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# Governing Amateur Biology

## Extending Responsible Research and Innovation in Synthetic Biology to New Actors

Research Report for the Wellcome Trust Project on 'Building a Sustainable Capacity in Dual-Use Bioethics.'

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## Introduction

Synthetic biology is a new area of biological research and technology that combines science and engineering. It involves the design and construction of novel artificial biological pathways, organisms and devices or the redesign of existing natural biological systems. A number of commentators have expressed concerns over the potential security challenges posed by synthetic biology, for example in the construction of novel pathogens, but also due to what has been labelled the 'de-skilling' of biology (Tucker, 2011). Concerns have been raised about the potential for rogue amateurs to utilise techniques made possible by synthetic biology in order to create biological weapons. The growth of citizen bioscience communities, such as DIYbio, that typically operate outside of traditional institutional structures have also fuelled these concerns. However, the link between the potential to design novel organisms and the actual projects being conducted by so-called biohackers is frequently overstated, and these concerns often overlook the extent to which a culture of responsibility has been fostered within the DIYbio community. Drawing on the emergent policy discourse of responsible research and innovation, this paper examines the link between synthetic biology and amateur biology and provides a critical assessment of what biohacking actually is; what the potential threats might be; and the governance options available.

## Synthetic Biology and the Dual Use Context

Over the past decade, synthetic biology has emerged as a major new development in the life sciences. Synthetic biology encompasses a diverse range of research and development activities and has attracted a number of different definitions. At the most fundamental level, synthetic biology seeks to apply engineering principles to the modification or creation of DNA (Royal Academy of Engineering, 2009). It is most commonly understood as: "the design and construction of new biological parts, devices or systems, and the re-design of existing, natural biological systems for useful purposes." (syntheticbiology.org, 2012).

One of the main goals of synthetic biology is to build a set of standard biological parts (ie, pieces of DNA) whose functions have been well characterised and which can be assembled into functional devices. The extent to which synthetic biology represents a significant paradigm shift has been contested (Zhang, Marris & Rose, 2011), but the ability to modify and create new life forms at the molecular level clearly represents an important shift from standard biology (Kelle, 2012a). Furthermore, the creation of standardised biological parts could make synthetic biology methods increasingly accessible to non-biologists and amateurs (Tucker, 2011).

Synthetic biology promises an enormous range of potential economic and societal benefits, including, for example, the development of cheap anti-malarial drugs, the production of green hydrogen for fuel and the use of programmable cells to treat cancer. However, it also presents a number of challenges, including concerns over potential environmental and health risks; issues surrounding intellectual property rights and the creation of monopolies dominated by large multinationals; the ethical issues of creating artificial life; and the risks and uncertainties around biosafety and biosecurity (Zhang, Marris & Rose, 2011).

This paper focuses primarily on the potential biosecurity risks associated with synthetic biology. While biosafety measures are focused on the prevention of unintentional or accidental release of harmful biological agents or materials, biosecurity measures are focused on the prevention of misuse of legitimate research. Biosecurity measures frequently go beyond laboratory security, eg, the prevention of loss, theft, diversion or intentional release of harmful material, to also include measures that target scientific funding, peer-review, publication, employment and post-graduate teaching (McLeish and Nightingale, 2007). However, given the extensiveness of biosecurity measures, concerns have been expressed about their impact on legitimate research, exemplifying the 'dual use' challenge (NRC, 2004).

The term dual use was originally applied in the context of defence procurement, referring to the benefits generated by transferring civilian technologies to the military sector in order to reduce costs. However, dual use is now more commonly taken to refer to the potential for the materials, hardware and knowledge of legitimate, peaceful research to be misused for the illicit production of prohibited military technologies. The potential for advances in the life sciences, as well as other areas of science and technology, to open up new opportunities for biological or biochemical weapons development has been recognised by the treaties that prohibit them – the 1972 Biological Weapons Convention (BWC) and the 1993 Chemical Weapons Convention (CWC).[1] Both treaties have mechanisms for the review of science and technology developments. The BWC's Implementation Support Unit (ISU), which provides administrative support and assistance in the implementation of the Convention, has identified synthetic biology as a key enabling technology of relevance to the BWC:

> "Biological engineering, or synthetic biology, has advanced considerably... Industry is becoming increasingly interested in these approaches. There has been a significant increase in the biological complexity of the biological systems and networks that can be engineered." (ISU, 2011)

Synthetic biology could conceivably be exploited to develop novel pathogens or to modify existing biological warfare agents that, for example, have enhanced stability or lethality or circumvent detection or diagnosis. While technical barriers currently remain, rapid advances are taking place which could present a future threat. As one study suggests, the potential for misuse will increase given the increasing speed and capability of the technology and its widening accessibility (Garfinkel, Endy et al, 2007). The BWC's ISU have also noted the trend towards widening access:

[1] Biological and chemical weapons are weapons that are intended to do harm by affecting life processes, either through the infectivity of pathogenic micro-organisms or the toxicity of chemicals. While there are a number of distinguishing features between biological and chemical weapons (such as, eg, contagiousness versus toxicity), some agents, such as toxins or bioregulators, are covered by both the BWC and CWC. Biological and chemical weapons are thus more appropriately conceptualised as a spectrum.

"Developments in information technology have affected how information is exchanged. New tools, such as wikis, blogs and microblogs have altered how information is gathered, handled, disseminated and accessed... It is not only information that is becoming more accessible. Amateur communities, scientific outreach and educational toys have all increased access to hardware for wetwork in the life sciences." (ISU, 2011).

