

Synthetic Biology Dialogue

This report presents the findings of a series of public workshops and stakeholder interviews on the science and issues surrounding synthetic biology. The project took place during 2009-2010 and was carried out by the TNS-BMRB, initiated by the Biotechnology and Biological Sciences Research Council (BBSRC) and the Engineering and Physical Sciences Research Council (EPSRC), and with support of the Department for Business, Innovation and Skills' Sciencewise programme.

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Biotechnology and Biological Sciences Research Council (BBSRC)

BBSRC is the UK funding agency for research in the life sciences. Sponsored by Government, BBSRC annually invests around £470 million in a wide range of research that makes a significant contribution to the quality of life in the UK and supports a number of important industrial stakeholders including the agriculture, food, chemical, healthcare and pharmaceutical sectors. www.bbsrc.ac.uk

Engineering and Physical Sciences Research Council (EPSRC)

EPSRC is the main UK government agency for funding research and training in engineering and the physical sciences, investing more than £850 million a year in a broad range of subjects – from mathematics to materials science, and from information technology to structural engineering. <u>www.epsrc.ac.uk</u>

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Sciencewise - ERC

Sciencewise - ERC is a Department for Business, Innovation and Skills funded programme to bring scientists, government and the public together to explore the impact of science and technology in our lives. It helps policy makers in Government departments and agencies commission and use public dialogue to inform decision-making in emerging areas of science and technology. Its core aim is to develop the capacity of Government to carry out good dialogue, to gather and disseminate good practice, have successful two-way communications with the public and other stakeholders, and to embed the principles of good dialogue into internal Government processes.

About TNS-BMRB

TNS-BMRB is one of the leading research agencies in the UK and a key operating company within TNS UK Ltd.

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Abbreviations

BBSRC	Biotechnology and Biological Sciences Research Council
EPSRC	Engineering and Physical Sciences Research Council
DNA	Deoxyribonucleic acid
FSA	Food Standards Agency
GMOs	Genetically Modified Organisms
GM	Genetic Modification
HSE	Health and Safety Executive
ICT	Information and communication technologies
NGO	Non-Governmental Organisation
SME	Small and medium enterprises

Glossary of Terms

- **Artemisinin**: An anti-malarial agent originally sourced from the dry leaves of the Chinese herb Artemisia annua (ginghaosu or sweet wormwood).
- **Biofuels**: Fuel such as ethanol produced from renewable biological resources such as plant biomass and treated municipal and industrial waste.
- **Bioremediation**: The use of biological agents, such as bacteria or plants, to remove or neutralize contaminants, as in polluted soil or water.
- **Garage biology or DIY biology**: stands for 'Do it yourself' biology and refers to biology becoming and accessible pursuit for citizen scientists and amateur biologists who may conduct experiments outside of laboratories and in their own homes.
- Genome: An organism's genetic material
- **Genetic engineering**: The deliberate modification of the genetic structure of an organism.
- **Micro-organism**: An organism of microscopic or sub microscopic size, for example a bacterium.
- **Plant cellulose**: A complex carbohydrate which forms the main constituent of the cell wall in most plants. It is largely indigestible to humans.
- **Synthetic biology**: In their recent report,¹ The Royal Academy of Engineering defines synthetic biology as aiming to: *"design and engineer biologically based parts, novel devices and systems as well as redesigning existing, natural biological systems."*
- **Transgenic organisms**: An organism whose genome has been modified by introduction of novel DNA

¹ The Royal Academy of Engineering (2009a). *Synthetic biology: scope, applications and implications*. London: The Royal Academy of Engineering

Executive Summary

- The synthetic biology public dialogue involved members of the public in discussions with specialists on the science, governance, application and control of this emerging area of science and technology.
- One hundred and sixty members of the public were engaged in the process, through three workshops which took place in London, North Wales, Newcastle and Edinburgh. 41 stakeholder interviews were also conducted.
- Findings from the dialogue showed there was conditional support for synthetic biology- 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.

Initial reactions to synthetic biology

- The opportunities and concerns around synthetic biology were both significant. Overall, there was a sense that the science was both exciting and scary.
- There was great uncertainty as to what synthetic biology would do and where it was going. Who was driving development of synthetic biology was a big topic of debate.
- Five central questions emerged for synthetic biology researchers:
 - What is the purpose?
 - Why do you want to do it?
 - What are you going to gain from it?
 - What else is it going to do?
 - How do you know you are right?

Hopes for synthetic biology:

 A key hope was that the science could address some of the big issues facing society today 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 the acceptability of the research.

Concerns for synthetic biology included:

 Concerns included the pace of development in the field and the idea that the science may be progressing too quickly when the long term impacts are unknown. Where synthetic biology was going and what it would look like in the future, together with the uncontrolled release of synthetic organisms into the environment, were also significant concerns.

The role of scientists

- One of the biggest issues was the motivation of scientists undertaking the research. Curiosity-driven research, coupled with a 'publish or perish' mindset, may mean scientists focus on the positive outcomes of synthetic biology, and miss the potential risks, or take short cuts.
- One of the key issues to emerge was the need for scientists to consider the wider implications of their work more effectively. There was a disconnect between individuals' own research which was seen as incremental or routine; and the field overall that was viewed as transformative.

Regulations

- The need for effective international regulation and control was one of the most important issues flagged up by participants. There needed to be greater capacity for regulators to be able to anticipate scientific developments. Given that any synthetic pathway or micro-organism is novel; there was doubt whether current regulatory systems were adequate.
- When reflecting overall on regulations the following observations were made by participants:
 - Mistakes are inevitable
 - You can't control all of the risks
 - There are unknown risks at this stage
 - Release into the environment is an issue
 - \circ Proceed with caution

Intervening in nature

 There was concern that scientists should afford dignity, responsibility and respect when intervening in the natural world. With regard to synthetic biology applications, people were increasingly uneasy along a continuum of use from biological pathways, to micro-organisms, to more complex and ultimately sentient creatures.

 Overall, the idea of creating life was acceptable when balanced with the benefits that synthetic biology can bring. It is of importance was that this is done with humility.

Applying engineering to biological systems

- People found the idea of treating nature as parts to be assembled as problematic – nature was seen as too complex – gene and environmental interactions too dynamic and stochastic to predict in a precise way.
- Engineering also anticipated the idea of being able to specify, replicate and develop on an industrial scale. The implications of this, in terms of magnitude of impacts if there were found to be problems, was a concern.

The role of research councils

- Research councils were seen to have a very significant role in the governance of synthetic biology.
- One of the key issues to emerge was what was meant by funding good science. Currently, this process was generally seen as focusing on technical excellence. Participants also wanted to see a broader definition of good science - in a normative or social sense.

Medical applications

- Initial reactions to medical developments were positive. People were more conformable with the use of synthetic biology as part of a medical production process, such as a drug development pathway, than they were with their direct use *in vivo*.
- There were concerns around the potential for misuse for instance the deliberate creation of new viruses or diseases. There were also concerns that it was not possible to predict the long term impact on synthetic biomedical products.
- In general, the discussion of specific medical applications for serious diseases was characterised by a debate on the risks and benefits of particular treatments, rather than wider implications *per se*. These risks and benefits were seen as individualised – and more a matter for private patient choice than for society more generally.

Energy applications

- Discussion centred on the development of biofuels and in particular the potential for synthetic micro-organisms to be used to help digest plant cellulose. Overall, synthetic biology was viewed as being one approach among many to address energy needs.
- One of the key conditions under which this technology should be progressed was that it should only focus on the more efficient use of agricultural waste, rather than placing greater pressures on arable land needed for food or precipitating greater demand for water.
- However there were concerns that if the market conditions were such, it may favour the planting of certain types of crops, selected more for their ability to produce fuel than for food. This would have all the attendant water resource and sustainability issues associated with the current generation of biofuels.
- As applications for use of synthetic biology in the area of biofuels were generally for contained use – essentially through closed industrial processes the potential health and environmental impacts were perceived as significantly lower than those involving deliberate release.

Environmental applications

- Discussions focused on bioremediation and the potential for synthetic microorganisms to be used to help clean up pollutants.
- While there was hope that this technology could find solutions for the "horrendous damage" already done to the environment, there were significant concerns around creating new forms of pollution by releasing synthetic microorganisms into the environment without knowing the possible long term effects of their release.
- Participants emphasised the need for global standards and regulatory bodies to monitor progress across countries. Regulation would also have to be constantly revised as the science grew and developed.
- Certain participants argued that rather than developing the science, the resources should be used to prevent pollution.

Food and crop applications

 Though the claims were contested, participants were initially encouraged by the potential of synthetic biology to address issues such as food scarcity. However, concerns arose regarding who would benefit from and own the technology.

- Prominent concerns were the ability of large corporations to patent developments and create monopolies. This could potentially maintain dependence of developing countries on the West.
- The potential impact on the surrounding environment potentially through cross-contamination of other plants, or through pesticide resistance – was also a concern.
- Transparency was also important in terms of food labelling so that the public could identify food produced from synthetic biology and make choices regarding consumption. There were concerns that 'synthetic food' may limit the availability of organic or conventional crops.

Six conclusions emerged from the project:

The Uniqueness of Synthetic Biology

- The tension between something that is both synthetic and biological is at the heart of public unease around the technology. Fundamentally, living entities which were synthetic were seen to have less intrinsic value than those considered natural.
- The prospect of being able to treat nature as parts to be assembled was problematic. Nature was seen as too complex, with gene and environmental interactions too dynamic and stochastic to predict in a precise way.
- Engineering also anticipated being able to specify, replicate and produce things on an industrial scale. The implications of this, in terms of magnitude of impact if there were found to be problems, were a concern.
- These three aspects (synthetic versus biological; nature as parts; and engineering biology at industrial scales) require thoughtfulness from the research community and that they take responsibility for considering these aspects.

The Leadership and Funding Roles of the Research Councils

- Participants wanted scope to feed public aspirations and concerns into research funding at an early stage. It should be incumbent on the research councils to make the science accessible and enable this.
- For certain grant applications, 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.

- Overall, scientists need to concern themselves with wider implications and see them as fundamentally embedded in the imaginations and trajectories of research. Judging research on technical merit alone is not sufficient.
- A role of the research councils relating to their leadership in science and a fundamental strategic consideration included having the right people, in the right place and for the right reasons in relation to the development of synthetic biology.

Developing the Capabilities for Scientists to Think Through Responsibilities

- There is a tension between the characterisation of individual scientist's work as incremental and unremarkable, and the transformative potential of the field as a whole.
- Enabling scientists to reflect on motivations was deemed very important.
 What is the purpose? Why are you doing it? What are you going to gain?
 What else will it do? How you know you are right? These are five central questions at the heart of public concerns in this area. It should be incumbent on scientists to consider them.

What Innovation Looks Like Under These Circumstances

- There is a need to develop a different type of conversation that leads to innovation: informing synthetic biology in new ways and involving people (citizens, consumers, other users) not just at the end of the process but throughout.
- Given the tension between organisms that were both synthetic and biological some big questions were raised for the field, such as: "What sort of technology is produced when you are respectful or mindful or nature?" or "What are the consequences of seeing life as nothing more than parts to be assembled?" It was not expected that scientists would have the answer to these or indeed that they are fully answerable.
- There was a need for a new style of leadership of science: with those running organisations such as the research councils to champion new ways of working, that help shape research by enabling it to be informed by social values.

Controlling the Science

• While the idea of regulation proceeding stepwise was valued, the institutional capacity to imagine the future and keep up with advances was questioned.

The idea of voluntary regulation in the absence of specific standards was also a concern. Adaptive governance will be needed.

- One of the biggest issues was the need for international co-ordination or regulation. There may be issues of using existing regulatory frameworks to control synthetic biology, given the current issues playing out between asynchronous approvals for GM foods.
- Regarding regulations there was the need to open up control to the scrutiny of others. Ultimately, control was not just about a technical debate around risk; it concerned the wider implications of the science. Greater thought needs to be given to the institutional arrangements to create the conditions for synthetic biology to be developed in useful and socially acceptable ways. Coupling these issues together –the need to open debate around innovation with the need for controls to be better at anticipating the future - may be helpful in this regard.

Future Dialogue

- Ultimately the progress of synthetic biology is conditional, and the participants were concerned their views would be ignored.
- This dialogue has begun to identify a number of public aspirations and concerns around synthetic biology. But, perhaps more importantly, it has begun to articulate some important questions of those developing the field.
- There is a duty for the research councils to respond directly to this and to reengage with participants in due course, to explain how some the conditions they have placed on the research have been met.

1. Introduction

Synthetic biology is an emerging area of science and technology, using developments in the engineering and biosciences to create new biological parts or to redesign existing ones to carry out new tasks. As one leading researcher noted – it moves us on from reading the genetic code to actually writing it.²

Synthetic biology has made significant strides in recent years. Building on advances in DNA sequencing and DNA synthesis, researchers have powerful tools to study, engineer and assemble genomes. It opens the door to the design of novel biological pathways, parts or devices, together with the potential to build synthetic biological systems.

Specifically, it offers the promise of creating new biological materials for a host of purposes: from food to biofuels, through drugs and diagnostics, to bioremediation and biosensors.

In turn, this broad potential gives rise to a host of concerns, from bio-security to social justice, as well as deeper ethical concerns such as "playing God". The effective governance of this emerging area of science will be particularly challenging and complex given the widespread public concerns over genetic engineering in the UK.

The Biotechnology and Biological Sciences Research Council (BBSRC), together with the Engineering and Physical Sciences Research Council (EPSRC) initiated this project to develop a dialogue with the public regarding their concerns and aspirations for this emerging field.

Overall, these two institutions invest over a billion pounds of public money annually in the engineering, physical and biosciences, with a clear strategic focus on improving the quality of life in the UK. In relation to this research, they have established seven Networks for Synthetic Biology across the UK, and the Centre for Synthetic Biology and Innovation at Imperial College London to assist with the communication and networking between researchers to take research forward and to encourage

2

Venter, C. From Reading to writing the genetic code. Talk to Cornell University. 17 November 2008.

consideration of the ethical and social concerns in the field. Moreover, both research councils have influential "societal issues" panels that have worked to help enable the voice of the public to get heard within their respective institutions.

This study represents a different way of thinking about the governance of synthetic biology. It has created a space through which citizens, scientists and stakeholders engaged in an informed debate on the public value, ethics and potential applications of synthetic biology.

2. Aims and Objectives

The overall aim for this research was set out as follows.

 To allow the diverse perspectives of a range of UK residents to be articulated clearly and in public in order that future policies can better reflect these views, concerns and aspirations.

In addition to this overarching aim, there were a series of specific objectives for the dialogue to meet.

