

SYNTHETIC BIOLOGY PUBLIC DIALOGUE



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Synthetic Biology Public
Dialogue

People have always been curious about how living things work. For centuries humans have studied micro-organisms, plants and animals (including of course ourselves) to try to find out how they are constructed and how they work. In the past 50 years this scientific endeavour has been extended to the molecular level, with spectacular advances in our knowledge of how genes work, how they are translated into cellular components, and how they control the whole organism. More recently researchers have been able to store genetic information on computer databases that can be accessed by the global scientific community. At the same time molecular biologists have learnt how to synthesise the basic genetic components of cells, RNA and DNA, with great accuracy; we can now assemble long lengths of these molecules, which are of course the blueprint for life, and we can do this increasingly rapidly and cheaply.

About 20 years ago, groups of biologists, chemists, engineers and computer scientists realised that it was now possible to radically *redesign* biological components such as DNA, proteins and molecular modules that assemble and run cells. The culture of synthetic biology was born, and multidisciplinary teams set out to make the aspirations real.

Pioneering researchers in the last decade have demonstrated

that working viruses can be assembled using gene sequence templates stored on computers, and a team led by Craig Venter in America this year demonstrated that bacterial chromosomes can be synthesised from scratch and successfully transplanted into cells. Synthetic biology has reached a new and important developmental stage, because in the near future we will be able to design and assemble micro-organisms to carry out a multitude of tasks currently done using rather crude and energy-intensive industrial processes. On a longer timescale it should be possible to design and build higher organisms and other biologically-based systems to produce fuel, industrial raw materials, engineering components, drugs and perhaps food more sustainably. Several eminent scientists have described synthetic biology as the "second industrial revolution". Undoubtedly there is great potential in this new scientific culture.

Like all new science and technology, beside potential benefits, societal and ethical issues will emerge from the use of synthetic biology. The Research Councils, especially BBSRC and EPSRC, who fund most synthetic biology research in the UK, together with the learned societies (especially the RAEng and Royal Society), realised several years ago that this was potentially a controversial scientific area. We could only guess at what these

issues might be, so in 2007 BBSRC's Bioscience in Society Panel commissioned social scientists Andy Balmer and Paul Martin at the University of Nottingham to give us a view of the societal and ethical issues that might arise from synthetic biology. Their excellent and widely-read report¹ confirmed that there would be significant issues arising from synthetic biology and recommended that we engage with the public at an early stage in the development of synthetic biology, before commercial products appeared, and that public engagement should involve scientific researchers, social scientists, NGOs and ethicists.

Partly as a response to that report, the societal and ethical issues panels of BBSRC and EPSRC combined forces to initiate the public dialogue that started in 2009 and has produced the report published this year². TNS/BMRB were commissioned as the main contractor and Laura Grant Associates as evaluators, with Sciencewise providing valuable advice and funding. We set out to capture a wide range of public views, including people's aspirations for synthetic biology, and their concerns. Most of all we wanted this dialogue to be the first phase in an ongoing conversation between the research community and members of the public, employing innovative techniques such as video ethnography, where researchers record their daily lives to show public

participants the world of science and scientists.

TNS/BMRB interviewed 41 stakeholders with a professional interest in synthetic biology, and then ran a series of three workshops at four locations involving 160 public participants and a number of researchers, including synthetic biologists and social scientists. Public participants were drawn from a wide range of backgrounds, ethnicity, faiths and abilities, making the group a representative sample of society. The whole process was overseen by a lively and diverse oversight group, including sociologists, NGOs and scientists, who were charged with acting as 'critical friends' to the contractors.

When first introduced to synthetic biology public participants mentioned that the ability to design and assemble novel biologically-based systems gave synthetic biology a "uniqueness" that both fascinated and excited them, not only because they could see the potential in this scientific area but they also felt that the science was "unimaginable", far removed from science with which they were familiar.

Participants were, as we expected, excited by potential outputs from synthetic biology, but were also deeply interested in the process of science. Scientists' motivations and aspirations were the subjects of much deliberation and debate, generating a series of questions that participants felt should be addressed by the scientific community. Amongst these were "Why are you doing this research?", "What do you hope to achieve?" and "What sort of technology is produced when you are respectful of nature?" People also felt there was a disconnect between individuals' own science, seen by

researchers as incremental or routine, and the field overall, viewed by the public as transformative. One of the key issues to emerge was the need for scientists to consider the wider implications of their work more effectively and to show the public that they had done so.

