RSC | Advancing the Chemical Sciences

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RSC Submission to Royal Society Call for Views on Synthetic Biology

Memorandum by the Royal Society of Chemistry

The Royal Society of Chemistry (RSC) welcomes the opportunity to comment on the Royal Society call for views on the emerging area of Synthetic Biology.

The RSC is committed to working with the life sciences community, and promoting the contribution of chemical sciences in this area. In 2001 the RSC established the Chemistry Biology Interface Forum (CBiF), a society wide grouping open to all RSC members working, or with interests in research at the chemistry biology interface. The CBiF Executive Committee, chaired by Professor John McCarthy has identified Synthetic Biology as a key strategic area for the RSC.

This document represents the views of the RSC. The RSC's Royal Charter obliges it to serve the public interest by acting in an independent advisory capacity, and the RSC is happy for this submission to be put into the public domain.

If you would like further information or need anything in this document clarified, please do not hesitate to contact me.

Yours Sincerely

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Synthetic Biology

i. Synthetic biology describes a burgeoning field in which bio molecular components (natural or synthetic) are newly combined or reorganised in order to create novel genetic and biochemical circuitry, pathways, and ultimately organisms.

ii. While it shares some of the goals of what is commonly referred to as genetic engineering, it extends the scope of such activity into many new areas and into higher levels of complexity.

iii. The most useful definition of synthetic biology is undoubtedly a more general one that incorporates a number of activities, thus it is useful to consider three categories of research in this area:

1. The development and testing of new biochemical and/or genetic circuitry in order to evaluate predictive models of function. Such activity is tightly coupled to the aims and philosophy of systems biology.
2. The development of novel, or modified versions of known, biochemical pathways and/or genetic circuitry to be used as tools such as sensors.
3. The development of new organisms with significantly novel properties with respect to naturally evolved organisms.

iv. Synthetic biology is distinguished by both a high degree of versatility in the approaches applied and by the highly multi- and inter-disciplinary nature of the science and engineering upon which it is based. This field has been attracting the attention of researchers with training in a wide range of disciplines, including electrical, mechanical and chemical engineering, molecular biology, computational biology, chemistry and maths.

v. Synthetic Biology is not simply the synthesis of new genes, regulatory sequences, RNA sequences or proteins. Such routine activities, however sophisticated in terms of technology, generate only the basic components; real synthetic biology includes the design of a device or module, frequently its modelling/simulation in silico, the testing of the assembled version in vivo and/or in vitro, and its utilisation in addressing specific scientific challenges or in various practical (potentially commercial) applications.

Applications of synthetic biology in relation to the chemical sciences

vi. Synthetic biology has a huge number and range of potential applications. The RSC believes that the most important applications will be found in:

- Developing sustainable energy sources
- Improving human health through better therapies and drugs.

vii. Applying synthetic biology to find viable alternatives to fossil fuels would have a great impact on global energy supplies and climate change. Particularly important applications are hydrogen production, microbial fuel cells, and improved biofuel production. By separating biological pathways from individual microbes researchers at Virginia Tech have been able to engineer a process that converts starch to hydrogen[a]. Synthetic Genomics, LS9 and Amyris Biotechnologies, all based in the USA, are isolating or engineering microbes that produce liquid fuels. Photosynthetic proteins could be developed to generate energy for solar cells.

viii. Engineered erythromycin and avermectin bacteria have been exploited to deliver health solutions for many years such as antibacterial agents. In addition engineered biocatalysts are used extensively in industry.

ix. Cheap and high-yielding drug production and better delivery of therapeutic agents to their targets could be achieved using specialised bacteria. Research groups are already using engineered strains of bacteria to produce natural products and their synthetic intermediates. Some of these processes are already feasible on kilogram scales. Jay Keasling (USA) recently engineered a bacterium to produce artemisinin, an anti-malarial compound[b]. Other techniques to benefit human health involve programming bacteria/viruses to target and treat malignant cells, leading to better treatments for cancer and other illnesses.

x. There should be a distinction between the genetic manipulation of micro organisms in order to manufacture existing drugs at lower costs, and the manipulation of micro organisms to produce novel drug leads and fine chemicals. The latter is the next step for synthetic biology.