These were to:

- facilitate discussions from diverse perspectives, which are undertaken by people who are inclusive of a range of people in society;
- support a diversity of key stakeholders and people with relevant knowledge (e.g. industrial, regulatory, NGOs, civil society) to oversee the dialogue to ensure its fairness, competence and impact; draw on and seek participation of a diversity of knowledges by working with a wide range of groups, including researchers, research council staff, social scientists and NGOs with an interest in issues related to technology options and/or synthetic biology; ensure that the content and format of the dialogues are open to influence by all of the participants; allow institutional learning about dialogue processes, including the diversity of views, aspirations and attitudes that exist with reference to scientific, ethical and social policy, and economic aspects of new technologies;
- develop a capacity amongst all of the participants for further dialogues in the future and seek views about priority areas/issues which would merit further substantive dialogue, debate and information-gathering; improve on what is seen as good practice and thus provide a foundation on which broader future engagement can build and inform the development of a longer term project of engagement;
- raise awareness and capacity within the research councils, policy makers and the scientific community of aspirations, concerns and views in relation to synthetic biology and the importance of dialogue; ensure that participants in

the dialogue have a meaningful route to potentially influence policy-makers and thus feel their involvement has been worthwhile; devise novel ways of dealing with an area of technological development in which very few specific details are known.

Our approach to meet these objectives is described next.

3. Sample and Method

3.1 Introduction

The study comprised two distinct phases. The first phase of the research included a series of in-depth telephone interviews with stakeholders (stakeholder interviews) to understand some of the technical, social and economic drivers that are shaping synthetic biology in the UK. This was used to inform content for the public dialogue.

The second phase of the research comprised three workshops with members of the public. These were designed to get to the heart of participants' aspirations and concerns around synthetic biology as well as to explore how different views and values come into play when considering potential applications of the research. Both phases are discussed in more depth below. A detailed overview of the method, accompanying topic guides and materials is available at:

www.bbsrc.ac.uk/syntheticbiologydialogue

3.2 Stakeholder Interviews

Stakeholder interviews were conducted prior to the public workshops in order to provide background to the study, understand the views of key stakeholders about the science and ethics of synthetic biology, and feed into the development of the workshops.

Participants were asked about their views on the following.

- The science of synthetic biology.
- Social and ethical considerations surrounding the science.
- Potential application areas.
- Any relevant lessons learned from the genetically modified foods controversy.

A total of 41 interviews were conducted as follows:

Stakeholder Group	Interviews		
	Conducted		
Scientists & Engineers	9		
Social Science/Ethics	7		
Religious/Faith	2		
Government/Regulators	5		
Funders	3		
Industry/Insurance	5		
NGOs	6		
Consumer Groups	4		

Total interviews conducted: 41

3.3 Public Workshops

In total, 160 members of the public were recruited to take part in three workshops each comprising 40 people/ The workshops were convened in London, North Wales, Newcastle and Edinburgh.

Of the total sample, 152 attended the first workshop, 137 attended the second workshop and 129 attend the final workshop. Participants were offered incentives in return for their time. Participants were recruited to reflect a wider cross-section of the public, with two sub-groups taking account of attitudes to the environment and levels of community engagement. The sample frame is shown on the next page.

Area/group	Gender	Socio-economic	Age group	Children in household	Faith
		group		nousenoiu	
London 1	Female	AB	18-34	Mixed	No
London 2	Mixed	C1 C2	35-54	Yes	Yes
London 3	Male	DE	55+	No	Mixed
Newcastle 1	Male	C1 C2	35-54	Mixed	Mixed
Newcastle 2	Female	DE	18-34	Yes	Yes
Newcastle 3	Mixed	AB	55+	No	Mixed
Edinburgh 1	Male	AB	35-54	Mixed	Mixed
Edinburgh 2	Female	DE	55+	Mixed	No
Edinburgh 3	Mixed	C1 C2	18-34	No	Mixed
Wales 1	Mixed	DE	18-34	Yes	Mixed
Wales 2	Female	C1 C2	35-54	Mixed	No
Wales 3	Male	AB	55+	Mixed	Yes

Area/group	Pro-environmental attitudes	Community engagement
London 4	High	Not recruited in this area
Newcastle 4	Not recruited in this area	Low
Edinburgh 4	Low	Not recruited in this area
Wales 4	Not recruited in this area	High

The first session was held in the evening and lasted approximately 2.5 hours. The second and third sessions were daylong events (approximately 5.5 hours) and held on weekends. Introductions and learning sessions were held in plenary, but for discussion sessions, participants were separated into their groups.

Workshop 1 explored views on science and technology in general and introduced the concept of synthetic biology.

Workshop 2 explored stakeholder views on synthetic biology, as well as exploring how this is funded and regulated.

Workshop 3 explored potential applications of synthetic biology, namely:

- environmental, with particular focus on bioremediation; energy, with particular focus on biofuels; food/crops, with focus on crop optimisation;
- medical, with Artemisinin used as a primary example.

Areas for future dialogue were also identified at this time. Findings are highlighted next.

4. Findings from the Public Dialogue

Our findings from the dialogue mirror the workshop structure, and consider how people come to understand the impact of science and technology developments on their daily lives, before exploring views on synthetic biology in terms of its development, governance and applications. We also highlight issues that the public feel are important for future discussion.

4.1 Public Views on Science and Technology

The impacts of science and technology were varied and significant – encompassing all aspects of people's lives. People's health, the food they eat, the environment they live in and relationships to friends and family have all been shaped by science and technology. Participants spontaneously mentioned a whole host of developments, particularly:

- information and communication technologies such as the Internet, mobile phones, social networking media and information management systems;
- new medicines and medical treatments with particular reference to medical biotechnologies such as stem cell research;
- food including genetically modified foods and intensive farming;
- energy including fossil fuels; nuclear power and green technologies such as biofuels;
- weapons technology particularly the capacity for "surgical strikes" in modern warfare.

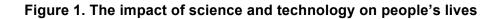
Technologies in particular were not only seen to **transform the material world**, but also seen to **shape social relationships**; to have become more **invasive** (in terms of our reliance on technologies); and be **removed from people's everyday understanding**. Distance from how things worked as well as control over how technology is developing was highlighted in this regard.

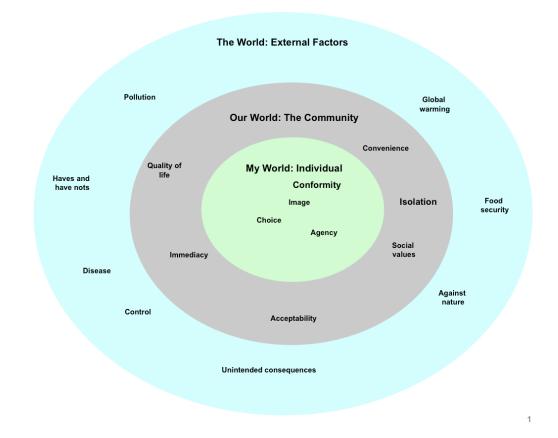
Moreover, the **capabilities of scientists to imagine the possibilities of research** was significant and seen to set them apart - with this imagination viewed as **amazing or extraordinary**:

"a lot of genetic engineering goes on, but.. 10 years ago it would have been considered completely amazing to do something like this... I think it's quite a positive aspect of science that ... people can come up with ideas like this. Certainly 99.9% of the population wouldn't be able to dream up things like this" (Mixed gender group, C1/C2, 35-54,)

A sophisticated picture emerged of **how technologies were intertwined with modern life** – creating new ways to live better, happier and longer; but also embedded in part of a wider system of consumption that had downsides. On the one hand science has provided the means to free ourselves from material and other constraints - increasing food supply, lessening impacts of diseases and promoting wellbeing. On the other, there are unintended consequences: on people's health and the environment; and on wider social values which, together with perceived lack of personal agency and control over technologies, created some unease amongst the public.

This **ambivalence towards science and technology was a central theme** - with people generally highlighting that wherever science enlightens people's lives it also casts a shadow. When exploring this ambivalence, it is helpful to examine how the public described the impact on different social domains: how it shapes people's identity and view of themselves (my world); how it mediates wider social relationships (our world); and how it fashions and transforms our broader environment (the world).





In terms of "my world", common themes included the **coupling of scientific developments and consumer culture**; particularly the capacity of science to modify and improve the image portrayed by individuals. Advances allowed them to enhance their image and to attempt to delay the ageing process via the use of cosmetic products and procedures.

- Male "...for me, how science has... impacted more how it can help people look young. There's constant pressure, I mean every other page there's beautiful women looking young and reversing the signs of ageing. I find it very interesting how there is this dependence on products to help us look younger."
- Male "It's just like... creating a culture isn't it, it's as if we can't get by without all these products. It's making it seem as if you need them and got no choice on it."

(Mixed demographics; low community engagement group)

In this regard, identity was formed in relation to the consumption of technologies which in turn created a need to adopt and conform to trends. This consumption was also discussed in terms of the need to have the latest mobile phone, iPod and other gadgets – and was particularly highlighted amongst younger participants.

Lack of agency to control developments in science and technology was a key issue across all groups. For 'bystanders' - the group generally were less engaged in community life - affects were seen to be more significant, feeling more disenfranchised from developments than other groups who were generally excited about the possibilities that technologies offered to them personally.

In terms of "Our World", the most significant change was the impact of ICT in transforming professional and social life through the use of mobile phones, computers and the Internet. **Ideas of speed and immediacy were all important**. The world seemed faster; blurring social and place-based distinctions that had previously existed such as between work and home; community and neighbourhood and so on. Again ambivalence was highlighted: the same technologies described as liberating, made others "*an absolute slave*", tied to the use of a mobile or forever emailing on a Blackberry.

This sense of immediacy and convenience was also key in thinking through the social impacts of other technologies, such as the food they ate, the cars they drove, the places they went to (real and virtual), the things they bought. There was an uneasy relationship to technological advances: greater choice, progress of sorts; but to a degree unsatisfying or unfulfilling.

Wider impacts of technologies were also discussed. These included direct and indirect consequences of the increasing use of ICT: from the rise of a surveillance society to more subtle changes, such as how access to the Internet has changed social norms. Other developments, particularly in biotechnologies and genetic sciences, were seen to be directly **pushing moral boundaries**.

"[It] depends on the extent of it. I think how far do you push it? Where is the boundary, where are the goalposts, and how far do you keep widening those goalposts? Does it impact on your values, your beliefs or religion?" (Female, AB, 18-34).

When considering the impact science and technology on "The World", big ideas were all important. Science was seen to embody a set of moral or normative commitments – finding cures to diseases; being able to address climate change or food shortages; helping people live better lives for longer; cleaning up our environment and so on – all fundamental to scientific purposes and greatly valued by participants.

However, the very impulse of science and technology to progress was also seen to be a problem in itself. Scientific development at times seemed to be unfettered – with certain participants highlighting that they feel it may be going too far:

"science has gone too far....look what we've done, look at the global warming, look the hole in the ozone layer, look at all of that, that's technology running away with itself without the long term thoughts." (Female, AB, 18-34).

Participants were concerned around the consequences of developments – particularly the unintended **impact on human health and the natural environment: though** a strong counter argument was that **progress should not be halted and there will always be downsides.**

Another major issue was that science and technology could also further the gap between the "haves and have nots" in terms of who is able to access and actually benefit from new technologies. Not only were there issues around access to new ideas, the focus of science itself was often seen to overlook the problems of those most in need.

One final issue relates to the views on nature and naturalness. Science was often viewed as transgressing nature – both in terms of manipulating nature itself (altering distinctions between human and non human; modifying an organism and so on); and the idea of natural balances and the "revenge of nature". The idea of being able to manage nature was also seen as problematic - with unintended consequences emerging from uncertainties in knowledge and limits to scientific understanding.

4.2 Views on Medical and Agri-environmental Sciences

In the first workshop participants were asked to consider their views and experiences of medical and agri-environmental (particularly food) sciences in more depth.

lssue	Medical	Agri-environmental
Aspirations	Impact on major diseases; ability to prolong life	Greater choice and convenience of foods
Concerns	Pill popping culture; ethics of certain avenues of science (e.g. stem cell research); affordability of treatments; people kept in the dark about problems	Messing about with food; distance from the natural world; little choice in developments
Relationship to individual	Greater empowerment of people by access to health information; risks of treatments seen to reside with individual	Production techniques have removed food from everyday practice; domestic science has become food technologies
Regulation	Seen as stringent in the UK	Stringent in relation to food safety; though other regulations open to pressure by food industry
Impact on nature	Distinctions between human and non-human nature; human enhancement	Strong distinction between natural (equated with good and healthy) and artificial (see as bad and unhealthy)
Who is driving developments?	Big Pharma; consumer culture	Biotech firms, food industry and supermarkets; consumer culture

The table below summarises the key themes that emerged.

4.2.1 Medical Sciences

When considering medical sciences, participants were generally **amazed at the scope of advances**, spontaneously citing development in stem-cell research; cancer research, infertility treatments, keyhole surgery and well as general improvements in medical technology to improve diagnostics – brain scans such as MRI; and tests for cancer and so on. There was a **tremendous potential to overcome serious diseases and injuries through the promise of biomedical science** – with people highlighting hope for treatments including spinal injuries, neurodegenerative diseases and leukaemia.

"I've got a friend who was kind of involved in a car accident. His spinal chord was only nicked, it wasn't completely severed. So things like stem cell research would be, he'd be a perfect candidate for that, 'cause it's only repairing a small area and that's where, sort of, the science for me is interesting, 'cause it could, you know, help him walk."(Female, AB, 18-34).

"I think it was Italy, this scientist in Italy is piloting this new treatment which inserts a tiny balloon into people with multiple sclerosis's veins and he's found that some people's veins who have MS are blocked and are far too small and by doing this, by putting this balloon in, it's relieved a lot of people's symptoms who have MS." (Female, AB, 18-34).

One of the most significant changes in healthcare over the past few years concerned the **increase in the amount of information available to patients**. For certain participants, particularly social group AB, this ability to "self-check" had empowered them to take greater control over their health and in doing so had **altered the relationship between doctors and patients**. Empowerment was also highlighted in relation to patient choice, with developments in science providing an array of new treatments – fuelling demand for increasingly effective healthcare. Others, particularly those over 55, were more sceptical about the competency of patients to make good choices in relation to the avalanche of information available.

The health impact of biomedical sciences was valued - with people generally living longer and with a better quality of health. Early screening of cancers was particularly highlighted by females. There was debate whether prolonging life in very old age was counter-productive, particularly when people had a poor quality of life. As one participant noted: *"there is a borderline between prolonging life and saving life"*. A minority of participants also highlighted that increasingly life expectancy caused greater pressures on the world's resources and created issues with regard to sustainability.

All groups noted that **developments in medical sciences precipitated ethical issues**: participants cited a range of things from sperm donation and the rights of the child; whether people should have to opt out of organ donation; the rights of embryos in relation to stem cell research; and the relationship between medical developments and personal responsibilities with significant concerns regarding a "pill popping culture" focused on quick fixes rather than addressing underlying problems. People highlighted a propensity to over prescribe or take a pill for every problem people face – from vitamins to antibiotics. The moral rights and wrongs of specific applications were also noted – with certain **respondents questioning the motivations of scientists** in creating *Dolly the sheep* or in undertaking cloning research more generally – which was described as an unnatural process. In this regard, the potential for medical science to be used ultimately for human enhancement was a concern. A lesser issue for participants was the idea that ethics also fetter science, by getting in the way of progress on issues like stem cell research.

