Actors Script: A scientist viewpoint

Q: How would you define synthetic biology?

At this stage there isn't a firm definition of what makes someone a synthetic biologist - but I would sum it all up as trying to design and build biological devices for useful purposes.

It's all made possible by the application of engineering principles to biology – understanding and controlling the building blocks of life.

Q: What sorts of approaches are there?

One approach being looked at is how to manufacture a range of standardised biological parts called bio-bricks, all with different functions. These could then be mixed and matched to create biological devices with a specific purpose. But we still need to understand how all the parts interact and get them to the point where they work together in a predictable way without altering each other.

Q: So where do you think it's going?
There's still a lot we don't know, but with time and money there is the potential to produce everything from industrial chemicals and biofuels, to bacteria clean up oil slicks, to new drugs, vaccines and ways to diagnose illness. We are a good few years away from producing the finished products just yet though; what draws people to the field is that the science itself is fascinating and there are still big juicy questions to be answered about how life actually works.

So far there has been quite a lot of hype around the field and there is certainly a growing interest from the research councils and governments. I think it's important for the UK to invest in this research; we don't want to get left behind. This could be an important area for the economy and with the right incentives we can encourage businesses working on synthetic biology to set up in the UK and provide high skilled jobs.

Q: What about the regulation and control of synthetic biology?

We do need to consider how to regulate the technology develops - and what security and safety procedures are put in place. While synthetic biology is done in a safe and totally controlled environment, we do have to consider the whole issue of bio safety and the potential risk it could poses to ecosystems or people without adequate bio-safety protocols.

With areas like this it can sometimes seem that things are developing faster than the regulations can keep track. I think people need to be assured that there's some regulatory framework there that ensure scientists act responsibly. I think we need to explain why we want to do these things and what the benefits are likely to be.

Actors Script: A commercial viewpoint

Q: So what do you think about synthetic biology?

You know, I think synthetic biology is tremendously important. It could be applied to resolving some of the pressing energy and medical problems that are going to beset the world. I see endless opportunities in this field, where we will continue to

find organisms that can produce new products. It has the potential to be one of the single most transformative technologies in the next 20-30 years with the capacity for doing tremendous good.

Q: And are there any downsides?

People often flag up the downsides, but I think the social and ethical issues are about not using synthetic biology effectively. I think that's a grave crime. What's the alternative: that we ration the allocation of things like energy to our kids? I struggle to see who will be harmed by synthetic biology unless you have some sort of fear that we're going to get superbugs.

Q: What is the role of business in synthetic biology?

I believe that ultimately if you want development in this area, you need to get business to invest it. Syn bio needs to be profitable. We would not be investing in research programmes if we didn't think that we would be able to get a benefit from that as a company. I would not be able to get the money to invest from my shareholders.

And if you want business to invest you need to allow them to take it in-house. Openness around developments and funding could act as significant barrier. We've been doing a lot of work with companies around synthetic biology on a new product - it could make us a lot of money. There is no way that I would have wanted to announce to the world that that's what we were doing.

Q: What about the regulation and control of synthetic biology?

I am glad you asked me that. If anything, the UK has a chronic set of regulatory obstructions which prevent the effective deployment of synthetic biology. Our academic effort is fragmented and we have a government that is over influenced by the voices of NGO's. As an investor, there is no sense for me putting money either into the technology or production facilities in the UK if its will be undermined by the attitudes and opinions of pressure groups.

Sure markets shouldn't run completely free. We need to make sure that mechanisms exist so that synthetic biology can be applied where it is going to be needed most. There will be times when market signals alone aren't sufficient to provide that guidance. But if we wait forever - if we are over cautious - others will get there before us.

Actors Script: A social science and ethics viewpoint

Q: How would you define synthetic biology?

Well synthetic biology is at a very, very early stage, and it is an ill defined field. I guess the overarching idea is to make biology as useful as things like chemistry have become to us - so that we can synthesise whatever products we need from biological components. At the moment scientists are asking 'can we do it', you know, it's kind of like trying to climb Mount Everest.

Q: Where do you think its going?

As for me, I am sceptical about how quickly applications in synthetic biology are going to come to fruition. It is being driven by a sort of vision of industrial applications around food and energy production which are primarily going to benefit large corporations.

Even though the applications are far off, issues are a bunch of big issues for this area: what might the technology lead to; who is going to gain; who drives the technology; and who should take responsibility for it.

Q: So what do you think some of the wider implications are?
One concern is that synthetic biology could alter the production of certain drugs or food, removing the benefit from local producers, and widening the gap between rich and poor nations. Also broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research.