This highlights the complexity of the dual use issue and the challenge of governing intangibles such as knowledge and information. The emerging field of synthetic biology has the potential to offer significant economic and societal benefits, but is also open to possible exploitation for nefarious purposes. How, then, should synthetic biology be governed? And, as access to and participation in the life sciences widens to amateur communities, can these governance approaches be extended to new science and technology actors?

## Governance Approaches to Synthetic Biology

Recent debates about the governance of emerging technologies have focused on the need for responsible research and innovation (RRI). RRI has gained particular currency within the new EU Framework Programme for Research and Innovation, Horizon 2020, and focuses on transparent, participatory and responsive governance processes. While it is a relatively new concept, and definitions are continuing to evolve, RRI can be summarised as:

1. The deliberate focus of research and the products of innovation to achieve a social or environmental benefit.
2. The consistent, ongoing involvement of society, from beginning to end of the innovation process, including the public and non-governmental groups.
3. The assessment and effective prioritisation of social, ethical and environmental impacts, risks and opportunities, both now and in the future, alongside the technical and commercial.
4. The adoption of oversight mechanisms that are better able to anticipate and manage problems and opportunities and which are also able to adapt and respond quickly to changing knowledge and circumstances.
5. The recognition of openness and transparency as integral components of the research and innovation process. (Adapted from Sutcliffe, 2011).

The RRI framework has been applied to a number of emerging technologies, including information technology and nanotechnology. A recent report, *A Synthetic Biology Roadmap for the UK*, identified RRI as a core theme for strong and sustainable growth in the UK synthetic biology sector (UK Synthetic Biology Roadmap Coordination Group, 2012). The Roadmap report emphasises three key issues in RRI: uncertainty, public acceptability and regulation. This section explores these issues in further detail and suggests that a number of 'soft law' and informal approaches should also be taken into consideration in the governance of synthetic biology.

## Uncertainty

Uncertainty is an important aspect to consider in the governance of an emerging technology like synthetic biology. It goes beyond risk assessment and narrowly defined 'science-based' decisions to account for incomplete knowledge and the possibility of dissenting interpretations (Stirling, 2010). As the Roadmap report highlights:

"...inescapable uncertainty must be acknowledged and accounted for. The aim of responsible research and innovation is not simply to predict and manage negative outcomes, but also to shape decision-making procedures that recognise such uncertainty across the whole life cycle of innovation."

Traditional methods of risk assessment are therefore of limited value in shaping governance approaches to synthetic biology. Rather, the implications of uncertainty, ambiguity and ignorance must be taken into account. Some commentators have emphasised the importance of applying a form of precautionary appraisal to synthetic biology (Kelle, 2012a). While the precautionary principle has been contested, a precautionary appraisal process is valuable in "broadening out" the inputs to appraisal beyond science-based evidence to recognise the plural, conditional nature of knowledge (Stirling, 2007, 2010). In this way, a wider range of stakeholder interests can also be acknowledged, including the public.

## Public Acceptability

As noted in the above definition, an important component of RRI is the consistent, ongoing involvement of society. Public acceptability has been widely recognised as a crucial issue for synthetic biology and is re-emphasised in the Roadmap report. In 2010, the Biotechnology and Biological Science Research Council (BBSRC) and the Engineering and Physical Science Research Council (EPSRC) performed a large-scale public dialogue on synthetic biology. The dialogue revealed that most people were supportive of research but with the caveat that synthetic biologists should be willing and able to answer these questions:

- 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?

The Roadmap report emphasises the importance of embedding these questions into decisions about the commercialisation, translation and regulation of synthetic biology. However, this also highlights the need for synthetic biologists to be aware of these concerns and the broader ethical and biosecurity frameworks in which they operate. Awareness-raising and outreach to the public is only one side of the equation and, as explored below, awareness-raising is also crucially important at the level of the scientist.

## Regulation

Finally, the Roadmap report identifies regulation as a key component of RRI. Regulation of emerging biotechnologies like synthetic biology is problematic given the seemingly competing interests of, on the one hand, managing and mitigating potential negative outcomes and, on the other, enabling or even facilitating beneficial applications (Nuffield Council on Bioethics, 2012). At present, synthetic biology is primarily regulated by frameworks that were developed for genetically modified organisms (GMOs), including regulations for the contained use and deliberate release to the environment of GMOs. The principles underlying current regulations are that they:

- Place the protection of human health and prevention of harm to the environment as the first priority.
- Take a risk-based approach, requiring proportionately more stringent controls for higher hazard work.
- Allow novel work to be carried out, without unduly hindering innovation, but for GMO work require that risk assessments are reviewed and for higher-risk work that the regulator gives consent before the work begins.

However, as explored above, a purely risk-based approach fails to taken into account the uncertainty and ambiguity attendant in emerging biotechnologies. This is particularly evident in considering the potential dual use implications of synthetic biology:

"What is often overlooked in discussions of the 'risk' of synthetic biology's dual-use potential being actually misused is the fact that in a strict sense we are no longer dealing with risk... It follows that traditional methods of risk assessment are of limited utility in the formulation of dual-use governance measures." (Kelle, 2012a)

Furthermore, while the focus of regulation tends to be at the national level, synthetic biology is a global enterprise that crosses borders at national, industrial, organisational and disciplinary levels (Zhang, Marris & Rose, 2011). Given the combination of uncertainty and "cross-borderness," no single regulatory body or regulatory mechanism is likely to have sufficient capacity to oversee the development of synthetic biology; rather, a web of governance measures is needed that also encompasses informal, self-regulatory mechanisms.