Building on this, the side effects, and in particular the unintended consequences of medical science, were also discussed. These issues were often debated in relation to the wider governance and transparency around science – with people believing that they are **kept in the dark about developments** and only shown the positive sides of science:

"I think that's like the darker side of science that you don't know a lot about. There will be all that research going on somewhere and you don't hear maybe as much about that, and you hear all the positives, all the breakthroughs and things that they have. If you know that there's all that other stuff going on that you're not 100% sure what it is, they don't maybe make as much of it either, because of what people's reactions and thoughts might be. So there'll be lots of things going on in research that maybe isn't highlighted every day, in a lab somewhere." (Mixed gender group, C1/C2, 35-54).

The relationship between medical science and profit was also discussed in some depth. Two key themes emerged: **the affordability of treatments**, with concerns that the best healthcare will only be available to the few (an issue exacerbated when considering access to healthcare in developing nations); and **the role of big business**, in particular pharmaceutical companies, in driving applications in biomedical sciences.

In this regard, it was noted that many applications focus on the "wrong" things by addressing the consequences of smoking, drinking and so on, which are **driven by a consumer culture and principally concerned with the generation of profit**.

The final discussion on medical applications concerned their regulation and safety. Overall, participants were **generally trusting of healthcare regulations** – believing products are effectively tested before being allowed on the market. However, it was also thought that most drugs or **treatments would have side effects**, **a** proportion of which could be both serious and unforeseen, and a range of health controversies were mentioned in this regard, from thalidomide to gene therapy.

However, the **risks** involved from the unintended consequences of medical applications were **generally seen to rest with the patient**, rather than with society more generally and the potential benefits were regarded as significant. A *laissez faire* attitude emerged, where participants believed that patients should be given access to new treatments for serious diseases, provided that they were also given appropriate information. As one participant noted:

"...what are they arguing about? If it saves someone's life... I know if anything was there that could make my child's life better, I would take it. I would grab it." (Female, C1/C2, 35-54).

4.2.2 Agri-environmental Applications

When discussing agri-environmental technologies, participants generally focused on food – in particular intensive farming, changes to food production and the development of GM crops.

When considering these areas, participants were generally struck by the availability of food in recent times. It was argued that while there had been an **increase in choice**, this was **at the expense of quality**. Food, once a domestic or common science, had become industrialised and disconnected from people – both in terms of their understanding of how to cook; and from the seasonal cycles that govern crop growth and availability.

A very dominant theme was that food was "messed about with" or "tampered with" - often for what was perceived to be little consumer benefit. There was a sense that food lacked authenticity – beneath a veneer of something looking attractive, it was believed to be full of "chemicals" or "additives": incorporated into the food to increase shelf life, yield and profits. A host of issues were mentioned in this regard: fortified foods; the use of growth hormones for livestock; use of pesticides and fertilizers for crops; the use of artificial colours and preservatives; mechanically recovered meat; processed foods and so on. People were very concerned about the motivation for this. What drove food scientists and industry to do it?

"Everything has something in it, nothing is what its meant to be, do you know what I mean? Tomato with fish bits in it, why do we need that in our lives, everything has some sort of pesticide, insecticide, special crap; They pick strawberries or whatever they pick and then they spray a hormone on it when it's on its way to the supermarket they ripen but they are not properly ripe, it's all mad, it's mad." (Female, AB, 18-34).

"Do you want to eat these vegetables where they're pumped full of chemicals? We don't know what's in there; we don't know what they're going to do to us." (Mixed gender group, C1/C2, 35-54).

GM crops were discussed within this context.. Participants were broadly split as to the pros and cons of this technology – certain groups highlighting there was no proof that eating GM foods was bad for you; it could mean using less pesticide, and it also offered potential to address global food supply issues. Other's principal concerns related to GM foods being unnatural or "not normal". As much as there was unease about the technology itself, there was anxiety about **people being kept in the dark about what they are eating or having little choice in the food offered to them**.

Views on organic foods were also mixed, with the claims of it being healthier to eat or better for the environment contested; rather it was seen by some as food for the wealthy. Overall when discussing this area, people were conscious that **intensive agriculture had brought great benefits in terms of the price and amount of food produced; but somehow this had gone too far and much had been lost in the process.**

A culture of consumption and the lifestyle aspects of food – such as convenience food freeing up people's time – were seen to be driving this. Whilst liberating for certain groups; a more dominant theme was that such practices wasted food and reinforced the idea that any food should be available at any time.

"If you go to a supermarket here in the UK you encounter the ready prepared meals and then you've got strawberries 52 weeks a year or whatever you know, and I think culturally it's a bad thing that you can get whatever you want when you want it here whereas like in other countries they've got more of an appreciation of nature and what's in season and what's out of season." (Mixed demographic group; low community engagement).

Participants were generally less convinced by the adequacy of regulation for food, relative to the systems controlling medicines and therapies. While they generally thought that food was technically safe (i.e. it would not give you food poisoning if eaten) there was a lack of trust regarding food governance and particularly a sense that people did not feel that they knew what was going on in the food industry or how claims about food could be trusted. Money was seen to be the primary motive of food manufacturers and supermarkets. Awareness of regulators such as the Food Standards Agency was relatively low.

4.2.3 Recurrent Themes

There was a series of recurrent themes that emerged when participants considered medical and food related science and technology developments. These themes were:

- 1. motivation: why are people doing this;
- 2. how has it shaped their relationship to the society or the world;
- 3. who was driving the area:
- 4. who were the winners and losers;
- 5. disconnection from science and technology;
- 6. health and environmental impacts of applications;
- 7. lack of transparency concerning emerging problems.

These seven themes were very important in terms the resources or heuristics that people use when asked to make sense of other scientific developments. How they relate to synthetic biology is explored next.

4.3 Initial Reactions to Synthetic Biology

At the end of the first workshop, participants were given a very brief **introduction to synthetic biology** and asked for their initial reactions. There were a number of common themes.

First and foremost, there was a great deal of **fascination** about the area. The very concept of being able to **apply engineering principles to biology** was viewed as **amazing or unimaginable**.

Second, there were generally big reactions to it and a **sense of extremes**: applications had huge potential; but concerns were very significant. Overall, there was a sense that synthetic biology was both **exciting and scary**.

Third, while there were major concerns around misuse, just as strong was the view that development should not be stopped. Rather **appropriate safeguards** were needed.

Finally, there was great **uncertainty as to what it would do and where it was going**. Who was driving development of synthetic biology was also a big topic of debate.

Between the first and second workshops, participants were asked to go and discuss the topic with their friends and were also given a list of websites to explore synthetic biology in more depth. They were specifically asked to think about the central question, I.e. what they felt were the most important issues for scientists and others with an interest in their area to consider.

The key issues emerging from this process are shown below.



4.3.1 Central Questions for Synthetic Biology

What is notable when considering these questions is that they focus on process;

they are predominantly concerned with the motivations of scientists undertaking research in this area, rather than the health and environmental harms *per se*. This is not to suggest that such impacts were not seen as important – they were – but rather that **immediate concerns focused far more on unease about such matters as who is driving these developments and why; about the inevitability of problems unanticipated by present science; and about the claimed benefits. These themes, also reflected in other research on GM crops,³ are of central importance when considering synthetic biology and also strongly emerge later when participants considered different scientific visions for the field.**

4.4 Hopes and Concerns for Synthetic Biology

After reflecting on their initial views and thoughts about synthetic biology, participants were provided with a presentation from scientists and social scientists outlining the science behind synthetic biology and some of the potential wider implications. Participants were then asked to reconsider their initial hopes and concerns for the field.

The most striking hope for synthetic biology was the potential to address some of the big issues facing society today such as global warming, serious diseases, energy problems, and food security. The ambition and imagination of the scientists working in these fields was viewed as astonishing by the participants, with the prospect of being able to achieve these goals a significant factor in the acceptability of the research.

Medical and health applications in particular were valued by participants. There was hope that synthetic biology could revolutionise drug production, and in the longer term help find treatments for terminal illnesses such as AIDS or cancer. The potential of finding cheap and effective ways of tackling malaria and other transmissible diseases in developing countries was also seen as very positive.

³ Grove-White, R., Macnaghten, P., Mayer, S. and Wynne, B., 1997. Uncertain World. Uncertain World: Genetically modified organisms, food and public attitudes in Britain; Grove White, R. 2001. New wine in old bottles: personal reflections on the new biotechnology commissions. Political Quarterly, Volume 72 Issue 4, Pages 466 – 472;

In other application areas, finding more efficient ways of meeting our energy needs was also cited as a major opportunity. There was also the hope that the science would be used to promote wealth creation and enhance Britain's economic competitiveness. Participants expressed pride in the fact that British researchers would be pioneers in this new area of science and technology.

As well as high aspirations for potential outcomes, there was also a great deal of hope that the processes through which science would be done from now on would be different. It was **hoped that science would be undertaken in an open and transparent way.** There was generally a **desire to know more and be consulted** as participants felt that science had the potential to affect them personally. There was hope that it could be regulated properly and adequate international safeguards could be put in place. There was hope that scientists would treat nature with respect.

There were however, **significant concerns**. The very **scope and ambition of the field** was a major cause of concern for people. This concern in part was due to some of the uncertainties and wider impacts of research. But it was also tied up in the idea of the breadth of applications – and that **anything may be up for grabs in a synthetic world**. This "exciting but scary" view - noted in terms of people's first impressions of synthetic biology - was amplified during these debates.

"I think it is very interesting that they are trying to do things like producing bio fuel from algae and things like that, I think that is really interesting in that respect, it's just the other side that scares the hell out of me, what they can produce and what the hell can be done with it."

(Female, AB, 18-34)

There was concern regarding the **pace of development** in the field and the idea that the science may be progressing too quickly when the **long term impacts are unknown**. There were concerns around where synthetic biology was going and what it would look like in the future – with particular concerns about the **use of synthetic biology in sentient creatures** or that it could be used in some way for human enhancement or to design complex organisms from scratch.

Concerns about **transgressing nature** were also noted. While not the most significant factor, there were concerns that scientists should "stop playing with things" (a phrase used in a number of groups) or that synthetic biology "goes against

nature". This was tied to ideas of unintended consequences and that any tampering with complex natural systems would have repercussions, or that there may be a "revenge of nature" in some way. There were significant concerns around the **uncontrolled release** of synthetic organisms into the environment - and their ability to evolve and change also heightened this sense of unpredictability. The idea that these risks could be engineered out – though the use of terminator genes for instance – were perceived to be problematic in this regard, as random changes or mutations could mean that some synthetic organisms may survive.

Participants also **perceived a distance of scientists from public needs.** They regarded scientists as so focused on the research and technical questions, that they miss the social significance of their work.

Strongly related to this were concerns about motivation and that the field would be directed by **profit-driven applications as opposed to addressing social concerns**. Tied to this were questions of social justice and concerns that only more technically advanced countries would profit. There was a great deal of scepticism regarding whether innovations would trickle down to bring developing countries out of poverty – or that the benefits of global science would reach those who most need it. In this regard, there was more support for government or charity funded research than research solely undertaken in the private sector.

"My concern is the financial aspect, you know, you can trust people but once it starts to be finance driven, who is going to get the profit out of it? That tends to be when it runs riot." (Male, DE, 55+)

On regulation and control specifically, there were concerns that other countries may have less stringent safety measures in place and that **developing global standards would be very difficult**. There were concerns raised about security and access to synthetic biology, particularly over the Internet; with particular reference made to DIY synthetic biology and bioterrorism.

There were also concerns about the dialogue itself - that the views of **the public would not be listened to** and Government would go ahead anyway.

"I don't know. It confuses me that they want to ask us now, why now? Just because it is all new? What are we actually going to do in the end? Yes, we are coming here and talking about it but if we say we don't like it are they going to change it? Stop it? Probably not, they are just going to carry on." (Female, AB, 18-34)

There were related concerns that there was a hidden agenda to synthetic biology or that people would be misled or kept in the dark about worst case scenario eventualities.

There was a general concern that the participants felt that they did not know enough about synthetic biology at this point to make an informed decision about it. They were also concerned that the media would hijack any debate, and that potential benefits may be lost, with parallels highlighted in relation to media coverage of stem cell research.

Hopes	Concerns
Address global problems such as climate change, energy needs, diseases and food shortages	Pace of developments is too rapid when long term impacts are still unknown
Contribute to wealth creation and economic competitiveness	Applications driven by profit rather than public needs
Research would be done in an open and transparent way	Problems would be covered up, with a focus placed on communicating benefits
The public would be consulted and engaged in its development	Any public dialogue would be ignored
Nature would be treated with respect	Nature is transgressed and we create a synthetic world
The science is used within clear limits	Boundary issue are ignored and the technology is used in more complex or sentient organisms

A summary of hopes and attendant concerns is given in the table below.

These concerns – though significant – did not mean that people felt that research should not be continued in this area – far from it. Rather, that the institutional practices governing the sciences would need careful consideration moving forward and that the motivation of researchers; the funding of research; the role of big

business; the ability of regulators to monitor and control developments would all need to be carefully considered to take public concerns into account.

4.4.1 Visions for Synthetic Biology

The participants were asked to review a series of viewpoints or visions for synthetic biology from stakeholders – namely a scientist, social scientists, an NGO representative and an industry representative. These viewpoints were constructs – based on issues that had been highlighted to us in the stakeholder interviews, though not reflecting the view of any single stakeholder. When considering the visions overall, the following key issues emerged.

4.4.2 The Motivations of Scientists

As noted earlier, and clearly articulated by participants during this session, one of the **biggest issues when considering synthetic biology was the motivation of scientists undertaking the research**. This was not related to a belief that scientists were deliberately setting out to cause harm or were driven by profits, but rather that in **the quest for knowledge itself and the need to break new ground in research things often get overlooked**. It was a belief that the motivation of scientists often created professional blind spots when considering the direction of their research.

"Why do they want to do it? What are they trying to do and for what reasons? Is it because they will be the first people to do it? Is it because they just cant wait? What are they going to gain from it? Well you know, the fact that you can take something that's natural and produce fuel, great, but what is the bad side of it, what else is it going to do?"

(Female, AB, 18-34)

Specifically it was the "excitement" and "passion" of scientists for their research that was at issue. The **culture of science** - the strong focus on curiosity-driven, basic research; coupled with a publish or perish mindset and short-term contracts – **may mean scientists focus on the positive outcomes of synthetic biology, and miss the potential risks, or take short cuts**.

"I hear the word 'excitement' a lot, they are excited about things and they are passionate and they are driven which is great, but I think that takes away the kind of 'Am I doing this for the greater good? Is it sensible? Is it reasonable?'. The word 'passion' scares me, because I think people just go ahead and do things, they don't think what can happen."

(Mixed gender group, C1/C2, 35-54)

4.4.3 Who Wins and Who Loses

There was an obvious and clear relationship between the motivation of individual scientists and eventual applications of synthetic biology. Who wins and who loses out in the process was important for participants. There were three broad issues that emerged.

The first was, as noted above, was the need for **scientists** to consider this issue was important. They should **reflect on personal benefits to themselves** and their universities, and how the things that they work on may **ultimately shape and affect society**.

