EU roadmap for synthetic biology



Source: Gaisser, S. (2009), "Making the most of synthetic biology. Strategies for synthetic biology development in Europe", *EMBO Reports* 10, S5-S8.

European Union

Roadmap

Research activities in synthetic biology are scattered across Europe and are still concentrated in a relatively small number of working groups. To strengthen European competitiveness in synthetic biology, it is necessary to integrate the various activities and to draft a comprehensive strategy for the field. This situation lends itself to a roadmapping exercise, and in 2008, an EU project outlined a synthetic biology roadmap to 2016, with individual roadmaps for regulation, funding and technology transfer. The exercise was performed in three phases:

1. co-ordinating roadmap committee workshops with representatives from on-going synthetic biology projects and funding agencies in the United Kingdom, France, Spain, Germany and Italy;

2. fact-finding workshops with representatives from European research projects in synthetic biology, in which milestones and possible scientific and/or political measures were discussed;

3. once the two workshop series were completed and a draft roadmap was written, an online survey of the broader scientific community was conducted, designed to involve as many persons with an interest in synthetic biology as possible.

The results were published in 2009 (Gaisser et al., 2009), and the resulting roadmap summary diagram is shown in Figure 7.4. It is clearly as much a policy roadmap as a technology roadmap. Such an exercise can be extremely useful for governments by framing the issues and placing them in a time-constrained context.

The rapid technological developments that characterise synthetic biology can change the situation rapidly so that roadmaps must be continuously updated as new technology is developed.

Infrastructure

The fragmented nature of EU research in synthetic biology, alluded to above, requires the involvement of groups in different countries working in various disciplines in infrastructure projects. FP6 and FP7, DG Research and Innovation, have financed 27 synthetic biology projects (Box 7.1).

Regulation

All European Union regulations on genetic engineering pertain to synthetic biology. As with genetic engineering, the contained use of microorganisms in closed systems (regulated by EU Directive 2009/41/EC)[25] has to be distinguished from the deliberate release (EU Directive 2001/18/EC)[26] of organisms into the environment. The European regulations tend to be stricter than their US counterparts, especially with respect to labelling and traceability requirements. The more stringent European rules can be attributed to public concern about the potential dangers of GMOs and food. SYNBIOSAFE[27] was the first project in Europe to research the safety and ethical aspects of synthetic biology and aimed to stimulate debate on these issues.

Box 7.1. Synthetic biology projects under the Framework Programmes

FP6

SYNBIOLOGY: A European perspective on synthetic biology

BIOMODULARH2: Energy project promises a new biotechnology

TESSY: Foundations for a European synthetic biology

SYNPLEXITY: Dynamics and complexity in synthetic protein networks (MOBILITY)

CELLCOMPUT: – Biological computation built on cell communication systems (NEST)

SYNBIOSAFE: Safety and Ethical Aspects of Synthetic Biology

FP7

KBBE-2007-3-3-01 Synthetic Biology for the Environment (CSA-CA): Targeting environmental pollution with engineered microbial systems a la carte (TARPOL)

KBBE-2009-3-6-05: Synthetic biology for biotechnological applications (CP-FP): Bacterial Synthetic Minimal Genomes for Biotechnology (BASYNTHEC)

KBBE.2011.3.6-03: Towards standardisation in Synthetic Biology (CP-IP): Standardization and orthogonalisation of the gene expression flow for robust engineering of NTN (new-tonature) biological properties (ST-FLOW)

KBBE.2011.3.6-04: Applying Synthetic Biology principles towards the cell factory notion in biotechnology (CP-FP): Products from methanol by synthetic cell factories (PROMYSE) and Code-engineered new-to-nature microbial cell factories for novel and safety enhanced bioproduction (METACODE)

KBBE.2011.3.6-06: Synthetic biology – ERA-NET. Call FP7-ERANET-2011-RTD: Development and Coordination of Synthetic Biology in the European Research Area (ERASynBio)

SiS-2008-1.1.2.1: Ethics and new and emerging fields of science and technology: SYNTHETICS and SYBHEL

SiS.2012.1.2-1. Mobilisation and Mutual Learning Action Plans; Acronym: SYN-ENERGY

Conclusion

It will be clear that the policy landscape for synthetic biology reflects the youth of the field. Not all countries have detailed policy agendas. However, synthetic biology also takes advantage of the several decades of policy development associated with biotechnology more generally. So there are familiarities in, for example, R&D subsidy approaches, biosafety and biosecurity. Policy may diverge if countries believe that synthetic biology is the start of a manufacturing revolution in which biotechnology takes its place in mass production. The earliest synthetic biology technology roadmaps have begun to appear. Roadmaps are considered to have been instrumental in the development of the semiconductor industry, and they can also be powerful instruments for policy makers, when considering, for example, the applications that are most important to a particular country or region, and how to go about public engagement. There have even been voices calling for a global synthetic biology roadmap.