## 'Soft Law' and Informal approaches

The Roadmap report's focus on the risk-based regulatory framework emphasises the role of legislative intervention, however governance mechanisms may also include 'soft law' approaches and informal measures that are not legally binding (Knowles, 2012). Such measures might include, *inter alia*:

## Self-regulation by the scientific community

Self-regulation by the scientific community can provide an effective means of oversight, and one which avoids the potential hindrance to innovation that could be caused by excessive legislative control. This is particularly so in the case of synthetic biology, given its interdisciplinary nature and the open source/open access model that it promotes. Furthermore, as noted in the summary of RRI, oversight mechanisms that are better able to anticipate and manage problems and opportunities and which are also able to adapt and respond quickly to changing knowledge and circumstances are an important aspect in the governance of emerging technologies. A self-regulatory approach can therefore offer a more agile response. Maurer and Laurie succinctly summarise the advantages of self-governance of synthetic biology through voluntary guidelines over legally binding regulation:

"First, community decisions can be made in months, not years. Second, solutions that require scientists' consent are likely to be far less disruptive for working labs than externally imposed rules. Finally, biosecurity policy needs to be consistent across countries, and community-based initiatives are inherently international." (Maurer & Zoloth, 2007).

Furthermore, some commentators have argued that top-down regulation could lead to a black market in synthetic DNA, which would erode openness and transparency and therefore make monitoring and control even more difficult (Carlson, 2003). Despite these advantages, self-regulatory oversight mechanisms can be perceived by some as a bureaucratic burden and without active buy-in and community-wide participation, their effectiveness is questionable. The importance of self-regulation must therefore be embedded in the synthetic biology community from an early stage.

## Codes of Conduct

Codes have formed an important part of a number of professional bodies, including medicine, law and engineering. However, formal professional codes for scientists have been largely lacking, although their importance has gained increasing recognition (Rappert, 2004). In 2005, codes of conduct for scientists were discussed during the Meeting of Experts and Meeting of States Parties of the Biological Weapons Convention. The meetings recognised that codes of conduct can make significant contributions to combating the present and future threats posed by biological weapons by, among other things:

"[Helping to] build a culture of responsibility and accountability among the scientific community... [and helping] scientists and others fulfil their legal, regulatory and professional obligations and ethical principles." (MSP, 2005).

It has been suggested that codes fall into three categories: codes of ethics; codes of conduct; and codes of practice (Rappert, 2004). Codes of ethics are aspirational and set the ideals that practitioners should adhere to. Codes of conduct are advisory and provide guidelines on how to act appropriately. Codes of practice are enforceable and provide more detailed guidance on professional conduct. In any of these examples, effectiveness depends upon meaningful buy-in by the community.

The utility of codes has been called into question recently following the dual use controversy over publication of research on the adaptability and transmissibility of avian influenza H5N1, conducted by groups in the US and the Netherlands. The Dutch Code of Conduct for Biosecurity had been widely regarded as a leading example in the development of a biosecurity code of conduct (Dando, 2008) and covers a number of areas, including research and publication policy. Following submission of the H5N1 research results for publication in *Science* and *Nature*, concerns were expressed over the misuse potential and the papers were submitted to the US National Science Advisory Board for Biosecurity (NSABB) for review. The NSABB initially determined that the papers should only be published in redacted form, with the methods section omitted (although the NSABB has subsequently revised this decision and has recommended that at least one of the papers be published in full). Given that the Dutch Code of Conduct for Biosecurity contained explicit reference to publication policy, ie, reducing the potential for publication of dual use research to contribute to misuse, the reaction caused by the H5N1 example has raised questions over its effectiveness. Nevertheless, the Dutch Code is not intended to perform a regulatory function but, rather, emphasises voluntary cooperation. From this perspective, the Code still provides a valuable tool for awareness-raising and promoting a responsible scientific community.

## Education, outreach and awareness-raising initiatives

Several studies on scientists' awareness of the potential dual use nature of research consistently reveal a high level of ignorance towards ethical and security issues. (Dando, 2009). That is worth emphasising, particularly in the context of public dialogue and public acceptability discussed above, as it highlights the need for scientists themselves to be aware of the broader social and ethical dimensions of their work. As one study suggests:

> "While there is evidence of public education – in the sense of informing members of the public about what synthetic biology is trying to achieve – there is little evidence that this involvement has led to what is usually considered to be the outcome of 'upstream engagement', ie, a visible impact of such engagement on the subsequent conduct of research and development activities. In other words: if there has been an educational effect, it seems to have been in one direction only." (Edwards & Kelle, 2012)

Many commentators point to the need for greater ethics and dual use education at university level in order to increase awareness of ethical and security issues. However, in the case of synthetic biology, this raises the question of who exactly is doing synthetic biology and whether university courses are necessarily the best target (and, if so, which disciplines). Synthetic biology practitioners have diverse academic and professional backgrounds that go beyond biology to include engineering and computer science.

Furthermore, developments in synthetic biology are perceived to have enabled the emergence of so-called 'do-it-yourself' biologists or biohackers, which also complicates the issue. Many of the 'soft' governance approaches outlined above favour a conceptualisation of science and technology as an institution or a professional community. These new actors, who operate outside of traditional research environments, present challenges to governance strategies that are typically aimed at 'science in the lab.' How, then, might these governance approaches apply to new actors? The next section examines who exactly is doing amateur biology and explores its relationship to synthetic biology.