Second, there was a view that as basic research developed and was ready to be applied, researchers needed to be careful about "getting into bed with business". Whilst participants generally did not consider academic scientists as doing research with profit as a main motive, the potential allure of private sector investment and relative inexperience of researchers in brokering effective business deals could mean that ideas and innovations get taken in directions that are much less socially beneficial. There was a view that all actors in the process, from research councils, and in particular universities and the researchers themselves needed to play an active role in ensuring that the work they do is used appropriately and that the need to protect intellectual property (IP) did not suppress the open and collegiate values of academia that were thought to be fundamental to the acceptable development in this area. The pace of innovation, the pressure of needing to grow the bottom line and to be first to market were also seen to be problematic – making people more likely to act before all the issues had been considered.

Finally, and related to the above point, were the broader **social inequalities of applications**. As noted earlier, it was thought that applications in healthcare, for

instance, could produce novel treatments that were not affordable for the NHS to make available generally. There was also a view that private investment would naturally focus on applications that could make money – and as a consequence diseases or environmental issues affecting much of the developing world may be overlooked. There were also concerns about who has access to and ownership of the technology: with concerns about disenfranchising different groups around the world, or that specific applications may affect local producers and render them beholden to large multinational companies to provide the tools for production rather than owning and developing the technology themselves. There was also a view that while commercial profit was absolutely necessary for encouraging innovation; the amount of money made and the **potential for greed to cloud judgement** was very problematic.

"[Industry] are so dismissive, and the whole idea that it is market led. That scares me. There will be times when market .. is not sufficient. ."

"It scares you? What scares you about the market? Doesn't it need the money to invest, to develop it?"

"It is greed led. Yes, it needs to be profitable, but how profitable? Like petrol companies, do they need to make all these multi million pounds?" (Mixed gender group, C1/C2, 35-54)

Ultimately, who wins and loses was perceived to be tied to the interplay of personal ambition, funding strategy, corporate goals, social needs and access.

Finally, related to discussion about the global and distributional impact of the science, a clear view emerged that **the UK should not get left behind in this emerging area of science and technology**. There was pride in the claim that the UK could be at the forefront of synthetic biology – and a strong view that we need to invest to reap the rewards of this knowledge, help create wealth and be less dependent on innovations from other countries and organisations.

4.4.4 Transgressing Nature

Whilst transgressing nature was considered to be a lesser issue, there were concerns about the use of synthetic biology in terms of the implications for our

relationship with nature. Participants generally found these concerns hard to articulate. Certain groups (pro-environment; DE; females ABs in particular) were very uneasy about the ability to create living entities. Though initially discussed in terms of "playing god", the conversations ran deeper that this and participants were concerned that scientists should afford dignity, responsibility, respect and attention when intervening in the natural world. In this regard, the boundaries around using synthetic biology were highlighted, with people becoming increasingly uneasy along a continuum of use from biological pathways, to micro-organisms, to more complex and ultimately sentient creatures. Whilst still a long way off scientifically, this area was noted as "Pandora's box" - creating parts was one thing, but creating whole new organisms was qualitatively different.

One final issue concerned the very **idea of synthetic biology and the dissonance between the two concepts**. "Synthetic" conjured up images of living things being artificial or not natural, which again made people feel slightly uneasy.

There was also concern about the authenticity of nature; particularly if synthetic biology involved creating and shaping the natural world. Artificial as opposed to 'natural nature' was seen to have less value for people – specifically less intrinsic worth. While people realised that the world was man-made and that our landscape, flora and fauna have been shaped by millennia of human activity – this was seen as different from the deliberate manufacture of nature.

This view of nature was not as something just to be broken down, engineered, predicted and controlled; but rather something that needed to be approached with respect. There were issues in treating nature as merely parts to be assembled.

Overall, the idea of creating life was acceptable when balanced with the benefits that synthetic biology. Of importance was that this was done with humility.

4.4.5 Responsibilities of Scientists

One of the key issues to emerge was the **need for scientists to consider the wider implications of their work more effectively**. In particular, the narrow focus of research and the relatively isolated manner in which scientists work limits the framing and the scope of relevant issues. Day-to-day work was seen as mundane – and scientists often described their work as unremarkable. However, scientists were collectively doing something that was extraordinary, and that had scope to affect numerous issues from how we live as a society to what we understand as natural. A duty for scientists to consider this was mentioned on a number of occasions; with other groups believing there was a need to formalise this sense of duty through a code of conduct.

This tension was also highlighted in the stakeholder interviews, with participants noting a disconnect between individuals' own research which was seen as incremental or routine; and the field overall that was viewed as transformative.

There was a view that scientists should consider these wider implications in more depth – **embedding it into the way they conceive of the research in the first instance, and developing a greater focus on the public interest**. While in part this related to a concern that scientists should not be driven by commercial gain or profit; it was much more related to thinking through personal responsibilities in terms of their work: why they are doing it; who wins and loses; what impact it may have and so on.

There was a strong sense that scientists are a closed community – while research was scrutinised by peers, it was hard to access by others. In part, this was because scientific expertise and knowledge of a field set them apart from others. However, it was also believed there was a cultural resistance to opening up science to the views and values of the public. This was particularly problematic as participants felt compelled to trust scientists, but ultimately felt powerless to have any control. As one participant noted:

"How can I stop a whole team of scientists doing something? I feel I can't, I feel powerless." (Female, AB, 18-34)

What participants wanted was support for scientists to enable them to understand the potential impact of their research – not just on human health and the environment, but also in terms of society more generally. There were a number of practical examples given for how this process could be achieved, including greater collaboration with the social sciences; greater openness about early research findings (particularly negative results); and focus on "open source" or mass

innovation, involving a range of people including the public in helping think through the trajectories of research.

It should be noted that social scientists were generally viewed as much more objective when reviewing the benefits and downsides of the research. These issues are very important and explored more depth in the conclusions section when considering funding and the role of the research councils supporting scientists.

4.4.6 Regulation and Control

The need for effective regulation and control was one of the most important issues flagged up by participants.

There were a number of potential risks discussed regarding synthetic biology: including impact on human health; fate and toxicity in the environment; and deliberate misuse – for instance for bioterrorism. Four key areas emerged:

4.4.7 Self Regulation

Regulation was seen to very important for safety, and there was a strong view that scientists should not be allowed to regulate themselves and people should not be allowed to do synthetic biology in their "back gardens". Given the stakes, voluntary standards developed through industry were also not seen as appropriate. A robust and independent regulator was considered to be fundamental in this area.

"There has to be some kind of outside regulatory body. I don't think scientists working in the field should regulate themselves......Because I think you need that sort of removal almost, to be able to see the bigger picture, because it is very easy to get, you know, focussed, sitting in your lab and you get a bit, you don't realise what's going on...outside."

(Female, AB, 18-34)

The transparency of regulators, opening their own work up to scrutiny by external interests such as NGOs and the public was also deemed important.

Those controlling the field need to need to be sure **that the right people work on synthetic biology in the right place and for the right reasons**. There also needs to be accountability for what is developed. It should be noted that the industry stakeholders we spoke to also wanted to develop good and effective standards to promote trust in the field. If something did go wrong, establishing liability in this context was also seen to be needed.

4.4.8 Current and Future Regulations in the UK

In terms of the UK, on the whole and given their experiences of other technologies, participants were reasonably trusting that the safeguards in place were likely to be effective at controlling current research. However, one of the **biggest issues was for regulations to be able to keep apace with scientific developments**. One concern was that, given that any synthetic pathway or micro-organism is by definition novel; whether current regulatory systems were adequate. As one participant noted:

"how would they know how to regulate it considering they don't have a knowledge field of what is actually going on"

(Recruited as a mixed demographic group with low pro-environmental attitudes)

The potential for "garage biology" also indicated the need for a more distinct approach to the regulation of the field.

"I think this biology is a bit more revolutionary to the ones previous because everyone has access to the basic building blocks of the whole thing, I think that kind of separates it from genetically modified organisms.... Do you know what I mean? They do differ so I think some like different laws or whatever should apply to them." (Female, AB, 18-34)

Whilst participants were very conscious that they did not have the necessary expertise to advise on the structure of regulations, overall a close watching brief for this area was vital. It was not understood how regulators proposed to develop the capabilities to anticipate and respond to advances to the science.

Overall, while the need to control was important, **regulation should also not stifle development and progress of synthetic biology** – and there was a significant view that a too conservative or precautionary approach would seriously affect innovation. "With regards to the risks, I think without taking the risks we would not be where we are today. There are so many things we have discovered by just throwing this in a pot and seeing what happens. It could be too regulated and could be missing out on many things'."

(Mixed demographic group; high community engagement,)

4.4.9 The Need for International Controls and Regulation

Perhaps the single biggest concern was in the area of international regulation. Globalised markets and the potential to source materials, equipment and know-how from many countries meant international controls and regulation were vital. Given the complexities involved, together with the time taken for governments to organise themselves effectively in this regard, many participants were sceptical as to whether effective global control could be achieved.

While certain participants argued that this could just result in a race to the bottom – with fewer controls needed as research would only be done elsewhere - a more dominant issue was the need to show leadership and to help shape regulation in this area.

"My concern is who controls the world as they start to study this? We have tight regulations in the UK, but is there an overarching council that sits and governs all the countries that are currently involved and the distribution of it and the regulations? ... I think that's the biggest concern. We have to be involved in it." (Female, AB, 18-34)

Related to this, one of the major concerns was how it would be **possible to regulate the people ordering parts, materials or equipment from the Internet**. Whilst effective regulation was seen as possible when dealing with closed and industrial processes, with checks in place through health and safety; the difficulties in managing people experimenting in their own back yards was near impossible. The potential for uncontrolled release of synthetic materials – with people pouring stuff down drains for instance – was a real concern.

4.4.10 Unknown Unknowns

However, no matter how sophisticated the regulatory structure, participants also felt that there would be unintended consequences and potentially harmful impacts emerging from the field. Synthetic biology applications were generally viewed as too complex to be able to adequately predict or control. The ability of microorganisms to adapt and evolve meant there would be unknown risks associated with the science. Even being able to predict the long term consequences of a synthetically produced crop would be tremendously difficult. Again liability was flagged up in this regard – generally there was a view that companies who developed the product should be only partly responsible if the product went through all regulatory and safety protocols and then later caused an unexpected problem. There also should be a focus on openness when developing the science and a need to encourage whistleblowing if business practices emerge that compromise safety and ethics in the rush to market.

Controls to help mitigate deliberate misuse, in particular bioterrorism, were also discussed. While participants generally noted there were probably easier ways to mount a terrorist attak than using synthetic biology; there was a concern that as the field advanced this could become a real issue. It was also thought that there would undoubtedly be military research undertaken examining the potential of synthetic biology for warfare. Control of access to the tools and materials needed to develop such applications needed to be very strict and again governed internationally.

When reflecting overall on regulations the following observations were made by participants:

1. Mistakes are inevitable

Despite the best intentions, mistakes are inevitable, and regulation will have to be revised on the go as new impacts are realised and discovered.

2. You can't control all of the risks

Regulators and scientists should not claim to be able to know everything or that everything is knowable. The idea of being able to control nature completely was also seen as problematic. Asking sensible *What if?* questions would help develop and manage appropriate regulatory responses.

3. There are unknown risks at this stage

Because the science is still fairly young, the long term risks are not yet known – if they are knowable at all. Uncertainties should be clearly acknowledged and discussed.

4. Release into the environment is an issue

Risks are more pronounced when synthetic materials are released into the environment. Extra care should be taken with these types of applications.

5. Proceed with caution

Overall, this does not mean that we should not move ahead with the science, but rather we should proceed with caution and learn from past mistakes.

4.5 How Science Gets Done: Scientists, Research Councils and Funding

4.5.1 Scientists in the Lab

As well as hearing about the visions for science, participants also examined video diaries of research and academic scientists and explored the structures through which research councils typically fund applications. The aim of these sessions was to open up and make clear to the public how science gets done.

Participants were struck by three things when exploring the video diaries.

First, the **reality of research was not what they were expecting** – there was a belief that scientists would work in much more "high-tech" and "clinical" environments, rather than the more humble reality. A sense of scientists engaging in a "regular job" with everyday professional and domestic ups and downs also came through.

Second, people were **surprised by the short term contract employment** of research scientists and that very few had job security. This was seen as placing a significant amount of pressure on researchers to publish to get funding and hence create a greater likelihood to overlook the impact of the science, or to downplay

negative results. Tied to this, the **amount of bureaucracy facing scientists** – from grant applications to health and safety forms – was seen to be cumbersome.

Third, this **bureaucratisation of risk also appeared to be ineffective** – promoting a tick box mentality that focuses on process rather than outcomes. The perceived disorganisation of some laboratories, together with what at face value seemed to be inadequate means of storing synthetic micro-organisms and other "miscellaneous nasties", led people to think it may be relatively easy to breach safety protocols, through people being careless.

4.5.2 The Research Councils and Funding

Research councils were seen to have a **very significant role in the governance of synthetic biology**. This role may be characterised in two ways. First is internal governance: the structures, cultures and processes of the research councils in funding science. The second external governance: the potential to influence and to play a leadership role in the lives of research scientists.

With regard to the internal role of the councils, one of the key issues to emerge was **what was meant by funding good science?** This process was generally seen as focusing on technical excellence. Participants wanted to know who was qualified make such judgements and whether good science anticipated ultimate applications or comprised just the research, independent of outcome. There were many questions about who was on the council's funding panels and that "self regulation" of research was insular and problematic.

Following this, **participants also wanted to see a broader definition of good science being applied in research council funding in a normative or social sense**. There was a great deal of debate about the relationship of funding to responsibility. On balance, it was thought that the research councils need to place much greater emphasis in this area – both in terms of their own funding processes and in supporting scientists to think through wider implications more effectively.

With regard to the grant application process, it was argued that the consideration of the science and the broader ethical issues by separate committees was unsatisfactory. The structures and processes themselves reinforced this distinction that scientists themselves only had to consider the technical nature of research applications and it was down to others to more deeply consider the ethical and social implications. These wider concerns did not just relate to risks to health or the environment, but to who benefits, reasons for doing the research and social impact.

A means of integrating these processes or having a more iterative review process between the merits of the science for its own sake and its implications for wider society was argued. For instance that projects put forward for potential funding were also more fully considered for ethical or social concerns at this time. This process could also include a public or lay review. These considerations could then be more fully taken into account by a single panel – with the range of necessary competencies to make socially *good* decisions. The checks and balances once grants were awarded also needed to be beefed up when considering the wider implications of the research to be funded. A minority of people also wanted to see an independent organisation monitoring both how research was commissioned and how funds were spent, together with associated impacts.

In terms of the more external role of the council, **a key issue was how to influence and support scientists in thinking through responsibilities**. It was noted that scientists did not naturally focus on the big picture or necessarily had the incentives to do so. The research councils therefore have a key role in helping scientists and engineers to think about the wider implications of their research. This could in part be achieved through training and early stage career support; but just as importantly by helping to shape the culture of science in terms of what is valued. The councils have powerful levers here in creating financial and professional rewards. They can also lead through their own thoughts, deeds and actions in this area. These issues are explored in more depth in the conclusions.

Finally, it should be noted that in terms of funding, the amount of money placed into the field relative to its stated potential was seen to be inconsistent. As one participant noted: *"to spend £33 million out of £2900 million is peanuts"*. If the potential of the science is genuine, then it should be given greater resources.