There is also the question of creating life. As much as asking whether creating life is right or wrong - I'd also like to know what people think makes something alive or not. Is there a difference between creating small micro-organisms and more complex organisms? Though total science fiction at this time, if we do create new life forms what sort of respect and treatment should we accord it?

There is also the issue of bio security. In the long run that it may be possible to recreate the polio and smallpox virus – though I guess in reality there may be easier ways of going about terrorism.

Q: What about the control of the area?
What is interesting is that the majority of scientists know little about the potential implications of the work they are doing or how it might be governed. So I think the real problem is trying to get the scientific community to be aware of the potential issues around their own work in general and to take greater responsibility.

Actors Script: An NGO viewpoint

Q: So what do you think about synthetic biology?

I think it's extremely interesting the way that computing, engineering and biology are being brought together in this field. But I do worry about issues arising from this mix of disciplines; engineering and computing are not the same as biology.

I mean in engineering if you build a new piece of equipment, it generally performs one job and you can modify it if it doesn't quite work. But in biology there is still so much to learn, genetics is incredibly complex, genes interact in different ways. Essentially, the biology aspect makes the engineering side of things much less predictable.

Q: Who might benefit or be harmed from synthetic biology?

We work to monitor new and emerging fields of science and technology and the ways in which they might impact on society. I think our primary role is to say: here's what might be done with this technology; is it useful or not useful; who owns and controls it; and here are some of the health, environmental and intellectual property issues around it.

And it's complicated. If we ask: who will potentially benefit from synthetic biology and who might be harmed - there is no simple answer. We have to consider the potential knock-on effects of the technology. For example: one of the major areas being talked about is energy and how we can use custom built organisms to produce a new generation of renewable bio-fuels. The idea is that you're transforming plants into fuels and plastics and so forth using synthetic bacteria.

On an industrial scale that means that you're either having large scale monoculture crops, which are competing for land with food production, or you're looking at destroying forest land or grasslands in developing countries to create space. There is also the question of what happens with these organisms if they are deliberately or accidentally released into the wider environment.

Q: What about the regulation and control of synthetic biology?

Well that's a big one. We are pretty sceptical about the idea of voluntary regulation, there is a lot of pressure to move forward as quickly as possible, release commercial products and recoup the money invested in research. How can the field be regulated in a way that protects people and the natural world while allowing scientists to move forward and increase their understanding?

Handout A: Key Points on Synthetic Biology

Synthetic biologists seek to design and engineer new biological systems, or redesign existing ones.

It involves the application of engineering principles to biology – attempting to build life for a specific purpose.

It aims to use standard procedures that can be replicated – designing biological parts in the same way that an engineer would make parts for a car. These biological parts or systems don't exist in the natural world

In one example, synthetic biology aims to produce an anti-malarial drug called artemisinin. In this case scientists are using synthetic biology to engineer genes from a plant which produces this anti-malarial drug into a bacterium. The bacteria can then produce a chemical component of the anti-malarial drug.

Handout A: Key Considerations

It is not as easy as assembling a car

The building blocks of life are not like the parts of a car. They have not all been tested to demonstrate what they can do – or they may exhibit properties or functions that change under different conditions.

Living organisms are unpredictable

Even if the function of each part can be defined, when you put them all together they may not work as expected. Living organisms are complex and unpredictable. Biological parts used in synthetic biology could be incompatible.

The living systems may not function reliably

Living organisms are prone to random changes and fluctuations. Complex synthetic biological systems could develop functions that differ from those that were initially intended. These unintended consequences could be beneficial, benign or harmful.

Handout B: Overview of the Social and Ethical Considerations

Uncontrolled Release:
One concern is that these organisms could evolve, proliferate and have unexpected interactions with existing ecosystems.

Bioterrorism:
Another concern is that synthetic biology could be used to design organisms which would be hostile to humans

Trade and Global Justice:
Synthetic biology could alter the production of certain drugs or food, removing the benefit from previous local producers, potentially maintaining the discrepancy of wealth and health between rich and poor nations.

Patenting and creation of monopolies:
Broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research.

Tolerable Risk
Can we balance the risks presented by synthetic biology with the benefits it offers?

Creating artificial life
An aim of synthetic biology is to create novel organisms or to modify existing organisms for our own purposes. This raises concerns that scientists could 'play God', or that they can apply 'design' to organisms in the way which evolution has never done before.

Issues of not investing in synthetic biology
There are a number of proposed benefits from synthetic biology – new ways to make fuels or medicines. If we were not to fund the field, future generations could lose out.

Handout C: The Research Councils

In the UK, most of the public funding of basic research in synthetic biology comes from the Research Councils - in particular, the Biotechnology and Biological Sciences Research Council (BBSRC) and the Engineering and Physical Sciences Research Council (EPSRC).