## What is amateur biology?

Amateur biologists are a diverse community who conduct biological experimentation as a hobby rather than a profession or, as a recent NSABB report puts it, as "an avocation rather than a vocation" (NSABB, 2011). Amateur biologists may comprise a wide range of participants of varying levels of expertise or professional affiliation, who typically assemble into community groups (both physically and electronically) to share their interest in biology. The largest such group is DIYbio, "an organization dedicated to making biology an accessible pursuit for citizen scientists, amateur biologists and biological engineers who value openness and safety" (DIYbio.org).

DIYbio was founded by Jason Bobe, Executive Director of PersonalGenomes.org (a non-profit organisation aimed at advancing personal genomics), and Mackenzie Cowell. Cowell had originally been involved in the International Genetically Engineered Machine (iGEM) competition while an undergraduate at Davidson College. iGEM, which grew out of the bioengineering programme at MIT, is an annual competition for undergraduates in which teams of students receive a BioBrick kit – a collection of standard, interchangeable biological parts – and "use these parts and new parts of their own design to build biological systems and operate them in living cells" (igem.org). Cowell's team entered the 2005 iGEM competition with a design for a fluorescent chemical sensor. Although his team did not win, Cowell was hooked on the challenge. Once he ceased to be a student, Cowell was no longer able to participate in the iGEM competition but continued his interest in do-it-yourself bioengineering by forming DIYbio (Wohlsen, 2011). DIYbio now has over 2000 members, with regional groups across the globe.

Participants in DIYBio call themselves biohackers. While the term 'hacker' invokes connotations of computer criminals hacking into secure IT systems, in the context of biohacking it is meant more in the sense of the computer enthusiast who tinkers with technology in order to understand it and improve it. Given the convergences and parallels with computing, the term biohacking seems particularly apt. As one commentator notes:

> "The more geneticist learn, the more tempting it is to think of DNA as the software of life... If computers can be programmed, and living things are not so different from computers, they [biohackers] reason that life too can be programmed." (Wohlsen, 2011).

Some of the most important figures that have been responsible for driving forward the IT industry – such as Bill Hewlett and Dave Packard (HP) or Steve Jobs and Steve Wozniak (Apple) – began as hobbyists. While the biotech industry remains the product of well-funded, well-equipped professional laboratories, biohackers argue that non-professionals can become innovators too. One of the early contributors to the DIYbio network was Meredith L Patterson, a computer programmer. In 2005, during CodeCon, an annual conference for hackers and technology enthusiasts, Patterson demonstrated the purification of DNA with common household items. Following the 2008 Chinese milk scandal, in which infant formula was found to be adulterated with melamine, Patterson also worked on creating a low-cost melamine contamination test (Wohlsen, 2011). This innovative approach to a social problem represents part of the biohacker ethos:

"The really cool ideas that end up making the world a better place, that end up curing disease and making the world healthier, often don't come from the corporate establishment. If we have to wait for university labs to do this, we're going to be waiting forever... As I think the open-source software world has shown us, innovation comes from people seeing there's a problem and deciding they're going to figure out how to solve it." (Patterson cf. Wohlsen, 2011).

## The Goals of Biohacking

For many, biohacking is simply a hobby, but for others biohacking has a number of related goals built around the philosophy of democratising biology. One of these goals, as Patterson's remarks demonstrate, is innovation based on open-source knowledge sharing. Building on the open-source model of innovation dominant in the arena of software development, biohackers promote openness and information sharing as a means to fuel innovation. Pearl Biotech, a small instrument supply company and an outgrowth of the biohacker movement, has also promoted open hardware in order to improve access to biotech tools. Pearl Biotech supply gel boxes for analysing the size of DNA fragments for just US$200 and supply the blueprint for free (Alper, 2009). Similarly, OpenPCR is an open source polymerase chain reaction (PCR) kit that can be purchased for US$599, compared to the several thousand dollars charged by large suppliers, and the blueprints are provided for free.

Another key goal of the biohacker community is empowerment. Part of the ethos of biohacking is to enable individuals to explore and experiment for themselves. This is exemplified in the genetic test built by Katherine Aull, a graduate of MIT and PhD student at the University of California, San Francisco. Using a PCR machine purchased on eBay for just US$59, Aull genotyped herself to see if she carried the gene for hemochromatosis, a common hereditary disease that afflicts her father and causes the body to absorb and store too much iron (Wolinksy, 2009). While she could have paid for a standard genetic test, Aull was able to 'hack' a cheap solution to obtain the result for herself. Of course, this example does raise important questions about the possible psychological consequences of self-diagnosis, particularly in the case of serious genetic disorders.

Finally, some biohackers are also motivated by addressing global inequalities in access to healthcare. Joseph Jackson, a self-proclaimed entrepreneur-activist from California, and Guido Nunez-Mujica, a computational biologist from Venezuela, have teamed up to build a cheap, portable thermal cycler known as LavaAmp (Ledford, 2010). The LavaAmp is an accessible hardware platform for running the PCR, which could be used as a key component of a diagnostic tool in developing countries. The main goal of LavaAmp is to help build local capacity and thereby reduce dependence on foreign aid (lava-amp.com, 2012). By circumventing the developed world's pharmaceutical-industrial complex, biohackers like

Jackson and Nunez-Mujica aim to provide affordable diagnostics tools for pandemics and neglected diseases in developing countries:

"Diagnostics for the developing world has become a rallying point for outsider biologists. Some on the scene have always tried to stress that ease of access to the tools and techniques of biotech is just half the goal. The other half is to make the output of all that innovative effort accessible to as many people as possible. And making biotech accessible means making biotech affordable." (Wohlsen, 2011).