Notes

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Annex 7.A1

Recent grants of the Gates Foundation for synthetic biology applications to health

A microbial platform for the biosynthesis of new drugs

The development of synthetic biology platforms to improve the scale and efficiency of microbial systems used to discover, develop, and produce drugs based on natural products. Such new biosynthesis approaches could lead to new and less expensive drugs for global health.

A predictive model for vaccine testing based on aptamers

The use of synthetic nucleic acid molecules known as aptamers to develop a model that can be used to predict the success or failure of new vaccines in clinical trials. This work could help to remove some of the uncertainty in the early-stage development of new vaccines.

A synthetic biosensor to find drugs targeting TB persistence

The use of a synthetic biosensor strain and high-throughput screening to discover compounds that inhibit tuberculosis persistence. Study of these compounds may lead to new drugs that limit the establishment of chronic tuberculosis infections.

Development of a microorganism to produce artemisinin

The production by an endophytic fungus of artemisinin, a key ingredient in malaria treatments. If the fungus produces artemisinin in the absence of light, an enzymatic mechanism is likely involved. This mechanism could be harnessed for a new production method to reduce treatment costs for malaria patients in developing countries.

Discovering new anti-microbial peptides against mycobacteria

The design and production of a large library of antimicrobial peptides (AMPS) that will be tested against *Mycobacterium tuberculosis* strains to identify potential new drugs that can damage the bacterial membrane and be less susceptible to evasion by the development of resistance.

The construction of an inexpensive and robust nanodevice that uses DNA as a scaffold to interact with proteins and nucleic acid markers of target pathogens. When this interaction occurs, the movement will be detected by a reader embedded in the device to create a visual readout of pathogen detection. Nature-inspired nanoswitches for HIV antibodies detection

The development of molecular nanoswitches that provide a visual cue when they bind to HIV antibodies for use in a rapid (one minute) diagnostic test to detect and quantify HIV antibodies in serum samples.

Plant-produced synthetic RNA vaccines

Testing of the ability of a low-cost plant-based synthetic biology method to produce a combined viral protein epitope with an antigen RNA expression system for use in an RNA malaria vaccine. Using plants for this viral transfection system could make RNA vaccine production scalable and cost effective.

DNA nanodevice for pathogen detection

The construction of an inexpensive and robust nanodevice that uses DNA as a scaffold to interact with proteins and nucleic acid markers of target pathogens. When this interaction occurs, the movement will be detected by a reader embedded in the device to create a visual readout of pathogen detection. Nature-inspired nanoswitches for HIV antibodies detection

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Protein-based low-cost metabolite biosensors for pneumonia

The use of synthetic biology to develop protein-based metabolite biosensors. These biosensors will be used to create a simple, low-cost diagnostic test for pneumonia that is based on specific metabolite signatures found in urine.

Reconstitution of a synthetic Mycobacterium tuberculosis system

The synthetic reconstruction of essential biological processes of *Mycobacterium tuberculosis* and the use of this system as a drug-testing platform for the screening of small-molecule therapeutics against multi-drug resistant *M. tuberculosis*.

Synthetic probiotic to identify and prevent cholera

The engineering of the probiotic bacterium *Lactobacillus gasseri* to detect and kill *Vibrio cholerae* in the human intestine. The probiotic could be supplied as an inexpensive lyophilised powder to endemic populations to prevent cholera.

Synthetic signals to eliminate essential Plasmodium proteins

The development of synthetic compounds that target essential proteins in the *Plasmodium* parasite for destruction by its own protein degradation mechanisms. This strategy could aid new small molecule drug development efforts to combat malaria.

Transcription factor screening for P. falciparum therapy

The development of a high-throughput screen to search for artificial transcription factors (ATF) that are candidates to treat *P. falciparum* infections. ATFs could be a gene-regulating drug resource for the study and treatment of malaria.

Wolbachia as a back door to synthetic entomology

The use of synthetic DNA techniques to transform *Wolbachia*, a bacterial parasite that infects most insect species, in an effort to engineer mosquitoes to be immune to malaria parasites.

Yeast receptors for a generic biomarker detection platform

Engineering of yeast-based biosensors that identify protein biomarkers in samples such as blood and urine. An array of yeast strains could serve as a low-cost, in-home device providing patients with a panel of diagnostics to improve treatment and diagnosis in resource-poor settings.