xi. Chemical and molecular sciences are clearly integral to enhancing the science of synthetic biology, particularly in the provision of robust chemical toolkits not only for the construction of synthetic organisms, but also for the understanding of complex molecular interactions and bio analysis. The chemical sciences will have a crucial role to play in training scientists, carrying out fundamental research and interacting with scientists from other disciplines.

xii. There are many other areas in which synthetic biology can offer environmental benefits, including:
- Green chemistry
- Carbon dioxide sequestration
- Bioremediation and decontamination
- Industrial emissions controls
- Artificial photosynthesis

Current research capacity, geographical distribution and funding

xiii. Research into synthetic biology is taking place predominantly in the USA. However, research groups can also be found in Europe and Japan, and the technology is spreading. There is a need to dramatically expand research capacity in the UK if synthetic biology is to flourish. Synthetic biology is multidisciplinary by its nature and research centres should reflect this by including biologists, chemists, biochemists, materials scientists, and engineers. This requires interest from a number of research councils, including the Engineering and Physical Sciences Research Council (EPSRC), Biotechnology and Biological Sciences Research Council (BBSRC), National Environment Research Council (NERC) and Medical Research Council (MRC). Funding bodies need to have a clear definition of synthetic biology and its scope, and funding should relate to particular applications. It is important that funding bodies maintain an overview of major initiatives to make sure funding is available.

Education and training

xiv. Currently there are few UK universities offering undergraduate courses specifically in synthetic biology although due to the interdisciplinary nature there are many related degrees. Cambridge University is aiming to establish an undergraduate course in Synthetic Biology[c].

xv. A number of research funders (Cancer Research UK and the Wellcome Trust) have set up doctoral programmes in multi-disciplinary areas, although synthetic biology is yet to be incorporated into this.

xvi. Synthetic biology tends to be integrated into a range of university departments such as Biochemical Engineering (UCL, London) and is taught as part of bioscience/bioengineering degrees. The interdisciplinary nature of this area is challenging for the traditional university department structures.

xvii. As with all sciences, education and training are vital to building and sustaining a scientific community and industry in the UK. The RSC recommends that the best strategy is to encourage good basic science and maths education to at least first degree level. Students can then diverge into interdisciplinary subjects at a higher education level.

xviii. Industry preferences are important to shaping education. Many large pharmaceutical companies prefer to recruit candidates with proven core skills, such as organic chemistry, and provide specialised training in-house. However, biotechnology companies will tend to value a more interdisciplinary skills base that is more relevant to future commercial growth.

xix. Undergraduate and postgraduate training is vital to long-term success. This will provide the skilled workforce needed to sustain synthetic biology research and industry.

The potential threats to the environment and human health

xx. Unintentional release of engineered biological materials into the environment could damage ecosystems or contaminate the environment. Impacts are difficult to predict because of the inherent variability in the way in which such material may interact with other biological systems once released into the environment e.g. the creation of hybrid organisms.

xxi. The risk to human health is likely to be the greatest for those who work with engineered biological materials. Negative impacts on the wider human population can be mitigated if proper emissions regulations and clinical procedures are followed. There is an obvious parallel with the debate over nanotechnology and its potential impacts.

The potential threats to national security

xxii. Bio-terrorism is a threat to society which could be enhanced with synthetic biology. Smallpox and other engineered viruses could be created and used to attack populations[d]. However this is unlikely to be a viable risk in the near future, as conventional chemicals and biomaterials, such as phosgene and anthrax-causing bacteria, are far more accessible and more easily deployed. Again, rigorous controls of hazardous materials and equipment should help prevent bio-engineered viruses becoming feasible weapons.

Intellectual property (IP) issues

xxiii. The discussion over patenting of biological parts has been ongoing for many years. Some recent discussions relate to the patent application filed by the J. Craig Venter Institute for the 381 minimum number of genes required for life. A 'blank' organism containing these genes could be customised by inserting various genes to produce almost any engineered organism. Currently the 'blank' organism has not yet been produced but there are questions over whether the organism could and should be patented. A viable alternative would be to patent applications rather than organisms. This would protect intellectual property without stifling innovation elsewhere. Patenting of individual genes would mean scientists spending a considerable amount of time clearing up IP issues. This could significantly hinder progress and innovation. Another option is being explored by a group at Massachusetts Institute of Technology (MIT) whereby a 'Registry of Standard Biological Parts' is created, placing these 'parts' in the public domain (similar to the electronics industry). Other solutions may be to use copyright or develop new novel legal frameworks.

xxiv. It is important to consider the differences between UK, European and US patent laws; any agreements would need to be internationally binding.

xxv. Despite these issues synthetic biology is not vastly different to other sciences in relation to intellectual property and the law.