## Enabling Technology

Several factors have enabled the growth of the biohacking movement. Since the completion of the Human Genome Project in 2003, huge advances have been made in the ability to quickly and cheaply decode DNA. Furthermore, major developments have occurred in the speed and cost of DNA synthesis. In the twenty years from 1989 to 2009, synthesis productivity has increased fivefold, whilst the cost of gene synthesis has decreased by nearly three orders of magnitude (Carlson, 2009). Synthetic DNA can now be designed and purchased online for prices that start in the pennies.

Furthermore, advances in synthetic biology, particularly in the goal of developing standardised genetic parts, are making biology easier to access for the nonspecialist. Indeed, a number of leading synthetic biologists have pursued a deliberate 'deskilling' agenda through, for example, the formation of the annual iGEM competition and through the dissemination of synthetic biology kits and how-to protocols (Kelle, 2012b). As one DIYbio group notes:

"The costs and complexity of the tools and techniques needed to understand and manipulate the living world around us are decreasing rapidly – we are now at a watershed moment where biology is breaking out of its traditional lab environment, and we are seeing a proliferation of garage biologists, biohackers, creatives and citizen scientists getting involved." (diybio.madlab.org.uk).

The availability of the necessary tools, coupled with the standardisation of biological parts, is thus making biology increasingly accessible to amateurs. Yet, while advances in synthetic biology have been enabling factors in the emergence and growth of the DIYBio movement, much of the work being carried out in hackspaces tends to be far less sophisticated. For the most part, synthetic biology and DIYBio share the goals of making biology easier to engineer and ensuring open access to knowledge and materials. Synthetic biology and DIYBio also share some institutional and personal connections. However, the connections between synthetic biology and DIYBio are often overstated, which is particularly evident in alarmist reports of the potential risks amateur biology could present in terms of the creation of novel pathogens, compared to what biohackers are actually doing. At the level of the science, DIYBio is a long way from the type of wetwork involved in genetic design (interview with Millet, 2012). So what are biohackers actually doing? The next section examines the example of two hackspaces in the UK and the types of projects being conducted.

## Biohacking in the UK

The London Hackspace is a community-run, non-profit hacker space in central London that provides an infrastructure for people to share knowledge and make things. It hosts, among other activities, the London biohacking group, a mixture of amateur and trained biologists who are interested in the potential of DIYbio and synthetic biology. The London biohacker group have been engaged in a number of projects to optimise techniques for DNA extraction and PCR process, including sex typing with amelogenin and plant species testing. During August and September 2012, they also worked with the University College London (UCL) iGEM team to develop a 'public BioBrick.'

The original concept behind the collaboration was to enable the UCL iGEM team to work with the biohacking group on an add-on component to their own project, which examined a synthetic biology approach for the bioremediation of micro-plastic pollutants in the marine environment.[2] The collaboration between the UCL iGEM team and the London biohacking group focused on developing a BioBrick containing antifreeze from the marine bacteria *Oceanibulbus indolifex*. The initial stages of primer design, generation of competent cells and amplification of plasmid backbone were conducted at the London Hackspace and transformation into *Escherichia coli* cells took place at the UCL laboratory to comply with UK and EU regulations.

The UCL iGEM team have heralded the collaboration as a positive example of 'extreme citizen science' in which amateur biologists were actively involved in problem definition, data collection and analysis. As well as producing the first public BioBrick, the collaboration also provided members of the London Biohacking group with the opportunity to work in an academic laboratory and learn new skills and techniques. In preparation for the collaboration, the UCL iGEM team provided a number of introductory workshops, including an overview of synthetic biology, an introduction to their project, and an extensive health and safety briefing. One of the major outcomes of the experience was to help instil good biosafety practice:

> "Now that the Biohackers have the experience of working in an academic laboratory, they pay more attention to reducing contamination, and health & safety." (http://2012.igem.org/Team:University_College_London)

Given the diversity of backgrounds of some of the participants in biohacking, this is an important lesson. Indeed, as one of the members of the London biohacking group notes, "one concern is that people with techy backgrounds might forget they are dealing with biology," (interview with member of London biohacking group, 2012). The biohackers involved in the collaboration identified health and safety and equipment hygiene as important lessons learned from the collaboration with the UCL iGEM team.

[2] The UCL iGEM team, for entry into the 2012 competition, attempted to engineer Escherichia coli and marine bacteria in order to degrade plastic pollution or to aggregate micro-plastic waste in a form that could then be collected and recycled.

Another burgeoning biohacker community is based in Manchester. Manchester DIYbio is based at the Manchester Digital Laboratory, or MadLab, a 3000 square foot community space for like-minded technical and creative innovators. The Manchester DIYbio group was formally launched in March 2011. Amateur biologists based at MadLab teamed up with researchers from Manchester Metropolitan University (MMU) in a bid to fund a 'citizen science' project. They were successful in obtaining a £29,705 grant from the Wellcome Trust Engaging Science Scheme for a twelve month project aimed at building an innovative citizen science community and enabling wider participation in biological research (madlab.org.uk). Dr Martyn Amos, co-organiser of the project based at MMU, states:

"The Trust was particularly impressed by the innovative nature of the proposal... They also pointed out that an organisation such as MadLab is really well-placed to explore the new idea of 'citizen science'..." (diybio.madlab.org.uk).