4.6 Synthetic Biology Applications

During the final workshop, four synthetic biology applications were reviewed in depth. These were:

- medical applications: drugs development and medical devices
- energy applications: particularly biofuels;

- food applications: such as synthetic crops
- environmental applications: particularly bioremediation.

For each, a general description was given to participants on the current state of the research in each area and alternative approaches to address the same goal. The group then explored regulations and the social and ethical context and finally they considered a scenario based on potential future developments.

Each of these will now be explored.

4.6.1 Medical Applications

Initial **reactions to medical developments were positive**, with participants encouraged by the potential of synthetic biology to address major health issues facing society. The initial case study explored the anti-malarial drug Artemisinin – which was viewed as **novel, exciting and impressive**.

"Yes, malaria is a massive problem and it is exciting that there is a new way, and it's the idea that it is a very different method to what has been tried before. There are issues but I kind of think there are issues with everything you know, nothing is ever going to be perfect. I was impressed."

(Female, AB, 18-34)

A less common view was that any intervention in the natural world will have other consequences – for instance the potential of the malaria parasite to quickly develop drug resistance. As such the role of synthetic biology to solve problems was limited, but the stakes were much potentially higher.

Overall, however, whilst people generally felt applications were risky, it was the promise of being able to address big health issues such as malaria which characterised these early debates. Central to this was the idea of new technologies such as synthetic biology being tied to human progress. and that without trying we would still be "living in caves" or would be less advanced as a society. Ideas of technology and modernity were intertwined – and with it the idea that we can intervene in and transform the world to create a better life or overcome

material constraints or disease. The need to try was therefore a necessity. For others, this view was tempered by the knowledge that, whilst seeming tantalisingly close, such goals will forever be out of reach.

The wider social impacts of Artemisinin were also discussed and included who would have access to the drugs or the means to control production; the resources that would need to be in place to support mass treatment programmes; and the impact of increasing life expectancy through drugs without first addressing the social and institutional issues that create poverty in the first instance. As one participant noted: *"the problems in Africa lie a lot deeper than malaria"*. The costs of development were a concern, given that social and economic reform and debt repayment were bigger issues than research into treatments for malaria.

When considering medical applications more generally, **a concern was the potential for misuse** – for instance either the **deliberate creation of new viruses or diseases** for use in warfare; or (and more commonly) the desire to keep redesigning things may result in **things being developed** that are so far removed from their "natural" counterparts that it was **not possible to predict their impact**.

As noted earlier, this latter issue was **a significant concern for regulation** and the potential of risk assessment to be able to understand and quantify risks. The issue of redesigning micro-organisms in particular was problematic – their diversity, resilience and adaptation to a range of very hostile environments meant they may be difficult to control.

"My thoughts were that they were talking about bacteria and... one point was mentioned that ... certain strains of bacteria that don't live outside the controlled environment, my thoughts are that bacteria is a living organism and the nature of life is to survive, to adapt, to evolve, to mutate to survive, and they found bacteria living in environments on this planet that they thought bacteria could not possibly exist in. Very acid conditions, very toxic conditions, very hot conditions, bacteria still lives there. So when they say that nothing will survive outside the controlled environment I'm very sceptical because the very nature of bacteria is they evolve, so I'm a bit dubious." (Male, DE, 55+)

The need for "**proper testing**" was highlighted, though it was difficult for participants to define what this would look like. For certain groups, it was technically defined – for

instance there was a debate on the need to test medical applications on animals. But for the majority it concerned process and the need for openness and transparency regarding the results of the research and its potential impacts.

The need for regulators to have a number of stakeholders overseeing their work (including the public) was highlighted to help promote this sense of openness and impartiality. It should be noted that participants were sceptical that only experts could regulate – with many examples given of unanticipated problems that have emerged from science and technology applications.

"...Joe Public has got to rely on the, well so called experts, and unfortunately the experts might not be as expert as they think they are in their particular field. I don't know, I mean someone says yes this car's safe, that's safe, this electrical appliance is safe, and you take their word for it because you think, right they know what they're talking about, hopefully, we don't, and we go along with it. It's only later on that you then say, oh well I'm sorry that that car's got to be recalled, that appliance has got to be taken off the shelves, whatever it is, because faults have arisen or problems have arisen with that product. But until then we've got to go along with the people who say they know what's happening. That's the problem, and do the experts know what's happening?"

(Male, DE, 55+,)

Boundaries and Tipping Points

A variety of potential medical applications for synthetic biology were discussed, from drug development, to their use in new medical devices such as biosensors. Generally, **people were more conformable with the use of synthetic biology as part of a medical production process, such as a drug development pathway, than they were with their direct use** *in vivo***. Internal use was seen to have greater risks due to the potential unpredictability when interacting with a body, together with the potential fate and toxicity of any device. However, the disease context was all important, together with the effectiveness of existing treatments. Participants were generally willing to try novel therapies for terminal conditions such as cancer and would consider the use of theranostic devices derived through synthetic pathways.**

"I would get fitted to something like that just now if it could detect cancer. If someone says, 'we're going to put this into you and it's going to show cancer, and it's going to fight,' I'd go gladly. That's what [it]'s saying, isn't it? It can detect and kill cancer, and manufacturer a drug to kill it off, gee-ho, is that not a good thing?" (Recruited as a mixed demographic group as having low pro- environmental attitudes)

The use of synthetic biology for enhancement or cosmetic purposes was also discussed and thought of as a less socially valuable application of the technology. For human enhancement in particular – such as the potential use for the boosting memory or IQ – the perceived unpredictability of the technology, the complex way in which the human mind works and the social consequences of such applications were seen to be significant factors that should prohibit use.

Other wider social impacts highlighted by participants concerned the following:

- Who was driving developments in healthcare applications
- The costs of treatments and affordability
- Who has access to the technology in terms of promoting access to developing nations and controlling access to unstable regimes
- The opportunity cost of synthetic biology and the potential to divert resources away from other areas particularly preventative medicine.

It should be noted that a number of earlier concerns regarding medical applications in general, particularly concerning the relationship between personal responsibility and the use of new treatments, were less dominant when considering synthetic biology applications in detail. This may be because most of the applications were discussed in terms of serious diseases – and the potential for treatment overrode these broader concerns.

In general, the discussion of specific medical applications for diseases was characterised by a debate on the risks and benefits of particular treatments, rather than wider implications *per se*. These risks and benefits were seen as individualised – and more a matter for private patient choice than for society more generally. This was more the case for medical application than other areas discussed.

This characterisation of the discussion is also reflected in voting on the medical applications. As the figure below shows, overall medical applications were generally viewed positively, with 1 in 5 seeing it as a risk to the environment, and 4 in 5 people

highlighting it as morally acceptable, useful for society and should be encouraged. Only 1 in 10 thought it was not how we should approach the problem.

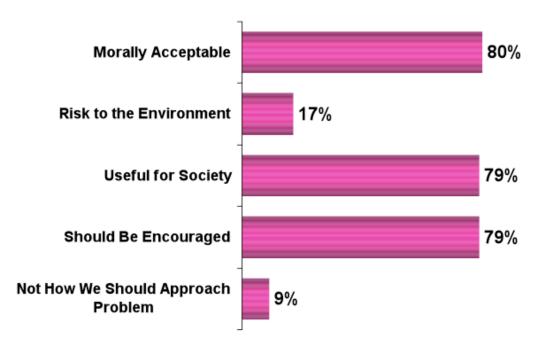


Figure 2. Public views on medical applications for synthetic biology

Sub-group analysis revealed that BME groups were less likely to find medical applications morally acceptable, with moral support from six in ten BME respondents compared to eight in ten white respondents. This pattern of lower support among BME groups was repeated when asked if medical applications should be encouraged.

4.6.2 Energy Applications

The main focus of discussion on energy applications concerned the development of biofuels - and in particular the potential for synthetic micro-organisms to be used to help digest plant cellulose, harnessed from agricultural by-products.

When considering these applications relative to medical uses, there was less amazement or wonder about the science, and a much greater focus on the efficiency of the technology. The language used to describe benefits was hence more business-like or managerial, with words like "efficiency" and "solutions" used. The initial discussions were also framed in terms of societal rather than personal hopes - with the promise of more environmentally sustainable way to help meet growing energy needs. Overall, synthetic biology was viewed as being one approach among many to address these needs.

In this regard, **there was strong view that technical solutions needed to be found**. There was scepticism that behavioural approaches to lower energy consumption would work. Using the car less or turning the heating down was viewed as inconsequential given the demand for energy from growing global populations. It was also considered hard to get people to do old things in new ways:

"We've got to a certain point now people aren't going to think 'ah well I'll just walk four miles to work rather than like driving the car'. You get to a point where people they're so used to doing what they do they're not going to take a step back....We live in a society where we haven't got an hour in the morning to take the time to walk to work because everything is on a time limit so we need fuel, it's just a way of life." (Female, AB, 18-34).

When considering energy needs in more depth, a more nuanced discussion emerged highlighting a range of potential challenges and concerns for synthetic biology applications in this area.

First concerned **land use**. People believed that the potential to turn cellulose into fuel meant that the use of this technology should not place immediate pressures on land by essentially using much of the waste from food crops. However there were concerns that **if the market conditions were such**, **it may favour the planting of certain types of crops**, **selected more for their ability to produce fuel than for food**. If this were the case, it would have all the attendant water resource and sustainability issues associated with the current generation of biofuels. Moreover, a **market in fuels could potentially stimulate greater agricultural cultivation of places like rainforests**.

The second was **affordability**. Concerns were raised that there would need to be significant infrastructure changes as well as conversion of current vehicles to be able to run on biofuels if these approaches were to be successful. Participants were worried that this had the potential to make biofuels expensive, with these production costs passed on to consumers. It was also argued by certain groups that the transition to such fuels may also have a significant carbon footprint – offsetting their impact on global warming.

Third, and tied to the above, was the question of who would be the **potential beneficiaries of this application globally**. While to some extent there was the possibility to democratise production as it would no longer be dependent on those countries with reserves of oil; there were concerns that certain places would get left behind either because they were precluded from investment in the science; or because their climate did not allow agriculture as a significant industry.

Finally, certain groups highlighted that there were likely to be **broader geopolitical consequences** if energy production shifted to being much more land-based – both changing economic power, as well as precipitating new wars or competition for land. The history and politics of energy was such that these consequences were seen as inevitable.

Regulation

As applications for use of synthetic biology in the area of biofuels were generally for contained use – essentially though closed industrial processes - the **potential health and environmental impacts were perceived as significantly lower than for those involving deliberate release**.

Overall, the containment of synthetic organisms, the use of risk assessment and the monitoring by the Health and Safety Executive reassured participants that potential for accidental release was lower – though it was noted that both human error or poor corporate compliance with legislation could still mean that an incident may be caused. In this regard, participants were keen to know details in this area, specifically how often sites would be monitored; whether spot checks would be carried out; how these systems would operate. There was also discussion on how well the HSE would be placed to have the necessary expertise to control risks emerging from the technology. The HSE and other regulators were seen to have a clear prospective role in this regard; proactively anticipating and managing the field rather than responding to an incident. As in previous discussions and in particular because of the likely global interest in this technology, the need for international standards was underscored. A further concern was that the by-products of the industrial process itself could cause contamination. In this regard, there were concerns about the ultimate fate of synthetic micro-organisms used in the industrial pathway.

Other Issues

As noted, the primary benefits of this technology were seen to be helping to provide an efficient low carbon means of providing fuel. In this regard, it should be noted that certain participants had difficulty understanding why growing biofuels should be broadly carbon neutral – it was therefore helpful to have specialists who could help explain how carbon is recycled through the growth and ultimately use of a plant as fuel.

The main **concern was that profit would ultimately drive applications in this area** – and as a consequence, rather than having environmental benefits, habitats would be destroyed in order to meet the growing demand for energy. This issue was seen to be acute in developing nations.

In this regard, one of the key conditions under which this technology should be progressed was that it should only focus on the use of currently wasted agricultural materials, rather than placing greater pressures on arable land needed for food or precipitating greater demand for water. There were greater concerns about the governance and markets for the technology, than there were for the specific technologies themselves.

Again, key themes from this discussion are also reflected in the voting on energy applications. As the figure below shows, overall, energy applications were generally viewed positively – albeit less so than medical applications - with 2 in 5 seeing it as a risk to the environment, 3 in 4 people highlighting it as morally acceptable and useful for society; and 2 in 3 believing it should be encouraged. Around 1in 8 thought it was not how we should approach the problem.

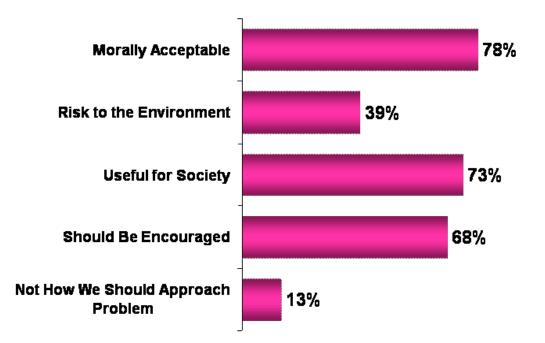


Figure 3. Public views on energy applications for synthetic biology

Sub-group analysis indicated that women were slightly less likely to see energy applications as useful to society. Parents with children living in the household were less likely to support energy applications, either as morally acceptable or useful for society. Both parents and BME groups were more likely to see energy applications as a risk to the environment.

4.6.3 Environmental Applications

The discussion on environmental applications focused on bioremediation and the potential for synthetic micro-organisms to be used to help clean up pollutants. While there was considerable hope that this technology could find solutions for the "horrendous" damage already done to the environment, this was tempered by a concern we could end up creating more pollutants by releasing synthetic organisms into the environment without knowing the possible long term effects of their release.

When considering these applications, relative to medical and energy uses, there was much greater concern and focus on regulation, testing and the potential risks – particularly those associated with this **uncontrolled release of synthetic organisms into the environment.** Such applications were viewed as inherently harder to control by participants.

"If it can be confined it sounds safer. I just think if you can box it, it just feels that much more safe. The minute you release it out there you just have no control, as much control you want to have, you don't, because you're in a natural environment." (Female, AB, 18-34)

In particular, should a synthetic micro-organism **mutate** or have an **adverse effect on an eco-system**, it was believed to be exceedingly difficult to contain and remove the organism. There were also a number of questions raised regarding the **by-products** of bioremediation and the potential creation of **new pollutants**.

"But at the same time we do not know the outcome, the progress of this microbes, whether they stay dead or whether they can have mutation... I don't know." (Male, DE, 55+)

As a consequence, certain participants argued that rather than developing the science, the resources should be used to prevent pollution.

"Well I mean it's like you are going to run out of fuel, you know you've got diseases and things which are there, you can't do a lot about it except cure them but you can prevent pollution. You know you can do a lot to prevent it without having to clean it up afterwards."

(Mixed gender group, C1/C2, 35-54)

Social Impacts

When considering environmental applications in more depth, a number of social impacts were highlighted by participants. These included:

- who would have access to the technology
- creating new technology to deal with pollutants may result in a cycle where the source of the pollutant is never addressed;
- unintended consequences in terms of the potential impact on environments;
- who was driving developments in environmental applications and the potential for corporate monopolies.