Regulation

xxvi. Since synthetic biology is potentially capable of engineering step-changes in genetic coding and biochemical/physiological properties that were previously not possible, the ability of scientists to anticipate the potential risks associated with release of such organisms will be reduced. What is not yet well understood is what kind of environmental and health effects would be expected i.e. will these give rise to new, as yet unknown effects, or will they simply give rise to known effects to a different extent? This will require the development of appropriate testing and monitoring procedures. More research is needed to develop the methods to acquire the data needed to understand the impact of synthetically engineered organisms. The RSC therefore recommends that a special set of guidelines is developed to address this aspect of synthetic biology.

xxvii. There are some existing regulations concerning genetically modified organisms and products, particularly for food, but these are not sufficient to cover the broad spectrum of synthetic biology. As well as controls on availability, the applications of synthetic biology must be regulated. International differences in regulations must be taken into consideration and reconciled where possible.

xxviii. The aim of legislation should be to develop proportionate, risk-based regulations that protect human health and the environment and that take societal concerns into account. In some cases this may be achieved by extending existing regulations, in others new regulations may be needed. It is also important that any proposed regulations do not stifle innovation in those cases where the risks can be adequately controlled and the potential benefits to society outweigh the risks.

xxix. Societal acceptance may be difficult due to the ethical questions raised by synthetic biology. Past experience with GM-crops has shown the importance of an early safety and ethics debate. The European Parliamentary Technology Assessment (EPTA) is leading a project –on the Safety and Ethical Aspects of Synthetic Biology4 (SYNBIOSAFE) to gather information on risk and devise appropriate bio-safety strategies. The project will focus particularly on safety and ethical considerations, and is the first of its type.

xxx. Appropriate regulations and controls on the accessibility and applications of synthetic biology should help allay societal concerns regarding bio-terrorism and environmental damage. Impact assessments will help inform policy.

Openness

xxxi. The Royal Society of Chemistry is pleased for this evidence to be made publicly available and will shortly be placing a version on www.rsc.org. Should the Royal Society have any queries regarding this evidence then they should address them to Dr Philippa Bell, Bioscience Manager, Royal Society of Chemistry, Burlington House, Piccadilly, London W1J 0BA. Email: bellp@rsc.org.

Background

The Royal Society of Chemistry (RSC) is the largest professional body in Europe for advancing the chemical sciences and can trace its origins back to the establishment of The Chemical Society in 1841, here in Burlington House.

In accordance with its first Royal Charter, granted in 1848, the RSC continues to pursue the aims of the advancement of chemistry as a science, the dissemination of chemical knowledge, and the development of chemical applications. The key role that the chemical sciences will play in the search for solutions to challenges which face humanity in the 21st Century, from finding cures for diseases to building a sustainable environment makes the need for such an advocate of beneficial scientific progress as strong as ever.

Over a century and a half on from its beginnings, the RSC has a global membership of over 43,000 and is actively involved in the spheres of education, qualifications and professional conduct. It runs conferences and meetings for chemical scientists, industrialists and policy makers at both national and local level. It is a major publisher of scientific books and journals, the majority of which are held in the Library and Information Centre in this building. In all its work, the RSC is objective and impartial, and it is recognised throughout the world as an authoritative voice of chemistry and chemists.

This response has been written from the perspective of the Royal Society of Chemistry and its members.

References

[a] http://filebox.vt.edu/users/ypzhang/research.htm
[b] https://keaslinglab.lbl.gov/wiki/index.php/Synthetic_Biology_-_Applications_-_Artemisinin
[c] http://www.plantsci.cam.ac.uk/Haseloff/syntheticbiology/page0/page0.html
[d] http://www.newscientist.com/article.ns?id=mg18825252.900