The dialogue reveals that both professional stakeholders and public participants found the technology fascinating and were excited by its potential, for example, to help us tackle some of the big challenges society faces, such as global warming, serious diseases, energy problems and food security. The prospect of being able to make progress towards these goals was a significant factor in public acceptability of the research. But coupled with this recognition of potential was a strong sense of trepidation and concern, for instance around the suitability of current regulations to cope with this new field, and for wider impacts of the technology. Concerns included the pace of development in the field, the idea that the science may be progressing too quickly when long term impacts were unknown. Other significant concerns focused on where synthetic biology was going, and what it might look like in the future, together with potential for uncontrolled release of synthetic organisms into the environment. The need for effective international regulation and control was one of the most important issues flagged up by participants, but a significant number also felt that overregulation could slow down important research especially in the medical field. There needed to be greater capacity for regulators to be able to anticipate scientific developments. Given the novelty of synthetic pathway or micro-organism there was doubt

whether current regulatory systems were adequate.

People were concerned that scientists should afford dignity, responsibility and respect when intervening in the natural world. Perhaps surprisingly, there was general agreement that creating life was acceptable when balanced with the benefits that synthetic biology could bring. However, people found problematic the idea of treating nature as parts to be assembled. Nature was seen as too complex with genetic and environmental interactions too dynamic and stochastic to predict in a precise way. Despite voicing these concerns, participants did not divide into 'pro' and 'anti' groups. Typically, excitement and trepidation resided within each individual.

Public participants felt that the Research Councils, as major public funders of synthetic biology research, should take the lead in making sure the discussions, concerns and hopes that the report highlights have real influence on Research Council policies and those of others; for instance regulators and the private sector. One of the key issues to emerge was what was meant by funding 'good science'. Currently, this process is focused on technical excellence, but participants wanted to see a broader definition of good science, perhaps in a normative or social sense. They also wanted scope to feed public aspirations and concerns into research funding strategy. To enable this it should be incumbent on the Research Councils to make the science publicly accessible. For certain grant applications, people felt that a more iterative process is needed not only involving scientists, but also the public, social scientists, ethicists and others to feed in views, with ideas shaped through debate.

This dialogue breaks new ground in public engagement, not only in terms of how it is planned and conducted but also because it is taking place at a very early stage in the science. This presents some real challenges, not least because at the start most public participants were completely unaware of synthetic biology, and as yet there are no tangible products. It is perhaps a measure of the success of this stage in the dialogue that many participants are now keenly interested in synthetic biology and have said that they want to continue their dialogue with researchers.

I hope we can enable them to do this, because as chair of the steering group, I would like to see the dialogue continue within institutions and through public debate; in other words become embedded in the business of science and technology. To my mind it is only right and proper that members of the public are able to make their views directly available to scientists and not just via the media, for those views to be taken into account, and for researchers to be able to engage easily and openly with the society within which they operate.

Finally, I would like to thank the steering and oversight groups for their hard work and professional stakeholders for their input. I also especially want to thank our public participants, some of whom are here today, for the time and effort they put into the workshop discussions.

1. Synthetic Biology: Social and Ethical Challenges. Balmer, A. & Martin, P., University of Nottingham. 2008. Available at: http://www.bbsrc.ac.uk/web/FILES/Reviews/0806_synthetic_biology.pdf
2. Synthetic Biology Dialogue. BBSRC/EPSRC 2010. Report available at: <http://www.bbsrc.ac.uk/web/FILES/Reviews/1006-synthetic-biology-dialogue.pdf>



SYNTHETIC BIOLOGY PUBLIC DIALOGUE



Professor Douglas Kell
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BBSRC and EPSRC recognised several years ago that synthetic biology was an emerging area of science that had great potential both to generate exciting beneficial outputs and to raise social and ethical concerns. In 2009 we commissioned a dialogue to begin to explore the diversity of views around this novel area of science so that our future policy and dialogue activities could be better informed. Workshops with members of the public took place in early 2010 and a report was published later in the year highlighting a number of recommendations for the Research Councils and others to consider when thinking about synthetic biology. Here, I will take the opportunity to explain some of the actions the Research Councils have committed to in our response to those recommendations. A number of the actions will be carried out jointly between BBSRC and EPSRC but, recognising that the communities of scientists that we fund are different from one another, we will also be working on some actions separately.

Firstly, it is important to convey that we view this dialogue as the foundation for an ongoing conversation about synthetic biology. As the field develops and matures and as applications begin to reach the

marketplace and consumers, it is vitally important that we stay engaged with those who have a stake in synthetic biology – that includes the public but also special interest groups such as NGOs, industrialists, environmental groups and others.