During the course of the project, Manchester DIYbio engaged over 350 people across a range of activities, from an introduction to making microbial fuel cells to producing a microbe map of Manchester by swabbing local bus-stops for bacteria. They also conducted a 'PCR challenge' in which they compared the results from a home-made PCR machine, an OpenPCR and MMU's commercial PCR. Though the Wellcome Trust funding has now ended, Manchester DIYbio continues to operate out of MadLab and encourages a diverse range of creative and technical people to get involved.

It is interesting to note that, both in the case of the London biohacking group's 'public BioBrick' project with the UCL iGEM team and the Manchester DIYbio's relationship with MMU, collaboration with researchers based at traditional academic research centres has helped to raise both the ambitions and the professionalism of the amateur biology community. Rather than being an underground, fragmentary collection of rogue individuals, as some commentators have implied, biohackers form part of a citizen science community, based on openness and a willingness to learn from professionals. To what extent, then, might responsible research and innovation and other dual use governance approaches be applicable to the amateur biology community?

## Biohacking and Responsible Research and Innovation

One of the key components of RRI, particularly in relation to the dual use challenge associated with emerging technology, is: The adoption of oversight mechanisms that are better able to anticipate and manage problems and opportunities and which are also able to adapt and respond quickly to changing knowledge and circumstances. As explored earlier, RRI necessitates recognition of the uncertainties inherent in emerging technologies, the need for ongoing public dialogue, and the role of soft law and informal governance approaches in addition to other regulatory frameworks.

To begin with the issue of public dialogue, this factor is somewhat complicated in the context of amateur biology. While some biohacking activity has aimed to promote public participation (such as the Manchester DIYbio citizen science project), at its most fundamental level biohacking is a hobby and, for the most part, is not funded by taxpayer money, nor likely to have the same scale of economic or social impacts. It therefore does not share the same necessity for public dialogue and public acceptability as synthetic biology. On the other hand, public perception of biohacking is important and some media reports have cast biohacking in a sinister light (Zimmer, 2012). This is significant not least because of the impact it could have on biohacking as an activity, but also because of the perceived (if not always actual) link to synthetic biology. As a recent UNICRI report suggests:

"A simple biosafety event, be it an accident or an irresponsible act, even without any potential for doing harm, could ignite public uproar and put pressure on policy-makers to react. This could lead to a ban on certain activities and hamper the further development of the [biohacker] movement. It could also cause collateral damage to science and industry by negatively affecting public attitude towards synthetic biology and related fields as a whole." (UNICRI, 2011).

The UNICRI report goes on to suggest that, in order to avoid a public backlash, it is in the best interest of the amateur biology community to demonstrate that it clearly engages in safety and security issues. It is also worth emphasising that, while amateur biologists typically operate outside of traditional research infrastructures, they are not entirely unregulated. Any activity in the UK involving genetic modification would be subject to GMO regulations, and even low risk activities require certain minimum containment measures and good microbiological practice. It is therefore important, from both a public acceptability and a regulatory perspective, for the amateur biology community to engage in biosafety and biosecurity issues.

Some concerted efforts have already taken place in this regard. The founders of DIYbio have partnered with the Synthetic Biology Project at the Woodrow Wilson Center in an effort to develop a long-term strategy towards a culture of safety and security within the amateur biology community. The collaboration is funded by the Alfred P. Sloan Foundation and seeks to establish a Code of Ethics, develop norms for safety, and create shared resources for the promotion of safe practice. An 'Ask a Safety Officer' web portal has also recently been launched in which anyone with a biosafety or biosecurity question can submit their query to a panel of experts.

In order to take forward the development of Codes, DIYbio.org organised a series of congresses during 2011 to bring together delegates from regional groups in North America and Europe to collaborate on the development of a DIYbio Code of Ethics. Regional groups from Europe, including participants from England, France, Germany, Denmark and Ireland, convened in May 2011 at the London School of Economics BIOS Centre to draft a Code of Ethics for the emerging amateur biology community. In July 2011, a second congress was held in San Francisco, with participants from regional DIYbio groups across North America. Despite the diversity of participants, both groups developed a similar set of themes, with a focus on transparency, safety and peaceful purposes (see Appendix). The development of a DIYbio Code is intended to serve as "a framework for helping us achieve a vibrant, productive and safe global community of DIYbio practitioners, regional groups, and community labs." (diybio.org).

As well as being an important step towards promoting best practice among community members, part of the motivation for the Code was also an attempt to respond to negative public attitudes. As one biohacker notes:

"The code, to many biohackers, was more of a defensive thing, in response to a perceived view that biohacking was dangerous." (Interview with member of London Biohacking group, 2012).

This attitude can be appreciated given the appearance of headlines such as, 'Amateurs are new fear in creating mutant virus,' (Zimmer, 2012). In this *The New York Times* article, the controversy over publication of the H5N1 bird flu experiments was reported alongside reference to the growing trend of amateur biology. Indeed, a member of the NSABB is quoted as saying, "I worry about the garage scientist, about the do-your-own scientist, about the person who just wants to try and see if they can do it." (Zimmer, 2012).