Regulation

Overall, the release of synthetic organisms into the environment was viewed as inherently risky. The need to **undertake extensive testing before deliberate**

release was underscored. However, given the complexity of the natural systems this was viewed as particularly difficult to achieve: how could scientists predict the interplay of factors such as chemicals in the soil, varying weather conditions, pH, interactions with other micro-organisms and so on.

"How can you control the variables? You can't control the variables......I mean tell me if I am wrong but if you make something from fuel you are controlling that environment or you are making some sort of gene or germ but it's something that's out there in the land or even oil if you mix it, something else is in there as well as another pollutant the variables are hard to control." (Mixed gender group, C1/C2, 35-54).

Release into the environment also raised concerns about the ability to regulate the science and conduct risk assessment when we may not fully understand how the organism may behave. This emphasised the need for **openness and transparency** regarding the progress and results of research and its impact. Similarly, participants also highlighted the need for thorough testing of organisms before they were released, more so than with contained applications.

Similar to other applications, a recurrent need here was that regulators be made up of a **number of stakeholders from differing backgrounds** (experts and public included) to consider all aspects of the science. As with current GMO regulation, the need for local consultation before any release was viewed as important:

"Because I think if you are going to release something into the soil or something into the air or something into the water near to where you live I think you need to be, every person living in that area needs to be aware of it." (Mixed gender group, C1/C2, 35-54)

Furthermore, given the potential for synthetic organisms to have an impact on environments, the participants emphasised the need for global standards and regulatory bodies to monitor progress across countries. Regulation would also have to be constantly revised as the science developed.

This discussion is also reflected in the voting on environmental applications – with just over half of participants finding the use of synthetic organisms for bioremediation both morally acceptable and risky. Around 6 in 10 though it was useful for society

and should be encouraged, with just over one third believing this is not how we should be addressing pollution.

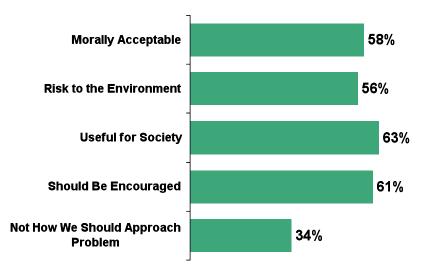


Figure 4. Public views on synthetic biology in bioremediation

Sub-group analysis indicated that men were considerably more supportive than women and were more likely to find bioremediation morally acceptable, useful for society and feel that it should be encouraged. BME respondents were less likely to find the application morally acceptable or useful to society and more likely to be concerned by risk to the environment.

Finally, the use of synthetic biology for cosmetic purposes was also discussed briefly as part of this session. While cosmetic uses were seen as being less socially valuable, they were seen as inevitable spin-off developments from the main research.

Use of synthetic or modified organisms in cosmetic products seemed more familiar to certain groups as commercial products were already advertised as using "enzymes and bacteria". Risks were also seen as being more individualised for products that were developed through closed industrial processes and used by consumers.

"...I think when it comes to like toothpaste, facial stuff I think I'd be more inclined, because its only affecting me, possibly to take the risk on doing that, you know the end product. When you talk about putting it into a field where it's going to affect a lot more people other than yourself it is a different ball game." (Mixed gender group, C1/C2, 35-54) It was noted in other groups, however, that use of these products may impact on the environment when washed down drains and so on.

4.6.4 Food/Crop Applications

Though contested, when considering this application area initially, participants were encouraged by the claimed potential of the science for food production to address major societal needs in the future, such as food scarcity.

When considering food/crop applications, participants related to this application in terms of GM foods and crops. Concerns arose regarding who would benefit from and own the application

Overall, initial discussion of this area focused on the idea of synthetic biology being one approach among many to address the food needs of the future. Similar to energy applications, there was a view that we could **not sustain food needs with traditional farming methods** and many different approaches are needed to keep up with the demand from a growing population. There was also support for developments in synthetic biology to be funded as one of the "faster" solutions to this problem, particularly for the developing world.

"We all need to eat, there's not enough food, there's too many of us, it's an answer to your problem." (Female, AB, 18-34)

One key alternative and concern was that of **food distribution and waste**. Some participants thought that if we could effectively distribute food and minimise current waste, food needs could be met and investments could be diverted to other important applications.

"... I remember years ago about Ethiopia and Sudan actually exported food throughout the famine, 'cause their governments exported food, so to me it isn't... an increase in the products, it should be addressing distribution." (Mixed gender group, C1/C2, 35-54)

Other alternatives also included consideration of **behavioural approaches** to addressing food needs, however this was met with scepticism. Participants believed

it was unlikely that we would convince the population to consume less meat to free up land for crop production, for example.

When considering food and crop applications in more depth, a discussion emerged highlighting a range of **potential challenges** and concerns for synthetic biology applications in this area.

The most prominent concern was that developments here would be **profit driven** and not necessarily address social needs. This was linked to discussions about the ability of large corporations to patent developments and create **commercial monopolies** as well as potentially control who would have access to seeds and fertilizers. This could potentially maintain dependence of developing countries on the West.

"You can grow food that is more nutritional etc etc, higher yields, well that can only be a good thing as long as you don't put all that power in a few people's hands." (Mixed gender group, C1/C2, 35-54)

Scepticism, stemming from the previous GM debate, also led participants to question the **actual impact of public consultation** in food or crop developments.

A further social impacts highlighted by participants was that of **accessibility to organic or conventional produce**. If synthetic biology were to offer modified foods at a lower cost, then natural products could potentially become more expensive, eroding consumer choice. Similarly, the growth of larger agri-businesses as a result of developments in this area could also marginalise local producers.

Similar to considerations of environmental applications, this application also was believed to be more risky because it involves **release of plants or organisms into the environment** as opposed to the contained use seen with energy applications. These could have an **unintended impact** on the surrounding environment – potentially through cross-contamination of other plants, or create an ecological imbalance through pest resistance. It was also noted that it would be hard to examine these factors in a laboratory or to minimise risks through a field trial.

An inability to test for every kind of condition in the environment would make prediction of the long term impacts very difficult. Of particular concern was the efficiency of current food regulatory standards. While the participants noted that current regulation for food "sounded fair" there was still a great deal of mistrust when it came to food in general, particularly when participants referred to the standard of food "already on the shelves".

"Not when you think about the current foods that are on the market. You think of processed food and micro meals that are allowed to be on the shelves but contain absolute horrific stuff in them. Turkey twizzlers, curly fries.

And that's allowed on the market quite freely, they're actually doing a lot of research now, after it's been on the market for a long time, to say that actually it's giving kids problems. And that's been regulated and that's been allowed to go on our shelves."

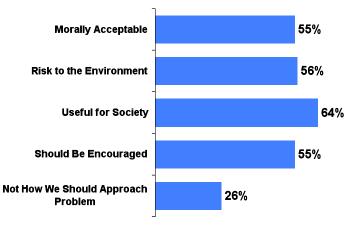
(Female, AB, 18-34)

Promoting trust in current food and crop regulatory systems would require absolute transparency and for a number of stakeholders to be involved (including the public). Transparency was particularly important in terms of clear food labelling so that the public could identify food produce from synthetic biology and make choices regarding consumption.

A final issue for this application related to a view that food biotechnologies had an uneasy history with the public. As one participant noted: "*scientists and crops have got bad written all over it.*"

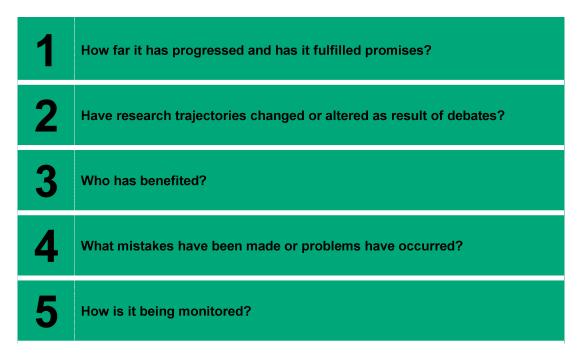
When voting on food technology, just over half of participants thought it was morally acceptable and should be encouraged; with a similar number believing it to be risky for the environment. Two thirds thought it useful for society, with around a quarter believing this is not how we should approach the problem.

Figure 5. Public views on food/crop applications for synthetic biology



There was slightly higher support for food applications among DE respondents compared to the ABs. Men were also more supportive than women, and parents more concerned than non-parents.

The final part of the workshop reflected on the potential areas for future dialogue. Participants described the process as very informative, constructive and enjoyable – however, its ultimate value would be if researchers, the research councils and others involved in the governance of the science took account of the findings in meaningful ways. When considering future topic areas five key themes emerged



These issues are explored in more depth in the conclusions.

5. Stakeholder Findings

There was significant variation in how stakeholders framed the discussion and gave different weight to consideration of political, environmental, social, technical, legal and environmental issues. It should be highlighted that a firm consensus on any given issue was rare, even within a particular stakeholder group. As such, the interviews revealed the diversity of possible futures for synthetic biology.

5.1 Defining Synthetic Biology

While all could agree that synthetic biology involves the application of engineering principles to biological systems, there was some debate as to what was novel about synthetic biology in comparison to genetic engineering or molecular biology. This distinction was particularly unclear for non-scientist stakeholders.

Stakeholders, particularly scientists, were cautious about "over-defining" the field. It was felt that meaning should come from practitioners and their work, rather than aiming for a firm theoretical or conceptual definition which might prove restrictive.

"It is a very, very young field, and I think we could strangle it if we over define it, that's one thing. The second thing is that if you look at any well-developed field, it's useless trying to define it. I don't think you can define nanotechnology, it's so broad, other than looking at things less than 100 nanometres." (Scientist/Engineer)

It was seen as a sign of a healthy young field that research was taking many different directions. A social scientist described current synthetic biology research as roughly dividing into three approaches as follows.

- 1. Work on synthetic or minimal genomes.
- 2. Work towards bio-bricks and standardisation.
- 3. Work on protocells and the origins of life.

This diversity of approaches was also noted by the stakeholders from the Government and Regulation group:

"I think it is a very general term to encompass an aspiration really, [rather] than a specific technology. I think if you drill down into it there's probably four or five or six different technological approaches that don't necessarily even have much relationship to each other."

(Government/Regulators)

There was a perception among scientists and social scientists that in some cases academic researchers were "rebranding" their research as synthetic biology in an effort to attract funding. At the same time others, particularly in industry, are avoiding using the label "synthetic biology" where it could be applied to their work, largely due to a perception that the word "synthetic" has negative connotations for the lay public.

"I think 'synthetic' to me, to the consumer, is already...you know, looks artificial, looks worrisome...we use 'industrial biotechnology." (Industry)

5.2 Drivers of Synthetic Biology

At present, synthetic biology is largely felt to be located within academia and driven primarily by intellectual curiosity, seeking to learn more about biological systems and how they might be manipulated and controlled through an engineering approach. This view was particularly strong amongst scientists and engineers working in academic rather than industrial or business settings. Two distinct narratives emerged from these practitioners when discussing the novelty of the field.

The first narrative tended to describe their own work on synthetic biology as part of an ongoing series of incremental advances in our collective knowledge of biological systems. Scientists and engineers tended to introduce themselves and their work with reference to the field in which they had originally trained; for instance, as a "chemist interested in biological problems", as a bio or research engineer, or with a "background" in molecular, systems, or microbiology. Current research interests in synthetic biology were usually discussed as a natural progression from these backgrounds rather than as a change in direction. As such their own work on synthetic biology, having a familiarity and discernible intellectual lineage, was often discussed as routine and unremarkable.

This contrasted sharply with discussion of the field as a whole, where practitioners often switched to a less personalised framing. This second narrative was far more

likely to describe the field as a novel approach to thinking about biological systems. Future development of applications and their associated benefits and risks were discussed in terms of national or global impact. Issues such as intellectual property, ethical boundaries, appropriate regulation, or maximising public benefit, were discussed as communal challenges rather than related directly to practitioners' own work. Finally, in relation to drivers from the point of view of scientists, at a national level it was noted that synthetic biology had "caught the imagination" of both the research councils and Government in the UK.

Non-scientists on the other hand, often argued that the main driver for the technology was external; a global "scarcity trend" and the need to address ever increasing demand for resources such as food, water and energy in the face of global warming and increasing population. The key factors deemed to have made synthetic biology possible were advances in computing power, faster and cheaper DNA synthesis technology, and a strong multidisciplinary culture bringing together researchers from different disciplines and with different mindsets.

There was some debate about the importance of moves towards the standardisation of biological parts. While some felt this was simply one possible approach among many, others insisted that a bio-brick approach was essential to maintain the momentum of the field:

"[If you were to approach any] molecular biologist on the planet and ask them to build something, and if you gave precise enough instructions, they'd do it. But they'd all do it in different directions, in different ways. As a field, biology is in the same position as chemical engineering was in about 1800 – you had the basic technology, but not the standards that allow the transfer of that technology into easy construction [...] that's where we are going." (Scientist/Engineer)

Scientists emphasised that the field is currently moving forward without significant industry involvement. However, there was a tendency to assume a commercialised future and the profit motive was acknowledged as an important motivator and driver of research. There was also a perception that while much work in the UK is publicly funded, industry is more involved in synthetic biology development in Europe and the US. This was met with a sense that development of the technology in the UK would inevitably and necessarily involve private funding and commercialisation going

forward. This also relates to issues of intellectual property and appropriate business models for an industry likely to be based on standardised parts, discussed in subsection seven of this chapter. Here stakeholders, including industry, often pointed to the benefits of an open source model for development as a spur to innovation and better products for their users. While collaboration is well ingrained in academic culture, it is also increasingly being seen as good practice in industry.

Social scientists, NGOs and consumer groups pointed to increasing interest in synthetic biology from large corporations, particularly around potential energy and environmental applications. This was met both with acceptance that private funding has a significant role to play in developing the technology, and matching concerns at the thought of any emerging monopolies stifling the research of others, or restricting access to applications and benefits.

It should be noted that not all stakeholders were comfortable with discussing potential future developments of the field at such an early stage, as one social scientist put it:

"I'm kind of wary of a lot of future speculations, I'm concerned about that. The scientists and bio-ethicists kind of get themselves into spirals where they are both trying to predict and extrapolate about dystopian or utopian futures, neither of which is particularly grounded."

(Social Scientist)

5.3 Perceived UK Performance

Stakeholders were asked for their views on the relative strengths and weaknesses of synthetic biology development in the UK in relation to the rest of the world. Responses had the caveat that they were largely based on anecdotal evidence and discussions with colleagues. It was also felt that the vague definition of the field further complicated such questions as not all researchers report their work as synthetic biology.

Caveats aside, it was considered that the UK was currently well placed in relation to Europe but struggles to compete with the US in terms of private sector investment. It was noted that the publication rate for the UK is second only to the US and there was some debate as to the real differences in rates of technological advance on either side of the Atlantic.

Respondents also pointed to the different funding cultures of the US and UK; it was generally felt that the UK has a broader funding base and a more collaborative approach akin to the European model. On the other hand, the US was felt to have a narrower approach, with the bulk of funding being allocated to established researchers dubbed "the usual suspects" by one scientist.