There are many ways of having these conversations and multiple routes for them to influence not just the Research Councils, but others such as scientists and policy makers. To facilitate ongoing discussion we will be producing a reader friendly digest of the report to help get its messages to a wider audience. In BBSRC we draw on the expertise of our Bioscience for Society Strategy Panel (BSS), with its diverse membership that includes social scientists, bioethicists and consumer groups. It was this panel who first highlighted the potential for synthetic biology to raise social and ethical issues to the Research Councils and in doing so sparked this whole exercise. BSS helps us to include perspectives in our policy making from beyond those of the close-knit scientific community and they will continue to keep a close eye on this area as the science develops.

Clearly, though, the report and dialogue call for much more than a watching brief, and our

response sets out our commitment to do much more. It is not necessary to repeat what is laid out in the response letter, but it may be helpful to outline the thinking behind the actions and illustrate it by pulling out one or two examples.

The report highlights that there are some issues that are particularly acute in synthetic biology: the juxtaposition of 'synthetic' and 'biology'; of 'artificial' and 'natural'; and, the potential for synthetic biology to have industrial scale impacts and so to be both very exciting and yet also very 'scary', are two that stick in my mind. This means that we do need to be particularly vigilant and attentive to synthetic biology as a scientific area. It is why we have committed to working hard, with our synthetic biology research community, to ensuring that we are open and engaged. I know that our Networks in Synthetic Biology are already doing a great deal to talk about their research and to bring in outside perspectives to their work. But we can do more which is why, with funding from Sciencewise, we will be holding a workshop with the synthetic biology community not only to discuss the report and its messages but also to share best practice in public engagement and to begin to build a tool kit that will help researchers talk about their

research and explore the issues around it.

The headline message from the report is, “conditional support of synthetic biology”. It’s striking that for all four applications discussed in the workshops each time at least half of people thought research should be encouraged.

But it would be a grave mistake to interpret this simplistic top line message as meaning that we need do nothing. The report really brings out the plurality of voices and views that were expressed during the dialogue. It was striking to me how people’s views were nuanced, for instance the same people would recognise the potential for synthetic biology to tackle global challenges whilst at the same

time expressing anxiety about regulatory and societal issues. Clearly discussion and debate about synthetic biology is not either black or white, nor should it be depicted or treated as such. Each new advance and novel application of synthetic biology will prompt a conversation to explore the grey areas and to try to decide whether the potential risks are or are not outweighed by the potential benefits.

The report has real value to us because as well as helping us understand people’s attitude to synthetic biology it also tells us about issues that stretch right across our work and indeed that of government and industry. For instance, there are messages about how innovation happens that are not just relevant to synthetic biology but can be

applied to any area of research that we fund. In fact, BBSRC’s Bioscience for Industry Strategy Panel has recently been discussing just these issues and has helped us put together a Knowledge Exchange and Commercialisation policy that aims to shift the focus of knowledge exchange towards recognising social goods as well as commercial potential research and its outputs. This work has the support of our Research Council colleagues.

The dialogue and report has also prompted us within BBSRC to review how we monitor the ethics of all our grant applications and to think about how we can encourage researchers right across the piece to consider the motivations for their work and to look at it in the wider social context.

Of course, the report touches on areas that are beyond the Research Councils’ sphere of influence. Far from ignoring these issues we are actively working to ensure that the report has influence beyond our walls, we know it is important that the messages from this report reach all those who have a stake in them.

Finally, I would like to thank all those who’ve taken part so far in this discussion, either as advisors or participants and by inviting those of you haven’t yet been involved to join in the ongoing discussion around this potentially life changing technology.

The recommendations that have arisen from the dialogue and the response that BBSRC and EPSRC have made to those recommendations are available through our website (www.bbsrc.ac.uk/syntheticbiologydialogue).

SYNTHETIC BIOLOGY DIALOGUE AND WHAT IS THE PUBLIC PERSPECTIVE?

SYNTHETIC BIOLOGY PUBLIC DIALOGUE



Professor David Delpy
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Synthetic biology provides us with a unique opportunity to engage the public early on in the future direction of an emerging and potentially revolutionary area of research.

The synthetic biology public dialogue, commissioned by EPSRC, BBSRC and Sciencewise, has been an extremely valuable and positive experience for the Research Councils. We hope this is the first step in building a

platform for ongoing communication with the public about important scientific advances – getting issues out in the open and engaging a wider audience in the debate.