Source:
www.grandchallenges.org/explorations/pages/grantsawarded.aspx?Topic=SyntheticbiologyandRound=8andPhase=all

Annex 7.A2

Synthetic biology research grants awarded in the United Kingdom by two research councils (BBSRC and EPSRC)

Holding organisation	Grant title	Total grant value (GBP)
Imperial College London	Data-based optimal control of synthetic biology gene circuitsa	99 918
University of Glasgow	Developing theory on the formation, composition and structure of open microbial communities that can be used in engineering design	518 536
University of Glasgow	The CHELL : A Bottom-Up approach to in vitro and in silico Minimal Life-like Constructs	373 250
University of Oxford	The CHELL : A Bottom-Up approach to in vitro and in silico Minimal Life-like Constructs	573 990
University of Nottingham	The CHELL : A Bottom-Up approach to in vitro and in silico Minimal Life-like Constructs	729 420
Imperial College London	Centre for Synthetic Biology and Innovation at Imperial College	4 710 140
University of Leeds	Self-assembling virus-like particles	489 951
King's College London	Molecular mechanisms of antimicrobial peptides: phase changes induced in endotoxic bacterial lipopolysaccharide.	195 662
Newcastle University	Sandpit: Cyberplasm	298 311
University of Bristol	Sandpit: Engineering genetically augmented polymers (GAPS)	628 055
University of Glasgow	Sandpit: Synthetic integrons for continuous directed evolution of complex genetic ensembles	907 086
University of Cambridge	Sandpit: The Programmable Rhizosphere	972 909
University of Cambridge	Towards Industrial Applications of Modular Languages for Biology	250 340
University of Edinburgh	Enabling Tools & Technologies for Synthetic Biology	807 438
University of Southampton	Engineering a semi-biotic immune system	1 031 745
University of Exeter	Evolving controllers and controlling evolution	416 929
London School of Economics & Pol Sci	Synthetic Biology: Generativity and the Limits of Intellectual Property	86 014
University of Oxford	Control Engineering Inspired Design Tools for Synthetic Biology	363 101
University of Cambridge	Control Engineering Inspired Design Tools for Synthetic Biology	313 139
Imperial College London	Control Engineering Inspired Design Tools for Synthetic Biology	429 418

Holding organisation	Grant title	Total grant value (GBP)
University of Glasgow	Bio-desalination: from cell to tap	1 040 620
University of Nottingham	ROADBLOCK: Towards programmable defensive bacterial coatings and skins	899 798
University of Warwick	ROADBLOCK: Towards programmable defensive bacterial coatings and skins	259 428
University of Sheffield	ROADBLOCK: Towards programmable defensive bacterial coatings and skins	601 135
University of Nottingham	Towards a Universal Biological-Cell Operating System (AUdACiOuS)	1 026 408
University of Glasgow	A synthetic biology approach to optimisation of microbial fuel cell electricity production	960 593
Imperial College London	An infrastructure for platform technology in synthetic biology	5 007 845
University of Sheffield	From Molecules to Systems: Towards an Integrated Heuristic for Understanding the Physics of Life	247 084
Imperial College London	Assessment of Integrated Microalgal-Bacterial Ecosystems for Bioenergy Production - Optimization-based Methodology	99 382
Imperial College London	Engineered burden-based feedback for robust and optimised synthetic biology	436 947
University of Kent	Bioengineering of complex metabolic pathways	742 283
Imperial College London	Investigation of water oxidising catalysis for renewable energy	490 684
John Innes Centre	The exploitation of viruses for bionanoscience and synthetic biology approaches to new materials and devices	519 797
Rothamsted Research	Rational metabolic engineering of oilseed fatty acid composition	1 178 692
Cardiff University	High-throughput engineering of proteins: Sampling extended chemical diversity by combining directed evolution with an expanded genetic code	314 171
University of Bristol	Synthetic components network: Towards synthetic biology from the bottom-up	125 833
John Innes Centre	Rational design of plant systems for sustainable generation of value-added industrial products (SmartCell)	261 357
University College London	Exploitation of Tat export machinery for protein production by bacteria	331 103
University of Warwick	Exploitation of Tat export machinery for protein production by bacteria	343 575
University of Edinburgh	Creating and evaluating a library of effector modules for synthetic morphology	418 263
University of Reading	A synthetic and recombinant approach to the production and characterisation of IAPV an associated agent of honey bee Colony Collapse Disorder	320 689
Imperial College London	Mapping combinatorial stress responses in bacteria using chimeric proteins and probabilistic modelling	2 900 932