Looking to the future it was seen as important that the UK encourages the development of SMEs and builds up an industrial biotechnology base to maximise benefits as the field begins to commercialise applications.

5.4 Social and Ethical Issues

Discussion of ethical and social issues was based on broad and open questions that sought to allow stakeholders to frame responses from their own perspectives. Responses tended to focus on societal impacts and weighing risks and benefits, rather than more abstract debates around creating life. Scientists and engineers often felt that this idea of creating nature was an unhelpful way of viewing their work, which would need public support if it was to deliver its significant potential benefits and address global challenges. This seemed to create a general resistance or unease at framing synthetic biology in anything but technical terms based around the weighing up of risk and benefit.

"In a research lab the view of life tends to be mechanistic, rather than emotional or ideological."

(Scientist/Engineer)

"I don't see any ethical issues; it's essentially clear cut. But I think the problem often scientists have is that lines which perhaps the general public would like to see are completely arbitrary. [...] I think the motivation, the end point, is often conditions of public opinion."

(Scientist/Engineer)

"I think the big social issue is that in people's minds you're manipulating life. To bring the argument down to 'is this really life, or is this organism that'...you know, I think you've lost the battle at that point." (Industry) Stakeholders from religious groups pointed out that there are theological arguments both for and against genetic engineering; furthermore it was noted that not all principled opposition to transgenic organisms is based on faith. It was felt that the bounds of public acceptability also relate to a more general unease around science running away with itself. The public workshops revealed a definite sense of apprehension at the lack of clear boundaries of acceptability around the potential applications of synthetic biology.

Scientists also tended to distinguish between current work on micro-organisms and simple systems, and an ethically problematic potential to create more complex forms of life in the long term. It was felt that scientists should involve bio-ethicists in their work but that we must be careful in the extent to which we "humanise a cell". Certain scientists did not see a distinction between creating life through everyday reproduction of micro-organisms in a laboratory and being able to manufacture life itself.

"I would need to understand why somebody thought this is a problem. We have always been creating life; we do it all the time. Getting bacteria to multiply in the lab, that is creating life.."

(Scientist/Engineer)

Social scientists called for careful consideration of the impact of any applications on a case-by-case basis. Bio-safety was seen as a key issue with many stakeholders pointing out that it was insufficient for scientists to be convinced of the safety of an application; public support and acceptance was seen as vital.

A scientist, together with NGOs and social scientists, noted that it was important to direct "an inherently cheap technology" to equalise rather than reinforce differences between the developed and developing worlds. All three groups warned of the need to consider the impact of the technology on the developing world and ensure broad access to its benefits. Traditional producers of drugs like Artemisinin were given as an example of those for whom synthetic biology would have a negative impact.

"Any systems that are amenable to the use of modified biological resources are gonna get a huge kick in the pants." (Social Scientist) Concerns around access also linked to unease amongst consumer groups at the potential of applications to place a burden on their end users, for example, would farmers need to invest in expensive and technical equipment and training? Would they need to replace seeds every year?

5.5 Regulation and Control

Across the stakeholder cohort there was a lack of consensus as to the adequacy of current regulatory systems in dealing with developments in synthetic biology. Regulators felt that existing GMO regulations were sufficient for the current situation, but will need to be updated as work progresses towards specific applications. This was described in practical terms as "horizon scanning", maintaining a watch on developments and beginning discussion, but with little detail of how or when a need for fresh regulations might be identified, or how they would be drafted and which stakeholders would be engaged.

Regulators acknowledged that the current approach to GMOs has been heavily based on risk assessment; synthetic biology was seen as a difficult case in that novel organisms would present complete unknowns in terms of assessing the risks they posed.

"How do you make a proportional and rational response to a completely unknown risk?"

(Regulator)

"Risk assessment is only as good as its component parts, those are essentially hazard identification, hazard characterisation, exposure assessment, and then you can do a risk assessment. So a risk assessment will only hold good for those hazards that have A, been identified and B, thoroughly tested.[...] We know that many relationships in eco-systems are incredibly non-linear and come to singularities which are irreversible [...] so there is an argument for going rather carefully with it." (Scientist/Engineer)

The problems posed by risk assessment of novel organisms led some stakeholders to call for a bespoke set of regulations covering synthetic biology. Regulators were divided on this point but emphasised the need for robust regulation while allowing for legitimate innovation and progress. It was also noted that at present regulators are beginning to pay greater attention to the field and that this scrutiny will only increase as the technology develops and specific applications become available.

While some scientists expressed a preference for bottom-up regulations led by the experience and needs of practitioners, respondents in the public workshops subsequently rejected this idea as insufficient. It was important from a public perspective to have more independent regulatory oversight to build trust and ensure that scientists were not too narrowly focussed on technical questions without considering the wider implications of their work.

Consumer groups suggested the possibility of any applications or consumer products being tested through statutory independent labs to test marketing claims and overall safety before the technologies go to market. NGOs further emphasised the importance of integrating social, economic and cultural factors into any risk assessment.

Few stakeholders suggested any specific alterations to current regulatory practice; this was often accompanied by the view that they did not personally have the expertise necessary to do so. However, there was a general view that science and technology have a tendency to develop faster than regulators can keep up. Reactions to this perceived gap between development and regulation were varied; while it was argued that this was grounds for caution and greater oversight, it was seen elsewhere as somewhat inevitable and certainly not restricted solely to biotechnology.

"I think, like a lot of other fields, the regulatory systems all lag a bit behind...you've got to make sure that the regulatory framework doesn't stifle, you know, legitimate innovation."

(Scientist/Engineer)

A social scientist suggested a multi-level governance approach that would emphasise professional education and training, regular reviews, creation of scientific norms, and tough regulation of both deliberate environmental release and contained use. The issue of exactly where responsibility should lie for enforcing regulations was also raised; consumer groups and NGOs expressed some unease around the current patchwork of regulatory bodies and a perceived lack of harmony between regulators in the US and Europe. The issue of "garage biology" was seen as a specific case in point; and while generally felt to be over-hyped at present, any future growth of "domestic" synthetic biology will raise issues around bio-safety protocols and the need for oversight to prevent accidents or even bio-terrorism. This was also regarded as a potentially exciting area in terms of innovation and expanding participation in science; one respondent evoked the success of companies such as Google, which was hugely innovative and founded out of a domestic garage. As such, regulation of garage biology was seen as needing to strike a balance between promoting the technology to the public and ensuring public safety.

5.6 Intellectual Property Issues & Open Source

Discussion of intellectual property in relation to synthetic biology often touched on a wider debate on the patenting of genes and DNA sequences. It was argued by one scientist that *"the notion of sequencing genomes and patenting genes doesn't stand the usual tests of patentability."* Overall however, concerns in this area related more to the control of, and access to, data and technology derived from synthetic biology, rather than wider arguments on the ethics of patenting life.

Much of the debate around IP hinged on the assumption of a future based around standardised biological parts. This was felt to raise an important dilemma around protecting access to research while simultaneously preserving the profit motive and attracting investment.

"[What we need is] some kind of solution which would allow investments to be protected, so if you want an industry to be based on interchangeable parts and construction of biological systems, you need to allow people to make money so they can invest in the technology, but at the same time, you don't want to limit the access of others to those same parts."

(Scientist/Engineer)

An open source approach was considered useful in encouraging collaborative development and sharing. Industry stakeholders weighed the potential advantages of open source as a spur to innovation, with the need to protect their commercial interests:

"If you make it completely open source, where does the funding come from and where does the motive for innovation? Where does the dynamism that's going to be necessary to drive the development of synthetic biology forward arise from?" (Industry)

A common suggestion to resolve this potential impasse was to protect the standardised parts themselves as open source, while allowing patenting of specific products constructed from those parts. A social scientist added that such an approach would allow a space for return on investment but cautioned that the debate on IP was extremely complex and not easily resolved.

A stakeholder from the consumer groups had a personal interest in IP issues and felt that common misconceptions around open source often arose in discussion of synthetic biology. The stakeholder explained that open source does not place the property in the public domain; rather it is protected by copyright and then licensed through standardised licensing options allowing others to work with it.

Scientists working in academia sometimes felt that the open source debate was something of a moot point in their own circumstances; as academics must publish their work to advance and access to materials is usually a condition of publication. That said, open source approaches were widely acknowledged as useful for encouraging collaborative working. Collaboration and sharing of results were seen as a major driver of creativity and innovation, useful both in preventing repetition of work and wasted effort and in promoting faster problem solving. Techniques based around communities of interest, such as crowd sourcing, are able to continually take into account the needs of end users during development to create better products.

5.7 Funding

Funding for work on synthetic biology in the UK was seen as coming predominantly from the public sector at present, particularly from the research councils. Stakeholders across the cohort felt that as research progresses a greater level of private sector funding will be attracted; this was already seen to be the case in the US and to a lesser extent in mainland Europe. The issue of opportunity cost was also raised, with finite resources for investment in public science; investment choices must attempt to weigh whole areas of research and their potential utility against each other.

While generally agreeing that science must be accountable to funders and the wider public, scientists were sometimes uncomfortable with the thought of allowing the public to have significant influence over funding priorities. It was also notable that accountability was not unpacked significantly as an issue but referred to in general terms rather than laying out specific roles for different actors.

"I think what you can't have though, if the government's job, the research council's job is to steer the science, I don't think there can be, you can't afford to go just down the route of having public dialogue about what areas of research we should and shouldn't be working on. Because I think most people don't have enough foresight to see what the big issues are and that's the sort of thing we pay the government to do to tell you the truth."

(Scientist/Engineer)

Government and regulators felt that it was natural to expect a mix of funding sources and that private sector companies should be free to use their resources as they feel is appropriate to meet their commercial objectives. However, this did open up a broader discussion on the maximisation of public benefit. It was felt that public support for the technology could be negatively impacted if profits and benefits were seen to accrue predominantly to big business interests. This also linked to the debate on intellectual property and access to research data; creation of monopolies was potentially a serious concern, particularly for NGOs and consumer groups.

NGOs perceived public/private partnerships in the US as often dominated by private interests when making investment choices; and that this balance should be carefully considered when establishing new partnerships. Consumer groups added that taxpayers are funding much basic research and should therefore have an influence on how this funding is directed, potentially placing broad consideration of public benefit ahead of narrower conceptions of economic impact. Funding stakeholders suggested maintaining a balance by encouraging private investment but also publicly funded work in collaboration with other countries:

"Listening to this discussion [...], they can seem rather national in terms of focus; when it's possible, one would imagine, given the changing geography of science and the way in which some nations have such larger resources, it's clearly going to be important to have connections between countries in this sort of area. I just don't know how individual countries like the UK are going to be able to compete against some of the really big investors in this area if they can't [form] properly international research collaborations which really deliver." (Funders)

Social scientists considered that synthetic biology may not yet be a tempting investment for industry; this linked to a perception that there has been much hype and over-promising around applications at such an early stage. It was felt that other research areas showing progress, such as stem cells and nanotechnology, were more likely to attract significant private funding for the time being.

5.8 Potential Applications

Before turning to the potential applications of synthetic biology it is important to highlight a significant trend across all stakeholder groups. When discussing the issues that will shape future development of the science, such as regulation, funding, intellectual property, and the risks, social and ethical concerns discussed above; it was rare for stakeholders to frame their answers in relation to themselves as actors, with the potential to influence these developments. This was linked to a sense that they were discussing the possible futures of the technology and highlighting issues that would need to be dealt with downstream, framing the issues as communal problems facing society, rather than linking specific actors to any strong set of interests or aspirations. Stakeholders varied in their levels of enthusiasm and appetite for discussion of potential applications. It was felt, particularly amongst social scientists, that there has been much hype and over-promising related to the field and its potential. To some it was seen as potentially counterproductive to discuss applications and their associated risks and benefits at such an early stage.

Regulators, consumer groups, faith groups and NGOs were maintaining a watching brief on applications so as to be ready with an appropriate response, preferring to consider each on a case-by-case basis. Consumer groups felt that it was important to be involved in the debate on synthetic biology as early as possible to ensure their credibility, rather than waiting for consumer products to be available.

Scientists and engineers tended to discuss applications and their benefits in broad terms, as helping to solve global problems and therefore of benefit to all mankind. However, while certainly enthusiastic about this potential it was usually underlined as

just that, potential but with much basic research and understanding still required. Industry stakeholders were generally more bullish and happy to discuss the potential of their work to address major global issues such as climate change.

An engineer explained that attitudes towards applications were partly dictated by different mindsets and research cultures, therefore as an engineer he was trained to think in terms of solving problems to produce a given result:

"I am an engineer as I said, so my take on some of these things is, not in everything but certainly in this area, much more pragmatic. In the sense that I can see some useful end points, that you could use synthetic biology, that you could get along the road to achieving. We have gone at it that way and said to ourselves what is the end point? Biofuels are an example; you pick a particular biofuel whether it is ethanol, butanol, and hydrogen, what are the best routes to get to that endpoint?" (Engineer)

5.8.1 Energy

Stakeholders felt that energy was seen as a key application area by researchers in both the public and private sectors. In the face of increasing environmental concern and depleting fossil fuel reserves, production of a biofuel alternative was seen as an environmental, economic and social imperative. While not seen as a panacea, synthetic biology was viewed as potentially providing an urgent stop-gap, buying more time to find superior alternatives.

There was a widespread perception of there being a higher level of private sector investment targeted at energy applications than at other areas. This was sometimes accompanied by desire for these transnational businesses to demonstrate a greater "social conscience" and consider public good as well as private gain. One scientist added that this was "*the most automatic of potential markets*" for the technology as there are official subsidies available to aid development.

Work towards clean energy solutions was seen as pursuing a number of different routes towards similar objectives, examples included work on artificial photosynthesis and fixing CO₂, as well as looking to derive biofuels from crop waste or algae. A key barrier in this area was felt to be the challenge of scaling up the technology to supply fuel on an industrial scale. There was also a sense that there is a limited window of opportunity in which to realise benefits and protect the environment before it is too

late to make a significant impact. There was also significant concern at the potential for biomass crops to compete with land needed to feed an expanding global population.

5.8.2 Agri-environmental

This was expected to be the most controversial of the application areas from a public perspective. While there was a sense of frustration among some stakeholders that public concerns were holding back work on GM crops; it was acknowledged that uncertainties still remain regarding the impact of GMOs on biodiversity and the likelihood of gene transfer.

Applications involving deliberate environmental release were certainly more controversial than contained industrial processes. One scientist also expressed concern at the potential for an indirect environmental impact of the technology. It was felt that by creating organisms designed to resist the effects of a "corruptive damaged environment" this could lead to ignoring the underlying causes of the environmental damage. This was seen as another important issue to consider when regulating environmental release of synthetic organisms.

There was some overlap with discussion of energy applications, particularly the "food v. fuel" debate over land use. However, applications in this area were seen as almost inevitable in the face of both climate change and increasing global demand for food. In light of this pressure some were concerned at a perceived lack of an agrienvironmental industrial base in the UK.