Conflating the two scenarios– the bioterrorist who may be tempted to recreate the mutated bird flu virus and turn it into a biological weapon on the one hand, and the biohacker who operates in a community lab, adopts a Code of Ethics and tinkers with basic DNA experiments on the other – is problematic. As Kuiken argues:

"...the risk of the amateur do-it-yourself (DIY) or citizen science movement is little to none when it comes to biosecurity or the risk of taking a federally funded project involving H5N1 and turning it into a bio-weapon." (Kuiken, 2012)

Given the type of work being conducted by amateur biologists, and given the trend towards a community lab model that instils best practice and openness, the biosecurity risks presented by biohacking are currently, as Kuiken suggests, relatively low. In terms of responsible research and innovation, then, the biohacking community has already taken significant steps towards self-governance through the development of Codes and increasing awareness of the need for public acceptability. However, one factor that has received less recognition, particularly in terms of biosecurity, is the issue of uncertainty. While biohacking is unlikely to represent a significant biosecurity threat, open access, easy-to-engineer biology is growing and, in opening up biology to amateurs, the challenges to biosafety and biosecurity have become less predictable. The following section examines the future threat and explores the governance options available in the face of uncertainty.

## A Future Threat?

As this paper has explored, the biosecurity threat posed by the amateur biology community is extremely low and headlines to the contrary tend to be based on faulty assumptions. Furthermore, while amateur biology and synthetic biology certainty share a similar mindset based on making biology more accessible, the vast majority of amateur biologists are not currently applying any synthetic biology techniques. However, if synthetic biology realises its aims of making biology easy to engineer, what might this mean for the governance of amateur biology?

Weaponisation of synthetic biology is currently very difficult due to the absence of weaponisable parts or devices (Kelle, 2012b).[3] Given the significant barriers to weaponisation, the primary biosecurity threat associated with synthetic biology remains illicit state-level programs. However, as access to the knowledge and wetware of synthetic biology broadens, the threat of non-state actor misuse increases. Given the de-skilling agenda of synthetic biology, access to synthetic biology techniques will become available to a wider and younger generation:

"As synthetic biology training becomes increasingly available to students at the college and even high-school levels, a 'hacker culture' may emerge, increasing the risk of reckless or malevolent experimentation." (Lentzos & Silver, 2012).

One company, Genomikon, has already built a kit for schools that enables the assembly of DNA from prepared, modular genetic parts, without the need for special expertise, time, or the expense of traditional genetic engineering. The kit is aimed at high school students to allow them to design, build and test genetic circuits in innocuous lab bacteria (www.genomikon.ca). While such kits are educational and unlikely to present a dual use threat in themselves, the increasing access to biology outside of traditional research environments increases the uncertainty around the range of possible threats:

"To the extent that more and more people in less and less formal and visible settings are able to engineer biological systems, the possibility of predicting the form and timing of such dangerous events, and thereby preventing them, becomes intractable." (Bennett, Gilman et al, 2009).

Given that the potential negative outcomes of synthetic biology cannot be reliably predicted, some groups have called for tighter controls. For example, in March 2012, Friends of the Earth, the International Center for Technology Assessment and the Canadian nongovernmental organisation the Action Group on Erosion, Technology and Concentration (ETC Group) released a report on *The Principles for the Oversight of Synthetic Biology,* calling for a moratorium on the release and commercial use of synthetic organisms until more robust regulations have been established. The report has been endorsed by over 100 NGOs and specifically calls for an outright ban on the use of synthetic biology on the human genome (FOE, CTA & ETC, 2012).

However, as explored earlier, managing and mitigating potential negative outcomes must be balanced against enabling or even facilitating potential beneficial applications. Some commentators have advocated the adoption of a 'proactionary principle' based on a right to innovate and a form of self-governance (Bennett, Gilman et al, 2009). A number of self-governance initiatives have already been proposed within the synthetic biology community, such as the Code of Conduct developed by the International Association of Synthetic Biology. However, the failure to produce consensus on self-governance measures at

[3] Furthermore, weaponisation requires a number of steps beyond procurement of an infectious agent, including consideration of delivery system, dissemination and uptake.

Synthetic Biology 2.0, an international conference on synthetic biology, highlighted the difficulty of establishing practical initiatives at community level (Maurer, 2012) and no comparable effort has since been made at subsequent conferences.

At the level of the amateur practitioner, significant steps have been taken to raise awareness of safety and security issues and promote a culture of responsibility, as explored above. Yet, while initiatives such as the DIYbio Code of Ethics are an important contribution, concerns remain as to the effectiveness of relying solely on self-governance measures. As Schmidt notes in the context of computing:

"This hacker ethics, however, did not and could not prevent the tons of malware programmes out there in the worldwideweb... An unrestricted biohackery scenario could put the health of a biohacker, the community around him or her and the environment under unprecedented risk." (Schmidt, 2008).

But if self-governance is not sufficient, restricting biohacking activity is not necessarily the best alternative. Any attempts to unduly limit the freedom of amateur biologists could drive what is currently an open and engaged community into an "underground activity" (UNICRI, 2011). Rather, an outreach approach should be encouraged, which performs the dual role of both helping to shape the development of the amateur biology community and providing an informal means of oversight to monitor the types of projects being conducted. The US Federal Bureau of Investigation (FBI) weapons of mass destruction outreach program have launched a series of efforts in this regard. As FBI Supervisory Special Agent Edward You notes:

"We want the science and security communities to come to an understanding to promote a culture of responsibility... [By bringing those communities together] we can identify what some of the risks and gaps might be, and then come up with strategies that make sense to both communities to mitigate those risks and gaps". (cf. Lempinen, 2011 – AAAS).