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Holding organisation	Grant title	Total grant value (GBP)
University of Kent	Mechanism of dimethyenzimidazole (DMB) synthesis and the metabolic engineering of a dietary useful form of cobalamin in Lactobacillus	407 274
University College London	Synthetic biology pathways of isoquinoline alkaloids	713 221
John Innes Centre	Plant production of vaccines	426 895
University of Bristol	A biomolecular-design approach to synthetic biology: towards synthetic cytoskeletons	673 294
University of Nottingham	Second generation sustainable bacterial biofuels	2 127 704
University of Dundee	Bacterial hydrogenases for biohydrogen technology	365 058
University of Oxford	Bacterial hydrogenases for biohydrogen technology	524 205
Plymouth Marine Laboratory	Integrated approach to cost effective production of biodiesel from photosynthetic microbes	823 495
Durham University	Integrated approach to cost effective production of biodiesel from photosynthetic microbes	844 536
University of Cambridge	SYNAPTA: An artificial genetic system and its application for the generation of novel nucleic acid therapeutics	275 007
University of Kent	Synthetic biology approaches to compartmentalisation in bacteria and the construction of novel bioreactors	874 606
University of Southampton	Modifying nucleic acid nanostructures using triplex formation	346 022
University of Oxford	Synthetic biology of bacterial cell division	355 946
University of Oxford	NANOCELL	319 781
Rothamsted Research	Engineering oilseeds to synthesise designer wax esters	444 370
University of Nottingham	Systems biology of the butanol-producing Clostridium acetobutylicum: new source of biofuels and chemicals / COSMIC2	452 694
University of Nottingham	Systems biology of the butanol-producing Clostridium acetobutylicum: new source of biofuels and chemicals / COSMIC2	230 848
University of Birmingham	Engineering biofilm catalysts	407 420
University of Bristol	Development of a systems biology for Bordetella pertussis metabolism	576 513
The University of Manchester	Conformational switching for trans-membrane communication	609 437
University of East Anglia	Engineered biofilm catalysts	313 977
University of Cambridge	Collaborative project MAGIC: A multi-tiered approach to generating increased carbon dioxide for photosynthesis	400 261
University of Glasgow	Collaborative project MAGIC: A multi-tiered approach to generating increased carbon dioxide for photosynthesis	401 332
University of Warwick	Collaborative project MAGIC: A multi-tiered approach to generating increased carbon dioxide for photosynthesis	199 054
Cardiff University	Design of bioactive sesquiterpene-based chemical signals with enhanced stability	390 616

…/…

Holding organisation	Grant title	Total grant value (GBP)
Rothamsted Research	Design of bioactive sesquiterpene-based chemical signals with enhanced stability	479 026
University College London	Characterisation of cellular assemblies in microfluidic systems (synthetic biology to obtain novel antibiotics and optimised production systems)	403 051
University of Oxford	Developing and investigating an ultra-stable molecular hub for bionanotechnology	339 378
University of Cambridge	Production of isoprenoid-based biofuel in algae using a synthetic biology approach	313 780
University College London	Production of isoprenoid-based biofuel in algae using a synthetic biology approach	408 529
University of Southampton	Plug 'n play photosynthesis for Rubisco independent fuels	300 609
Imperial College London	Plug 'n play photosynthesis for Rubisco independent fuels	339 879
University of York	Biotransforming phenylpropanoids derived from biorefining: A toolkit approach	352 972
University of Nottingham	Quantification of promoter activity using Lux read-outs and mathematical models.	606 738
University of Southampton	Extending the boundaries of nucleic acid chemistry	1 829 817
University of Oxford	Extending the boundaries of nucleic acid chemistry	1 659 227
University of Sheffield	Design synthesis and evaluation of novel nucleotides for use in nanowire-based DNA analysis and diagnostic devices	91 932
The University of Manchester	A synthetic biology approach for engineering the biosynthesis of new friulimicin lipopeptide antibiotics	75 281
University of Birmingham	Selective biochemical and synthetic biology approaches for improved delivery of recombinant proteins to the extracellular milieu	444 102
Rothamsted Research	Collaborative Research: Exploiting prokaryotic proteins to improve plant photosynthetic efficiency (EPP)	210 284
John Innes Centre	CAPP: Combining Algal and Plant Photosynthesis	313 802
Oxford Brookes University	CAPP: Combining Algal and Plant Photosynthesis	159 329
University of Cambridge	CAPP: Combining Plant and Algal Photosynthesis	372 138
The University of Manchester	Bioorthogonal site-selective protein immobilisation and labelling	475 116
University of Bristol	Alpha-helical peptide hydrogels as instructive scaffolds for 3D cell culture and tissue engineering	659 988
University of Nottingham	Engineering biobutanol production in a cellulosic clostridium using synthetic biology principles	74 410
University College London	MRes in Synthetic Biology	247 204
John Innes Centre	Sandpit: Synthetic integrons for continuous directed evolution of complex genetic ensembles	43 340