In 2007/8, the Research Councils spent approximately £20million on synthetic biology research of an overall budget of £2.7billion. The estimated expenditure for 2008/9 is £33million – of an overall budget of £2.9billion.

Most research is funded through 'responsive mode'. Here an academic will have an idea and will apply to a Research Council for funding. Under this mode, the direction of the basic science is driven by researchers.

An expert panel will review an application and make a judgment about which proposals should be funded – the decision is primarily based on excellence in science or engineering.

When applying for funding, researchers also need to provide an impact statement for their work (e.g. its use to society or how it would be commercialised) as well as flag up any ethical concerns. The research councils look to ensure that some thought has been given to these issues in the application – though they are generally not used for funding purposes, except when judging two proposals of equal merit.

In the case of BBSRC, if social and ethical issues are thought to be significant, applications will be flagged up to a separate 'science in society' committee. Each year approximately 8 proposals are referred in this regard. The science in society committee works with applicants to help them consider the social or ethical issues raised by their proposal or to resolve specific problems.

EPSRC has a senior advisory panel who reports directly to the Chief Executive and its governing Council and which provides strategic advice about the potential societal and ethical impacts of EPSRC sponsored research and training.

There is no further requirement for researchers to report on impact, social or ethical issues other than at then end of the grant. However, researchers are expected to engage with the public about their research throughout the duration of their grant.
Both Councils have made synthetic biology a strategic priority area. Councils can also fund under specific research initiatives - synthetic biology applications for energy for instance. Under this mode, the direction of the science would be driven by research councils.

Beyond trying to ensure that researchers consider the issues around the research, the Research Councils also work at a higher level to consider those issues , by conducting public dialogues for example.

Handout D: Commercialising Research

To create wealth for the UK, the research councils encourage the commercial exploitation of the research they sponsor. There has been increasing efforts by government to ensure there is a return on investment in university research over the past few years.

Academics value the exchange of ideas and the open communication of results is an inherent part of science and engineering research. There are some concerns that the commercialisation of research will decrease openness and transparency.

For instance, if commercialising research, researchers are encouraged to delay the announcement of results or the publication of papers to ensure that ownership of the 'intellectual property' (IP) has been secured. Granting a patent to protect IP can take 3-4 years in the UK – and the patent typically lasts for 20 years from the time of application.

Research institutions, or spin out companies from universities, will often go into partnership with industry to make money from ideas – either giving them ownership of IP or granting them an 'exclusive exploitation agreement' in return for a fee.

Conflicts of interest may also arise whenever researchers' commercial interests have the potential to compromise their professional judgment – for instance disclosure of negative results.

However, it is also argued that protecting IP is essential to commercialisation and synthetic biology has potential to help create jobs and money in the UK. Without sufficient incentives for the private sector investment will go elsewhere and other countries will get there first. In 2008, the global synthetic biology market was estimated to be $234M– this s expected to grow to $2.4bn by 2013.

Handout E: Synthetic Biology and Regulation

Regulation will play an important role in the development of synthetic biology. The official view in the UK is that the majority of synthetic biology research will be covered by current regulations that apply to genetically modified organisms, and that there is no need for any new regulations relating specifically to synthetic biology at present. In the future it is possible that new regulations will be needed and this situation is kept under review.

At present all synthetic biology is being developed under laboratory conditions. In the UK this is regulated by the Health and Safety Executive. A thorough risk assessment is carried out before research can begin. If approval is given appropriate steps must be taken to prevent release to the environment.

With further development synthetic biology applications may be ready for use outside the laboratory, for example in medicine or agriculture. Depending on the use, this would be regulated by different bodies, who currently assess the safety of other products for human health or the environment.

Most of the challenges faced in regulating synthetic biology involve how best to protect the environment and human health in light of the uncertainties surrounding a new technology. How can regulations keep pace with the technology without stifling its development? How best can we deal with risks when there are still so many unknowns? History has taught us that risks are not always obvious and can take years to emerge, consider examples such as the BSE crisis, Asbestos and Thalidomide.

Who should be responsible for regulation? Should it be the remit of government, an independent body, or indeed scientists or industry themselves? Would regulations be effective without the setting up of international standards?

The potential for "garage" synthetic biology – where people can order parts on line and potentially do the science in their own back yard – may present further complications for effective regulation of synthetic biology.

The need for specialised equipment and facilities might limit the likelihood of such home uses. However, if individuals were to choose to work in their homes on private projects how could this be regulated and monitored both to protect their own health and that of the wider public and environment? As well as uncontrolled release, there are also potential bioterrorism risks in this regard.

Note: there were originally images included in this stimulus material; however these have been removed due to copyright restrictions.