Two of the main themes emerging from the dialogue responses, which I will explore further here, were regulation and an approach to responsible science and innovation.

REGULATION

The issue of regulation for synthetic biology is a problematic one as framing regulation when hypothesizing about future technology is fraught with difficulties. However, strong concerns were expressed by all participants in the dialogue about the need for effective regulation and adaptive governance, with regulators seeking to anticipate and



respond to scientific developments. Doubts were also expressed about the ability of the current regulatory systems to cope if a breakthrough led to an increase in synthetic biology applications.

If these issues are not satisfactorily addressed then there could well be a public reaction against synthetic biology, limiting our ability to realise the potentially huge benefits of the technology.

Much of our existing regulation uses conventional risk assessment to assess the safety of, for example, a genetically modified (GM) organism by comparing it with that of a predecessor. If synthetic biology were to create totally new entities without provenance or predecessors this approach would not necessarily work. To complicate things further, research is still in its infancy and the hypothetical applications cross over the boundaries of different Government Departments, potential regulators, and international bodies.

This is an area where the Research Councils have limited influence, but I have alerted Sir John Beddington in his role as the Government's Chief Scientific Adviser. We have discussed this and corresponded and I know he is giving this his active consideration.

I do believe that the Research Councils and our research communities can and should seek to identify at an early stage the potential wider

impacts of emerging technologies (on society, health and the environment) and in so doing inform regulatory decisions. The researchers we fund should form the first link in an anticipatory and adaptive governance partnership.

RESPONSIBLE SCIENCE AND INNOVATION

A key message from the dialogue is that the public have an interest not just in the outcomes of research, but in the process and conduct of the research itself. The public rightly expect to be able to trust funders to ensure that scientists think about the potential impacts of their research and act responsibly, and that government puts in place appropriate and timely regulatory processes.

These are generic issues that are not limited to synthetic biology, but apply across the whole spectrum of research and innovation.

Research Councils have a responsibility to scrutinize the potential impacts and risks of emerging technologies, and encourage the researchers we fund to do likewise. This is an area that EPSRC's advisory body, the Societal Issues Panel¹, is considering closely. Such processes must not be about necessarily stopping areas of research in response to potential risk and uncertainty; we need to identify how to proceed responsibly. The challenge will be to define an approach that promotes creativity and

innovation in research underpinned by a commitment to its responsible development.

DEVELOPING A FRAMEWORK FOR THE FUTURE

Through a pilot project in partnership with the Economic and Social Research Council (ESRC) we have been exploring ways to encourage and embed such 'upstream' reflection. As part of the pilot EPSRC included a specific section on responsible innovation for the first time within a major funding call.

For more detail on the pilot project see *Rising to the Challenge of Responsible Innovation* by Professor Richard Owen on page 5 of this publication.

In conjunction with ESRC we are looking at how we might build on this pilot and develop an outline Responsible Science and Innovation Framework as a basis for a wider discussion and to explore how we might develop a unified, consistent approach across Research Councils and other partners. Although any potential framework would be made available to all research areas, it would not be expected to be used in all cases. We must take care not to be heavy handed and force an approach on areas where it might not be appropriate. This is about creating the opportunity for reflection within the whole life cycle of research and innovation, encouraging researchers to think imaginatively about the potential

applications and impacts of their science, and helping to inform policy and regulation discussions.

CONCLUSION

We have embarked on the first step in establishing a route to responsible innovation, but there is much left to do. If successful we believe this will lead to a positive culture change for research and innovation funders and those who are funded by them. It will be an important start to translating the concepts of adaptive and anticipatory technological governance into practice at an early stage in the innovation process.

I would like to thank all those who contributed to the dialogue, especially the members of the public and the scientists who found time to participate. Special thanks should go to BMRB who conducted the exercise and also to Sciencewise whose resources and wealth of expertise contributed so much to the process.

¹ EPSRC's Societal Issues Panel is chaired by Professor Lord Robert Winston. The current membership comprises: Professor Jim Al-Khalili (University of Surrey and EPSRC Senior Media Fellow), Anita Charlesworth (Nuffield Trust and Chief Scientific Advisor to the Department of Culture Media and Sport), Professor Richard Jones (University of Sheffield), Professor Phil Macnaghten (Durham University), Professor Judith Petts (University of Southampton), Tim Radford (Freelance Journalist), Professor Tom Rodden (University of Nottingham), Professor Kathy Sykes (University of Bristol) and Professor Paul Younger (University of Newcastle).