…/…

Holding organisation	Grant title	Total grant value (GBP)
Imperial College London	Modular design of a bioinspired tandem cell for direct solar-to-fuel conversion (Solarfueltandem)	175 476
Rothamsted Research	Engineering oilseeds to synthesise designer wax esters	79 704
University of Exeter	Decreasing the oxygenase activity of Rubisco: a synthetic biology approach	174 567
The University of Manchester	Orthogonal riboswitches as tools for controlling gene expression in bacteria	639 275
University of Glasgow	Plug'n Play Photosynthesis for Rubisco Independent Fuels	327 929
Rothamsted Research	Design of bioactive sesquiterpene-based chemical signals with enhanced stability	39 326
University of Bristol	Engineering purple bacterial photovoltaic complexes for device applications	360 080
University of Bristol	Assembly of Artificial Oxidoreductases	294 752
Cardiff University	Controlling cell death and proliferation with encodable visible light responsive proteins	441 375
University of Essex	Metabolic engineering to enhance photosynthesis based on empirical data and in silico modelling	352 167
University of Warwick	Studying stochasticity in eukaryotic gene expression using novel tools of synthetic biology modelling and analytical science	1 150 283
University of Sheffield	Development of an integrated platform for transient production of recombinant protein biopharmaceuticals using disposable processing technology	72 540
University of Cambridge	Mimetic IgG binding ligands	72 540
University of Reading	The Biosynthesis of Artemisinin	387 616
University College London	Use of transaminase enzymes for the synthesis of pharmaceutical intermediates	83 281
University of York	Exploiting the genomic diversity of bayer-villiger monooxygenases for new industrial oxidation reactions	75 281
University of Edinburgh	Biosensors for real-time monitoring of waterborne pathogens and viability determination	75 281
University of Oxford	Bionanopore Function via In Silico Design: A Biomimetic Approach	91 932
University of St Andrews	Development of artificial metalloenzymes for highly efficient catalytic processes.	91 932
John Innes Centre	Integration and coordination within complex antibiotic biosynthetic pathways	462 572
University of Bristol	Novel hybrid anti-MRSA antibiotics from manipulation of the mupirocin and thiomarinol biosynthetic pathways	434 747
University of Birmingham	Novel hybrid anti-MRSA antibiotics from manipulation of the mupirocin and thiomarinol biosynthetic pathways	524 711
University of Leeds	Real-time high sensitivity detection of biological agents	129 242.76 …/…

Holding organisation	Grant title	Total grant value (GBP)
Imperial College London	Engineered security systems for environmental synthetic biology	120 073.40
Imperial College London	Logic-directed evolution of new biosensor molecules in vivo	127 392.67
Cardiff University	Biological Amplification of Chemical Warfare Agent Sensors - Towards 'Deviceless Devices'	120 080.82
University of Reading	Smart Materials for Wound Healing: A New Fast Acting in situ Method to Treat Skin and Eye wounds	
Queen Mary, University of London	Site Directed Inactivation of Biological Agents	114 721.04
Cardiff University	The ostracod carapace window as a biomimetic basis for development of a novel eye shield.	119 583.50
University of York	Exposing explosives: novel synthetic gene circuits for explosive detection via innovative waveguide sensing	119 258.26
University of Bristol	A synthetic biology approach to fighting Francisella tularensis: Development of aptamer presenting DNA-nanorings	122 666.08
The University of Manchester	Exposing explosives: novel synthetic gene circuits for explosive detection via innovative waveguide sensing	44 773.89
University of Birmingham	A homogenous bimodal (immuno/PCR) pathogen detection system based on a bio-nanoparticle	119 898.38
University of Glasgow	Generation of a large family of genetic logic gates for applications in biosensing and information processing	120 185.17
Newcastle University	Surveillance of toxic threats by electronic supervision of synthetic neurons in 3D	100 186.48
University College London	Self-regenerating, suspended-phase whole-cell biosensor system employing micro-chemostat and cell engineering technologies	120 561.78
University of Oxford	Single-molecule DNA biosensors for rapid microbial detection	119 863.42

Source: Adapted from the UK Biotechnology and Biological Sciences Research Council (BBSRC), www.bbsrc.ac.uk/home/home.aspx.


Emerging Policy Issues in Synthetic Biology
OECD