FBI outreach to the biohacking community was initiated in August 2009 during an FBI sponsored conference on synthetic biology. Jason Bobe, co-founder of DIYbio, was invited to give a presentation at the conference and leaders in the field of amateur biology were invited to participate alongside FBI officials, academics and industry representatives. The FBI's interest in DIYbio initially created some friction for the biohackers and, given the arrest of bioartist Steve Kurtz in May 2004, suspicions could be well understood.[4] However, the event was successful in building dialogue and formed the foundation for future outreach activity.

In July 2010, the first FBI-DIYbio workshop was hosted in Washington DC. The dialogue focused on safety and security issues and the importance of instilling a form of self-policing

[4] Kurtz had been working on an art installation about genetically modified agriculture and his home contained a range of laboratory equipment, including Petri dishes and non-pathogenic bacteria. In May 2011, Kurtz's wife collapsed from heart failure. Paramedics and the police responded to his 911 call and were alarmed by the material they found at his home and contacted the FBI. The FBI detained Kurtz for 22 hours on suspicion on bioterrorism, although no charges for bioterrorism were ultimately brought forward.

in the amateur biology community. The most recent FBI-DIYbio workshop, held in June 2012 in San Francisco, was extended to biohacking groups outside the US. Participants from around twenty groups internationally, including members of the London biohacker group and MadLab, were invited to attend the event, which was fully sponsored by the FBI. The three-day event covered a range of issues in safety and security and participants were given a take-home pack containing resources on biosafety and biosecurity.

One of the most important roles of this outreach activity is to help empower the amateur biology community to develop and maintain community-based standards and best practice in biosafety and biosecurity. Yet, notwithstanding the efforts of the FBI, there is currently no international process or forum to support outreach to the amateur biology community, nor a mechanism to ensure dialogue with relevant national authorities. In order to address this gap, the BWC ISU have submitted a proposal to the G8 Global Partnership Biosecurity Sub-Working Group to support, among other initiatives, an annual international meeting of citizen science groups active in biology. The project aims to:

- "keep the activities of these groups sufficiently transparent so as to provide confidence that they are not undertaking security-relevant activities;
- ensure that these groups are able to communicate with the relevant national regulatory and enforcement authorities;
- equip them with the knowledge and tools to be able to engage with potential security issues; and
- build robust working relationships to foster ongoing collaboration." (ISU, 2012)

Given the uncertainties around the possible future threat posed by increasing access to biology, outreach and dialogue with the amateur biology community at an early and formative stage of its development is crucial to raise awareness of biosafety and biosecurity issues and instil best practice.

## Conclusion

Synthetic biology promises a number of benefits to society, but also poses a number of potential security concerns. In particular, a parts-based approach to genetic engineering could significantly reduce the level of skill and expertise required to construct synthetic organisms, raising concerns over the possibility of misuse by terrorists or malicious actors. The growth of an amateur biology movement that experiments with biology as a hobby has further fuelled concerns over the growing accessibility of synthetic biology to non-experts. However, as this paper explores, the UK amateur biology community is some way off from the type of wetwork involved in genetic designing and the links to synthetic biology are often overstated.

Drawing on the emerging policy discourse on responsible research and innovation, this paper has identified a number of issues relevant to the governance of amateur biology: the recognition of uncertainty inherent in emerging technologies; the importance of public acceptability; and the role of 'soft law' governance approaches in addition to other regulatory frameworks. This paper has argued that, far from being a significant security threat, the amateur biology community are taking tangible steps towards responsibility through self-governance measures such as the adoption of codes and the promotion of biosafety and biosecurity best practice, and they are cognizant of the need to promote public acceptability.

However, while these efforts are laudable, concerns remain over the potential future threat posed by increasing access to biology. As emphasised in the context of RRI for emerging technologies, uncertainty must be acknowledged and to the extent that biology could become easier to engineer, the biosecurity implications become more unpredictable. This paper suggests that mechanisms to improve outreach to the amateur biology community, such as those presented by the BWC ISU, should be implemented. Such outreach would provide an informal means of oversight as well as, and perhaps most crucially, a means to help raise awareness and empower amateur biology communities to develop and sustain biosafety and biosecurity best practice.

## Appendix

DIYbio Code of Ethics
Draft from the European Delegation
09/07/2011

**Transparency**
Emphasize transparency and the sharing of ideas, knowledge, data and results.

**Safety**
Adopt safe practices.

**Open Access**
Promote citizen science and decentralized access to biotechnology.

**Education**
Help educate the public about biotechnology, its benefits and implications.

**Modesty**
Know you don't know everything.

**Community**
Carefully listen to any concerns and questions and respond honestly.

**Peaceful Purposes**
Biotechnology must only be used for peaceful purposes

**Respect**
Respect humans and all living systems.

**Responsibility**
Recognize the complexity and dynamics of living systems and our responsibility towards them.

**Accountability**
Remain accountable for your actions and for upholding this code.

Draft DIYbio Code of Ethics
as agreed by US delegates
July 2011

**OPEN ACCESS**
Promote citizen science and decentralized access to biotechnology.

**TRANSPARENCY**
Emphasize transparency, the sharing of ideas, knowledge and data.

**EDUCATION**
Engage the public about biology, biotechnology and their possibilities.

**SAFETY**
Adopt safe practices.

**ENVIRONMENT**
Respect the environment.

**PEACEFUL PURPOSES**
Biotechnology should only be used for peaceful purpose.

**TINKERING**
Tinkering with biology leads to insight; insight leads to innovation.

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