5.8.3 Medical

Medical applications were thought to rival energy in terms of the level of commercial interest they attract, this was linked to perceived higher profit margins and return on investment in comparison with other sectors.

Potential uses included remedial therapies and treating hereditary disease, improved drug and vaccine development, and theranostics. Scientists also identified a potential interface between synthetic biology and nanotechnology in healthcare.

In terms of bio-safety, concerns centred on in-body applications rather than external tools – for instance for drug development. This was also predicted to be the reaction of the general public. Social scientists underlined that any in-body applications of

synthetic organisms would raise a host of legal and ethical concerns before any testing could begin. Consumer groups mentioned the caution and rigour of clinical testing as a model for other industries in seeking to minimise any risks associated with synthetic biology.

Drug development was seen as an area where progress has slowed in recent years and remaining challenges facing researchers are particularly difficult, as such synthetic biology could be a "major boon" in speeding up delivery of new drugs and vaccines

"In ten years we will be making synthetic proteins, which will have the potential to be as important as the development of small molecules in creating what we now call drugs."

(Scientist/Engineer)

5.9 The Value of Public Engagement

Overall, stakeholders were positive about the value of public engagement on emergent science and technology issues. However, not all engagement activity was seen as equal and it was emphasised that good engagement processes are clear in terms of the questions they ask and their motives for asking them, ideally laying out how the process will feed into later developments.

Scientists acknowledged a responsibility to explain and communicate their work, but while engagement activity was seen as a useful means of building public trust and consent, emphasis was not always placed on the importance of deliberation and listening to the aspirations and concerns of the lay public. Mixed responses indicated that while engagement was becoming more embedded in their work, the deficit model still holds some sway. This related to an anxiety around the level of influence that engagement should have on researchers, summed up as follows:

"The root of it is respect for other people's views; we need to find the balance between respect, and holding on to being scientific." (Scientist/Engineer)

A social scientist warned that 'upstream public engagement' could potentially risk building up unrealistic expectations or cause unfounded concerns in the absence of tangible applications to discuss. A regulator took the view that early engagement was a useful way to discuss issues before the emergence of significant media interest and hype. Funders felt that the field would be far more established and tangible in a decade or so and that this would make public engagement simpler.

6. Conclusions

As can be seen from the findings, overall public participants were capable of engaging with the complex issues around synthetic biology and reflecting on the views of experts in ways that helped to open up the debate. In this regard, the dialogue should not be viewed as trying to provide all the answers regarding public aspirations and concerns around the science but rather providing some ideas for future discussion - in academic institutions, at the research councils, by regulators, with the public - on how to begin to think about governance and control the area in the future.

Overall, it is important not to reduce the findings to a view that the public were either for or against the technology; indeed there was a fundamental tension between the aspirations and concerns for the science, which were seen as interrelated. While certainly there was no call for a moratorium on the area, **progress in the field was conditional** and subject to a different way of thinking about the science and technology.

In this regard, when considering the overall conclusions from the project six themes or key questions emerged. These are as follows.

- What is unique about synthetic biology?
- What are the leadership and funding roles of the research councils?
- How do we develop the capabilities for scientists to think through responsibilities?
- What does innovation look like under these circumstances?
- How do we control the science?
- What should future dialogue look like?

A small group of eight participants was involved in helping to develop the conclusions.

Each is now explored.

6.1 What is Unique About Synthetic Biology?

When considering this question, one of the key themes to emerge was the sense of extremes that characterise the field. The public saw within the science tremendous potential – for biomedical science and drugs; for new and more efficient ways of making fuels; for cleaning up things such as oil spills or contaminated land; and for growing new crops. But they also saw big downsides – the difficulty of controlling novel organisms in the environment; that the technology will profit the few and not the many; the potential health or environmental impact; the problems of the technology falling into the wrong hands; the belief that there would be implications that are unknowable.

What is interesting is that these two factors - the great enthusiasm and the big fears were viewed as related and to some extent co-determinate. The breadth and scope of the science was huge and deeply ambitious, and while people were inspired by this, the very ambition and imagination made them uneasy – specifically because in the attempt to stride forward, wider issues and implications were missed. Experience of other technology had seen the promise of science only partially realised – and there was an expectation that there would be unintended consequences for synthetic biology. This made the case all the more fully for scientists working in the field to develop greater responsibility.

Second there were issues around the field itself and a tension at the heart of the idea of "synthetic biology" and the ability to manufacture a synthetic organism. These arguments were not so much around "playing god"; while this phrase did emerge though the discussions it was not a defining way of thinking about the technology. Rather it concerned the idea of authenticity and the intrinsic value of nature. The possibilities of people living in a synthetic world made them uneasy – and there were concerns about where applications might stop. These concerns were over and above any direct health or environmental risks from applications, important though those issues were. Rather, they specifically related to the value of living in a synthetic world – and fundamentally that living entities which were artificial had less value than those considered natural.

In this regard, there were boundaries around different uses of synthetic biology: while the synthetic engineering of biological parts was one thing; the creation of life itself was another – particularly if, in the future, such techniques could create multi-cellular and ultimately sentient beings. This conflict between something synthetic and biological; between something artificial but alive, is at the heart of public unease, and helps to understand why this area needs a distinctive approach moving forward.

Finally, there was also an underlying disciplinary tension in the field in terms of the application of engineering principles to biological systems. There were three aspects to this. First, the prospect of being able to treat nature as parts to be assembled was very problematic. Nature was seen as too complex, with gene and environmental interactions too dynamic and stochastic to predict in a precise way.

Second was that engineering anticipated the idea of being able to specify, replicate and produce things on an industrial scale. The implications of this, in terms of magnitude of impact if there were found to be problems, were a concern.

Finally, and related to the above, was the idea of speeding up nature. Evolution, under these approaches, had been removed from gradual and random changes in the living world, to one which could be manufactured with relative speed. Again this carried with it the need for responsibilities and thoughtfulness by the research community when moving forward.

6.2 What are the Leadership and Funding Roles of the Research Councils?

When considering the conditions under which science and engineering should develop in this area, there was a clear role for the research councils. This fell into two broad areas: the internal systems and processes through which science was funded; and the external training and leadership of the scientific community. Both will now be explored.

Funding

When considering funding of synthetic biology by the research councils one of the biggest concerns was the disconnect between technical and ethical appraisal of grants.

In particular, **participants wanted scope to feed public aspirations and concerns into research at an early stage**. There was a need to re-imagine funding; to look at the opportunities to open up the science from the initial application to the research councils to when the research actually gets the go-ahead.

Specifically, this was not about placing a lay member of the public on the two-day technical appraisal meeting – which by its nature may exclude people from debate. But rather, that **it should be incumbent on the research councils to make the science accessible**, to consider the views of the public throughout the process, and to build in this knowledge so that funding panels consider more than just the technical nature of applications. While science and the peer review process was seen as open, it is only open to elites and there was a need to rethink this given the potential implications of synthetic biology. **Overall, scientists need to concern themselves with wider implications – and see them as fundamentally embedded in the imaginations and trajectories of research.**

There were concerns that the grant process seemed too formulaic; reducing complex sets of discussions to box filling on a form, which may or may not then get flagged up as significant.⁴ For certain grant applications, a more iterative process involving the scientists, but also the public, social scientists, ethicists and others was needed, with ideas shaped through debate. The research applicants themselves could be involved in this process. Overall, there needed to be more effective checks and balances on applications that had wider social possibilities; both through the funding process and during the research itself.

Leadership

The second role for the research councils relates to their leadership of science. The idea of having the right people, in the right place and for the right reasons in relation to the development of synthetic biology is a fundamental consideration for the councils and clearly articulated by participants. What this looks like in terms of funding, research groupings, the sharing of learning, wider involvement and networks is a key strategic question.

There is also a direct role for the research councils in helping and enabling scientists to think through responsibilities more effectively. This not only needs to be embedded

⁴ There may be scope to build on risk register developed by EPSRC for the nanotechnology grand challenge in this regard.

in the training of scientists, but beyond this too when people are actively developing research. This issue is explored in more depth next.

6.3 How Do We Develop the Capabilities for Scientists to Think Through Responsibilities?

One of the main conclusions to emerge from the study was the need for scientists to consider their motivations for research more effectively. Curiosity-driven science, though very important, was not reason enough to pursue ideas when the implications may fall on others. In this respect, there was an underlying issue that emerged from the stakeholder interviews with scientists and engineers – a disconnect between the unremarkable nature of their own work, which was seen as incremental and minor; and the transformative nature of the field as a whole. This tension between the unremarkable and transformative needs to be examined; it was not an artefact of the sum of the parts and there is a need for individual scientists to think more carefully about the significance of their work.

Exploring motivations is fundamental: What is the purpose? Why are you doing it? What are you going to gain? What else will it do? How you know you are right? These are five central questions at the heart of public concerns in this area. It should be incumbent on scientists to consider them. To there is a need to talk about uncertainties and reflect on these "*what if*?" questions. It should be noted that there was an expectation that things will go wrong in the development of synthetic biology – describing a technology as inherently safe is likely to be counter-productive. Participants stated they were more likely to trust those scientists who had previously admitted failure.

There are a number of cultural and systemic barriers to enabling broader consideration of research: the relative insular nature of science; the "small world" focus of projects; the need to gain further research money tied to a "publish or perish" mentality; the short term contracts and so on.

However, such cultures and systems are not immutable; they exist because organisations -and the people who lead them and act in them do things and say things in particular ways. They are open to influence by those with power. Having a different type of structure, culture and reward system can lead to new conversation by those developing and governing the science, and may ultimately lead to new more socially beneficial technologies. This is explored in more depth next.

6.4 What Does Innovation Look Like Under These Circumstances?

Underpinning much of this was the need to examine the conditions of innovation and open up the science. As Charlie Leadbeater⁵ and others have noted, until now a pipeline model of innovation has characterised science: ideas get created by bright people in the lab; those ideas are embedded in physical products; which are then engineered, manufactured and distributed to consumers waiting at the other end of the pipeline.

There is a need to develop a different type of conversation that leads to innovation: informing synthetic biology in new ways and involving people (citizens, consumers, other users) not just at the end of the process but throughout.

It should be noted that synthetic biology is already moving in this direction – initiatives such as bio-bricks were seen as opening up access to the science. There are a variety of products and services that have been developed though ideas of mass innovation; crowd sourcing and co-creation, and drawing on the experiences of others may well provide insights for this field.

However, much of the concern for the public in this space was not about the potential for synthetic biology to create some unmet consumer need, but rather for the whole innovation process to be more thoughtful. Given what is unique about synthetic biology there were some big questions for the field, such as: "*What sort of technology is produced when you are respectful or mindful or nature?*" or "*What are the consequences of seeing life nothing more than parts to be assembled?*". It was not expected that scientists would have the answer to these – or indeed that they are fully answerable.

But the need to have a different conversation was underscored, and the potential role for the research councils in helping to facilitate this was noted. In part this could be through better dialogue with the social science and humanities within research

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Leadbeater, C. (2006) The Ten Habits of Mass Innovation. Nesta: London.

institutions. The recent synthetic biology networks are a useful development in this regard. It could also be about better dialogue with the public, and this initiative was also welcomed.

More fundamentally it was about the leadership of science: about those running organisations to champion new ways of working and create rewards for doing so. There is an opportunity for the leaders of research councils, learned societies, universities and Government to help shape research by enabling it to be informed by social values. For instance, Government's Foresight work and the development of new research programmes, either the cross-council programmes or new areas such as synthetic biology, have tended to be led from the technical side rather than being informed by public input or social science scholarship. Who gets involved in setting the agenda is all important.

6.5 How Do We Control the Science?

Much of the conclusions about control have been characterised by discussion about the formative side of research. As highlighted throughout the findings, there were both aspirations and concerns when considering the benefits from specific applications of the technology and in particular how to manage risk.

Regulation is key in this discussion and there was an inherent tension at the heart of current systems: *"How is it possible to understand the impact of a novel device or organism through existing regulations?"*. While the idea of regulation proceeding stepwise was valued, **the institutional capacity to imagine the future and keep up with advances was questioned**. The idea of voluntary regulation in the absence of specific standards was also a concern. The idea of adaptive governance, grounded in reflective and informed technical and social intelligence, and including robust arrangements for environmental monitoring, will be important in this regard. The concept of adaptive governance is explored in depth in relation to nanotechnologies by the Royal Commission on Environmental Pollution⁶ and similar insights could be applied to synthetic biology.

Perhaps one of the biggest issues was the need for international co-ordination or regulation, though participants were aware of how very difficult this would be to

⁶ RCEP (2008). 27th report: Novel Materials in the Environment: The case of nanotechnology. (see in particular pages 21-22 for discussion). Available at: <u>http://www.rcep.org.uk/reports/</u>

achieve in practice. The ability to control access and development of the technology in global markets was a major challenge, made all the more difficult when considering the potential for DIY and "garage biology". This was not so much regarding misuse of synthetic biology. Rather, it was much more about the control of releases into the environment, which was seen as one of the biggest concerns around application of synthetic biology, even when being managed within regulated industries. The possibilities of opening up access to the science was concerning in this regard; there was only so far the hand of the Health and Safety Executive could reach.

Moreover, there may be further issues of using existing regulatory frameworks for GMOs to control synthetic biology, given the current issues playing out between asynchronous approvals for GM foods between the European Union and imports from other countries such as the US, Brazil and Argentina. If the system is currently creaking under the ability to keep up with pressures on it, how would it cope if there were a breakthrough that led to an increase in synthetic biology applications?

A final point regarding regulations was the need to open up control to the scrutiny of others: with food and fuel applications in particular viewed as an issue. Both were seen as particularly susceptible to the influence of big business.

Ultimately, control was not just about a technical debate around risk; it concerned the wider implications of the science. Overall, greater thought needs to be given to the institutional arrangements to create the conditions for synthetic biology to be developed in useful and socially acceptable ways. Coupling these issues together – the need to open debate around innovation with the need for controls to be better at anticipating the future - may be helpful in this regard.

6.6 Future Dialogue

The final conclusion concerns future discussions in this area. First and foremost, it should be noted that participants valued the opportunity to take part in this dialogue. They also highlighted a number of themes that they would like to hear more about in the future, including progress in the field; winners and losers; how regulations were working; and problems or mistakes that have occurred.

Ultimately the progress of synthetic biology is conditional, and the participants were concerned their views would be ignored. Future dialogue is not just about talking to the public in processes like this; it is also about embedding public views on synthetic biology in the cultures and practices of research. Participants have highlighted where this may take place: during funding; in training; in the day-to-day activities of researchers; in innovation and R&D processes; and in regulatory systems.

Innovation in dialogue and finding new and meaningful ways of engaging people in debate in these complex issues is important. But just as important is the social and institutional innovation that will be needed to direct and control these technologies in the future.

This dialogue has begun to identify a number of public aspirations and concerns around synthetic biology. But, perhaps more importantly, it has begun to articulate some important questions of those developing the field. There is a duty for the research councils to respond directly to this and to reengage with participants in due course, to explain how some the conditions they have placed on the research have been met.

If no action is taken, the dialogue will have been meaningless. However, if this foundation is built upon, a different set of conversations will take place as synthetic biology develops – the insight from which may also become embedded in the technology itself over the coming years.





